

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

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MESSAGE FROM THE DIRECTOR
SUB-SECTION 1005**

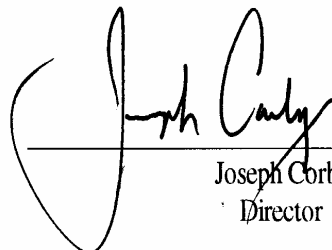
To: Division of Food Safety and Inspection Staff

One of the more important activities of government is the protection of the food supply from harmful agents. The Division of Food Safety and Inspection provides this vital service which is critically important to the health of New York State citizens. We should all be proud of our role in the food safety system of New York and the national reputation we have attained.

The FSI Field Operations Manual is a living document that must be altered and changed whenever we meet new challenges to food safety and food science.

The Department is committed to providing you the best information and tools to complete your difficult and very important work. I think this manual is testimony to that commitment.

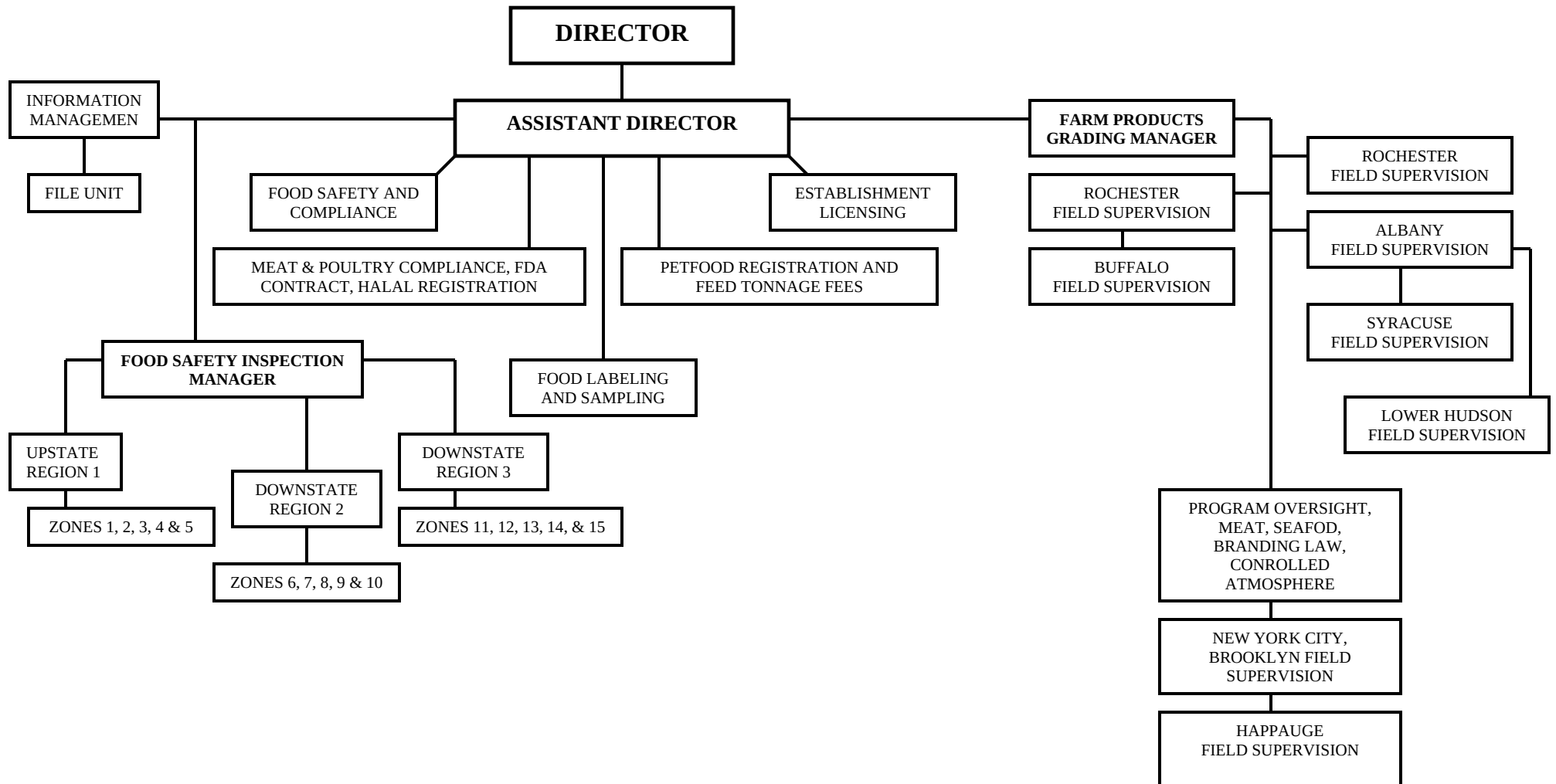
Thank you for your dedicated work and service.



Joseph Corby
Director

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**ADMINISTRATIVE AND FIELD STAFF ORGANIZATIONAL CHART
SUB-SECTION 1010**



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ABSORB

To take in through pores, soak in or up, permeable by liquids and gases.

ACCESSIBLE

Conveniently located to facilitate use: also easily or readily available for cleaning and/or inspection, with or without the use of simple tools, such as those normally used by maintenance personnel.

ADEQUATE

That which is needed to accomplish the intended purpose in keeping with good public health practice.

ADSORB

To adhere, in an extremely thin layer, as of the molecules of gases, of dissolved substances, or of liquids, to the surface of solid bodies with which they are in contact.

ADULTERATED (Article 17, Section 200)

Adulteration of food. Food shall be deemed to be adulterated:

1. If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this subdivision if the quantity of such substance in such food does not ordinarily render it injurious to health.
2. If it bears or contains any added poisonous or added deleterious substance other than one which is (a) a pesticide chemical in or on a raw agricultural commodity, (b) a food additive, or (c) a color additive, which is unsafe within the meaning of section two hundred two, or if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section four hundred eight-a of the federal food, drug and cosmetic act, as amended, or if it is, or it bears or contains, any food additive which is unsafe within the meaning of section four hundred nine of such federal act, as amended, provided, that where a pesticide chemical has been in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section four hundred eight of such federal act, and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating or milling, the residue of such pesticide chemical

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remaining in or on such processed food shall not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of such residue in the processed food, when ready to eat, is not greater than the tolerance prescribed for the raw agricultural commodity.

3. If it consists in whole or in part of a diseased, contaminated, filthy, putrid or decomposed substance, or if it is otherwise unfit for food.
4. If it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome or injurious to health.
5. If it is the product of a diseased animal or of an animal which has died otherwise than by slaughter, or that has been fed upon the uncooked offal from a slaughterhouse.
6. If its container is composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health.
- 6-a. If it has been intentionally subject to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to sections one hundred ninety-nine-a or one hundred ninety-nine-b.
7. If any valuable constituent has been in whole or in part omitted or abstracted therefrom.
8. If any substance has been substituted wholly or in part therefor.
9. If damage or inferiority has been concealed in any manner.
10. If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength or make it appear better than it is or of greater value than its true value.
- 10-a. If it is, or it bears or contains, a color additive which is unsafe within the meaning of section seven hundred six-a of the federal food, drug and cosmetic act, as amended.
11. If it falls below the standard of purity, quality or strength which it purports or is represented to possess.
12. If it is confectionery and it bears or contains any alcohol or non-nutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four tenths of one per centum, harmless natural gum and pectin; provided that this subdivision shall not apply to any confectionery by reason of its containing less than one-half of one per

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centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless non-nutritive masticatory substances.

APPROVED

Shall mean acceptable to the enforcement authority having jurisdiction for appropriate standards and/or good public health practice.

BAG-BY-BAG (Item By Item)

Examination of each bag (container) in a lot with notes being taken to record the type and quantity of contamination found on the individual basis.

BATCH

A quantity of material produced at one operation. Thus a batch is limited in size to the quantity that the machinery can hold at one time.

BLACKLIGHT - UV LIGHT

A light source that emits ultra-violet light. Used to discover fluorescent contaminants such as rodent urine.

BULK FOOD

Processed or unprocessed food in aggregate self-service containers from which quantities desired are withdrawn by the consumer.

CLEAN IN PLACE (CIP)

Clean In Place (CIP) by the circulation or flowing, by mechanical means, through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine.

CLEANABLE

Easily or readily accessible and of such material and finish and so fabricated that food residue may be completely removed by approved cleaning methods.

CLOSED

Fitted snugly, leaving no opening large enough to permit the entrance of insects, rodents, or other vermin, as well as filth.

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CODE

Numbers and/or letters placed on the label or package of a product in order to identify it with a certain batch or production date.

COMMINUTED

Reduced in size by methods including chopping, flaking, grinding or mincing.

COMPETENT PROCESSING AUTHORITY

A qualified person who has expert knowledge and appropriate background acquired through training and experience in the packaging of food in reduced oxygen environments.

CONFIRMED DISEASE OUTBREAK

A foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative organism and epidemiological analysis implicates the food as the source of the illness.

CONTAMINATE

To make impure or unclean, to soil, stain, or corrupt by contact. Foods may be contaminated by filth, bacteria, unsafe chemicals, foreign objects, insects or rodents and their excreta or body fragments.

COOK-CHILL

The process which uses a plastic bag filled with hot cooked food from which air has been expelled and which is closed with a metal or plastic crimp and rapidly cooled to the correct temperature.

COOKED FOODS

Either single or combined ingredients, which through the application of heat, microwave energy, or other acceptable methods have been prepared and are ready for human consumption.

CORROSION - RESISTANT MATERIAL

A material which maintains its original surface characteristics under prolonged influence of the food, cleaning compounds, sanitizing solutions, and/or other normal components of the environment which may contact it.

DECOMPOSE

To rot and break down into component parts. Decay; a deterioration away from a sound condition by natural change. May or may not emit offensive odors.

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DELETERIOUS

Injurious to health, harmful.

DENATURING

To change in such a way that the product is rendered unsuitable for normal food use but does not alter the usefulness for other purposes, such as for animal feed.

DESTROY

To render useless for food, man or animal; demolish.

DISPLAY CASE

Any cabinet or other facility used for showing food for sale. May or may not be refrigerated.

EASILY CLEANABLE

A characteristic of a surface that:

1. Allows effective removal of soil by normal cleaning methods,
2. Is dependent on the material, design, construction and installation of the surface, and,
3. Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose and use.

EMPLOYEE

The license holder, individual having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or any other person working in a food establishment under the jurisdiction of this Division.

ENRICHMENT

The improvement of food in nutritional value by addition of vitamins and minerals during processing.

EQUIPMENT AND/OR FACILITIES

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Items other than utensils used in the storage, preparation, display, and transportation of food such as stoves, ovens (including microwave), hoods, slicers, grinders, mixers, scales, meat blocks, tables, food shelving, reach-in refrigerators and freezers, sinks, ice makers, and similar items, used in the operation of a food establishment under the jurisdiction of this Division. This item does not include forklift trucks or dollies.

FIELD EXAMINATION

Any examination or analysis of a sample made by the inspector under working conditions, without sending the sample to the laboratory.

FOOD (Article 17, Section 198.1)

The terms “food” and “food product” shall include all articles of food, drink, confectionery or condiment, whether simple, mixed or compound, used or intended for use by men or animals, and shall also include all substances or ingredients to be added to food for any purpose. This definition shall be construed as including chewing gum.

FOODBORNE DISEASE OUTBREAK

An incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiological analysis implicates the food as the source of the illness. An exception to this includes a single case of illness such as one person ill from botulism or chemical poisoning.

FOOD CONTACT SURFACES

Those surfaces of equipment and utensils with which food normally comes into contact, and those surfaces from which food may drain, drip, or splash back onto surfaces normally in contact with food.

FOOD SERVICE ESTABLISHMENT

Any place where food is prepared and intended for individual portion service, and includes the site at which individual portions are provided, whether consumption occurs on or off the premises, or whether or not there is a charge for the food.

FROZEN FOOD

Any article used for food or drink which has been processed, packaged and/or preserved by good commercial practices and is in a frozen state.

GAME ANIMAL

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An animal, the products of which are food, that is not classified as cattle, sheep, swine, goat, poultry or fish. They include animals such as reindeer, elk, deer, bison, rabbit, squirrel, bear and muskrat; aquatic and non-aquatic birds such as wild ducks and geese, quail and pheasant; non-aquatic reptiles such as rattlesnake and aquatic mammals and, exotic animals, such as lion, tiger, leopard, elephant, camel, antelope, anteater, kangaroo and water buffalo and species of foreign domestic cattle, such as Ankole, Gayal and Yak.

GROSS FILTH

Filth on a food product that can be seen with the naked eye without a microscope or chemical means.

HACCP

A Hazard Analysis Critical Control Point system consists of:

1. An assessment of hazards associated with growing, harvesting, processing/manufacturing, distribution, marketing, preparation and/or use of a given raw material or food product,
2. The determination of critical control points required to control any identified hazard,
3. The establishment of procedures to monitor critical control points.

“Hazards” include contamination of food with unacceptable levels of food-borne disease causing organisms and/or contamination with spoilage organisms to the extent that hazards occur within the expected shelf life or use of the product.

“Critical Control Point” is a location or a process which, if not correctly controlled, could lead to contamination with food-borne pathogens or spoilage microorganisms or their survival or unacceptable growth.

“Monitoring” is the checking or verifying that the processing or handling procedure at the critical control point is properly carried out.

HERMETICALLY SEALED CONTAINER

A container which is designed and intended to be secure against the entry of microorganisms and to maintain the commercial sterility of its contents after processing.

IMPERVIOUS

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Incapable of being penetrated; nonporous; not capable of absorbing matter.

INFESTATION

The presence and multiplication of unwanted varieties of living organisms in any location.

INJUNCTION

A court order requiring the enjoined party to do or not to do certain acts.

INTEGRITY

Used in the phrase “The integrity of a sample.” This means to seal or retain possession of the sample in such a way that it can be testified that the sample could not have been tampered with since collection. Open consumer samples are not actionable except as a means of determining identification of adulterant.

INTERNAL PRODUCT TEMPERATURE

The innermost temperature of a food which has been received, processed, prepared, packaged, frozen or stored.

LABEL

Written or printed matter accompanying an article to furnish identification or other information.

LABELING

All labels and other written, printed or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such articles.

LOT

A quantity of a product to be considered a unit, by reason of:

1. Having all been shipped at one time,
2. Having the same code number so as to be identified as all having been made at the same time,
or

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3. Being all in one place without any means to separate into further sub-units. A “lot” is the amount of material represented by one official sample.

MACROSCOPIC

Large enough to be observed by the naked eye, as contrasted with microscopic.

MICROORGANISM

Microscopic one-celled or multi-celled living organisms which include mold, yeasts and bacteria. These organisms require food, moisture and proper temperature for growth; some produce toxic waste materials.

MICROSCOPIC

Invisible or indistinguishable without use of a microscope; very small or fine or precise.

MISBRANDING OF FOOD (Article 17, Section 201)

Misbranding of food. Food shall be deemed to be misbranded:

1. If its labeling is false or misleading in any particular.
2. If it is offered for sale under the name of another article.
3. If it is an imitation of another food, unless its label bears the word “imitation” and immediately thereafter the name of the food imitated in type of uniform size and equal prominence, followed by a statement showing the constituents thereof.
4. If its container is so made, formed, colored or filled as to be misleading.
5. If in package form, unless it bears a label containing the name and place of business of the manufacturer, packer or distributor.
6. If any word, statement or other information required by or under authority of this article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

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7. If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed, unless (a) it conforms to such definition and standard, and (b) its label bears the name of the food specified in the definition and standard, and, in so far as may be required, the common names of optional ingredients present in such food.
8. If it purports to be or is represented as (a) a food for which a standard of quality has been prescribed by this chapter or by regulations as provided in section two hundred fourteen-b, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or (b) a food for which no definition and standard of identity and/or standard of quality have been prescribed, and it falls below the standard of purity, quality or strength which it purports or is represented to possess.
9. If it is not subject to the provisions of subdivision seven of this section, unless its label bears (a) the common or usual name of the food, if any there be, and (b) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings, without naming each; provided that, to the extent that compliance with the requirements of clause (b) of this subdivision is impracticable, or results in deception or unfair competition, in the judgment of the commissioner, exemptions shall be established by regulations promulgated by the commissioner.
10. If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the commissioner determines to be and prescribes as necessary in order to inform purchasers fully as to its value for such uses.
11. If it bears or contains any artificial flavoring, artificial coloring, or permitted chemical preservative, unless it bears labeling stating that fact: provided, that to the extent that compliance with the requirements of this subdivision is impracticable, exemptions shall be established by regulations promulgated by the commissioner. The provisions of this subdivision and subdivisions seven and nine with respect to artificial coloring shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.
12. If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical; provided, however, that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

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13. If it is a color additive unless its packing and labeling are in conformity with such packing and labeling requirements, applicable to such color additive, as may be contained in regulations promulgated by the commissioner.

MODIFIED ATMOSPHERE PACKAGING (MAP)

The process that employs a gas flushing and sealing process or reduction of oxygen through respiration of vegetables or microbial action. Modified Atmosphere Packaging (MAP) is defined as packaging of a product in an atmosphere which has had a one-time modification of gaseous composition so that it is different from that of air, which normally contains 78.08% nitrogen, 20.96% oxygen and 0.03% carbon dioxide.

OFFAL

Waste parts of a butchered animal.

ORGANOLEPTIC

Analysis or examination of a product by use of one's senses, i.e., smell, taste, touch, sight.

PACKAGED

Bottled, canned, boxed, bagged or securely wrapped.

PARTIALLY COOKED FOOD

Food which has been heated to a temperature for a time considered insufficient for complete cooking.

PATHOGEN

A microorganism which is capable of producing disease in a human or animal.

PERISHABLE FOOD

Any food of such type or in such condition or physical state that it may spoil or otherwise become unfit for human consumption.

pH

The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

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Values between 0 and 7 indicate acidity and values between 7 and 15 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

PLATE COUNT

The number of visible microbial colonies found on inoculated plates of nutritional media which have been incubated under specified conditions.

POLLUTED WATER

Water fouled by foreign materials, such as sewage, which make it offensive to sight and smell or a danger to the health of the public.

POTENTIALLY HAZARDOUS FOOD

Any food that consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustacea, or other ingredients, including synthetic ingredients, and which is in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms. The term does not include foods that have a pH level of 4.6 or below, a water activity (a_w) value of 0.85 or less under standard conditions, or food products in hermetically sealed containers commercially processed to prevent spoilage.

PRESERVATIVE

A chemical additive which will preserve some desired characteristic of a food by making certain chemical structures more stable or by retarding microbial growth.

RAW FOOD

Food which may or may not be frozen, has had little or no heat applied, and/or may be consumed in the raw state or receive sufficient heat for complete cooking by a food establishment and/or consumer.

READY-TO-EAT FOOD

Food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form. "Ready-To-Eat Food" includes:

1. Unpackaged potentially hazardous food that is cooked to the appropriate temperature,
2. Raw, washed, cut fruits and vegetables,

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3. Whole raw, fruits and vegetables that are presented for consumption without the need for further washing, such as in a buffet, and
4. Other foods presented for consumption for which further washing or cooking is not required from which rinds, peels, husks, or shells are removed.

REDUCED OXYGEN PACKAGING

The application of any packaging process which reduces the oxygen content in a hermetically sealed package to a level below that ordinarily found in the surrounding atmosphere [see *cook-chill*, *sous vide*, *vacuum packaging* and *modified atmosphere packaging (MAP)*].

REMOVABLE

Component parts of a piece of food equipment capable of being separated from the principal part without the use of tools or with the use of simple tools such as those normally used by maintenance personnel.

RETAIL FOOD STORE

Any establishment or section of an establishment where food and food products are offered to the consumer and intended for off-premise consumption.

SAFE TEMPERATURES

When considering potentially hazardous food, food temperatures of 135°F (57°C) or above, 40°F (4°C) or below, except that during storage and transportation of all frozen food, it shall mean 0°F or less.

SANITIZATION

Effective bactericidal treatment of clean surfaces or equipment or utensils by a procedure which has been approved by the regulatory authority as being effective in the destruction of vegetative cells of pathogenic bacteria and in substantially reducing other microorganisms.

SEALED

Free from cracks or other openings which would permit the entry or passage of moisture.

SINGLE SERVICE ARTICLES

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Cups, containers, lids, closures, trays, wrapping materials, and all similar articles, which are constructed wholly or in part from paper, paperboard, molded pulp, foil, wood, plastic, synthetic or other materials, which are considered by the regulatory authority as single-service articles and are intended by the manufacturers and generally recognized by the public as for one usage only, then to be discarded. Single-service articles shall be free from deleterious substances and conform to any applicable food additive regulation.

SLACKING

The process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23°C (-10°F) to -4°C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach.

SOUS VIDE

The specialized process of reduced oxygen packaging for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service. The sous vide process is a pasteurization step that reduces bacterial load but is not sufficient to make the food shelf stable.

The process involves the following steps:

1. Preparation of the raw materials (this step may include partial cooking of some or of all the ingredients),
2. Packaging of the product, application of vacuum and sealing of the package,
3. Pasteurization of the product for a specified and monitored time/temperature,
4. Rapid and monitored cooling of the product at or below 3°C (38°F) or frozen; and, reheating of the package to a specified temperature before opening and service.

STERILIZATION

The process of killing all living microorganisms.

SUBPOENA

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A writ commanding a person designated in it to attend court or an administrative proceeding under a penalty for failure to do so.

SURVEY SAMPLE

Usually one of a number of samples taken at random from commercial channels in order to get information about a product as it is currently manufactured. Usually taken of the same product from a number of different manufacturers.

TARE

A deduction of weight made in allowance for the weight of the container.

TOXICITY

Quality, state, or degree of being poisonous.

TOXIN

A chemical produced by living organisms which is poisonous to man or animals.

UTENSIL

Any implement (knives, forks, spoons, tongs, spatulas, scoops, pots, pans, mesh gloves, etc.) used in the processing, preparation, storage, handling, or conveying of food.

VACUUM PACKAGING

The process which reduces the amount of air from a package and hermetically seals the package so that a near-perfect vacuum remains inside. A common variation of the process is vacuum skin packaging (VSP). A highly flexible plastic barrier is used by this technology that allows the package to mold itself to the contours of the food being packaged.

VECTOR

An organism which mechanically carries and transmits disease-causing organisms.

VEHICLE

Any van, truck, trailer, cab, bus, cycle, automobile, shopping cart, wagon, or other conveyor of food.

VISCOSITY

A measure of the resistance to flow of a liquid.

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WAREHOUSE

Any structure, room, or part thereof, used for the purpose of storing food or food containers.

WAREWASHING

The cleaning and sanitizing of food contact surfaces of equipment and utensils.

WATER ACTIVITY (a_w)

A measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature and is indicated by the symbol a_w .

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**NEW YORK STATE DEPARTMENT OF HEALTH
COUNTY, REGIONAL AND DISTRICT OFFICES
SUB-SECTION 1045**

COUNTY HEALTH DEPARTMENTS

County/Region	Comm. &/or Public Health Dir.	Address	Env. Health Responsibility	Env. Health Telephone	Env. Health Fax	Env. Health Email
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ALLEGANY	Gar Ogden, MD, CM	Co. Office Building, 7 Court St., Belmont 14813-1076	Thomas E. Hull, M.S.	(585) 268-9250 ext. 254	(585) 268-9712	hullte@alleganyco.com
BROOME	Claudia Edwards, BA, MS	225 Front St., Binghamton 13905	Robert Denz, P.E.	(607) 778-2895	(607) 778-3912	rdenz@co.broome.ny.us
CATTARAUGUS	Barbara J. Hastings, RN, BSN,MSN	1 Leo Moss Drive, Suite 4010, Olean, 14760-1154	Eric W. Wohlers, P.E.	(716) 373-8050 ext. 3437	(716) 373-0942	ewwohlers@catco.org
CAYUGA	Elaine Daly, RN, BSN	160 Genesee St., PO Box 219, Auburn 13021	Eileen O'Connor, P.E.	(315) 253-1244	(315) 253-1478	eileen.o'connor@dca.state.ny.us
CHAUTAUQUA	Edwin Miner	Hall R. Clothier Bldg., 7 N. Erie St., Mayville 14757	Steven M. Johnson, P.E.	(716) 753-4481	(716) 753-4344	stevej@health.co.chautaugua.ny.us
CHEMUNG	Robert E. Page	103 Washington St., PO Box 588 Elmira 14902-0588	Thomas G. Kump, P.E.	(607) 737-2021	(607) 737-0437	tkump@co.chemung.ny.us
CHENANGO**	Marcus W. Flindt	County Office Bldg., 5 Court Street, Norwich 13815	Glenn Kaiser	(607) 337-1673	(607) 337-1720	gkaiser@co.chenango.ny.us
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GENESEE	Christopher M. Szwagiel, DPH,CHE	3837 W. Main Street Road, Batavia 14020-9406	Randy Garney, Sr. PHS	(585) 344-2580	(585) 344-4713	rgarney@co.genesee.ny.us
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MADISON**	David Dorrance	Public Health Building, #5, PO Box 605, Wampsville 13163	Geoffrey Snyder	(315) 366-2526	(315) 366-2207	geoffrey.snyder@co.madison.ny.us
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PUTNAM	Sherita Amler, MD	1 Geneva Road, Brewster 10509	Loretta Molinari	(845) 278-6130 ext. 2151	(845) 278-7921	loretta.molinari@putnamcountyny.com
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SCHOHARIE	Carl J. Stefanik	275 Main Street, PO Box 667, Schoharie 12157-0667	Janice Herick	(518) 295-8382	(518) 295-8786	janhe@co.schoharie.ny.us
SENECA	Vickie Swinehart, RN	31 Thurber Drive, Waterloo 13165-1660	Vickie Swinehart	(315) 539-1920	(315) 539-9493	vswinehart@co.seneca.ny.us
SUFFOLK	Brian Harper, MD, MPH	220 Rabro Drive East, Hauppauge, 11788-4290	Vito Minei, P.E., Dir. Env. Quality	(631) 853-3062	(631) 853-3075	vito.minei@suffolkcountyny.gov
			David Graham, MD, MPH Dir. of Public Health	(631) 853-3058		David.Graham@suffolkcountyny.gov
TIOGA	Johannes A. Peeters	1062 State Route 38, P.O. Box 120, Owego, NY 13827-0220	Johannes Peeters	(607) 687-8630	(607) 687-8636	peetersh@co.tioga.ny.us
TOMPKINS	Alice Cole, RN, MSE	401 Harris B Dates Drive, Ithaca 14850-1386	John Anderson, P.E.	(607) 274-6688	(607) 274-6695	janderson@tompkins-co.org
ULSTER	Dean N. Palen, PE, MBA	300 Flatbush Avenue, Kingston 12401	Allan M. Dumas, III, P.E.	(845) 340-3035	(845) 340-3045	adum@co.ulster.ny.us
WESTCHESTER	Joshua Lipsman, MD, MPH	145 Huguenot Street, 8 th Floor, New Rochelle 10801	Gregory Camiccioli, PhD, Dep. Comm. for EH	(914) 813-5171	(914) 813-5158	gac7@westchestergov.com
WYOMING	Gregory Collins, DO	338 North Main Street, Warsaw 14569	Gary Bonarski	(585) 786-8894	(585) 786-8167	gbonarski@wyomingco.net
NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE						
NEW YORK (NY)	Thomas R. Frieden, MD, MPH	125 North Street, Room 331, Box 28, New York 10013	Jessica Leighton, Ph.D., M.P.H. Deputy Commissioner of EH	(212) 788-4646 (In NYC 311)	(212) 788-2159	jleight@health.nyc.gov
		2 Lafayette Street, 11th Fl., New York 10007	Jim Luke	(212) 676-1520		jluke@health.nyc.gov

** Use Full Address for Mailing *** Acting Public Health Director **** Acting Commissioner

P:\dshp\County Telephone List revised 12-1-05

**NEW YORK STATE DEPARTMENT OF HEALTH
REGIONAL AND DISTRICT OFFICES
SUB-SECTION 1045**

REGIONAL OFFICES			
REGION	STAFF	ADDRESS	TELEPHONE
WESTERN REGION (W)	Salvatore Page – Associate Commissioner (SWP01)	584 Delaware Avenue, Buffalo 14202	(716) 847-4505 Fax # (716) 847-4681
– Rochester Field Office	Bill Hoogland - Asst. Regional Director (WAH01) (Western Region)	Triangle Building, 335 East Main Street, Rochester 14604-2127	(585) 423-8082 Roc. (Secx8067) Fax # (585) 423-8028 Cell (585) 329-1691 (585) 423-8042
	Diane Fox-Knoll (DLK02), Administrative Assistant		
	Ralph VanHouten- Reg. Env. Health Program Dir. (RRV01)	Triangle Building, 335 East Main Street, Rochester 14604-2127	(585) 423-8072 Cell (585) 233-8108 (585) 423-8067 (Fax (585) 423-8128)
	Veleta Muhs, secretary (vgm01)		
	Field Coordinators		
	Anita Bonamici- Principal Public Health Sanitarian(AMB18)	Triangle Building, 335 East Main Street, Rochester 14604-2127	(585) 423-8088
	Robert Thompson – Sr. Sanitary Engineer (REH03)	Triangle Building, 335 East Main Street, Rochester 14604-2127	(585) 423-8070
	April Steenburgh, Public Health Specialist I (ALS03)	584 Delaware Avenue, Buffalo, 14202	(716) 847-4558 (Fax (716) 847-4333) cell (585) 329-2419
	Jeff Booth – Principal Sanitarian (JWB03)	584 Delaware Avenue, Buffalo, 14202	(716) 847-4500 (Fax (716) 847-4333)
	Regional Toxics Coordinators		
	Matt Forcucci, Public Health Spec. III, (MJF13)	584 Delaware Avenue, Buffalo, 14202	(716) 847-4513
	Cameron O'Connor, Public Health Spec. III, (CHO01)	584 Delaware Avenue, Buffalo, 14202	(716) 847-4507
	Deborah McNaughton, Public Health Spec. II, (DAM20)	Triangle Building, 335 East Main Street, Rochester 14604-2127	(585) 423-8069 (Fax (585) 423-8128)
	Regional Environmental Radiation Coordinators		
	Barbara Ignatz, Assoc. Rad Health. Spec. (bxi02)	584 Delaware Avenue, Buffalo, 14202	(716) 847-4512
METROPOLITAN NEW YORK REGIONAL OFFICE (M)	Sara Koch, Assoc. Rad. Health Spec., (sak06)	584 Delaware Avenue, Buffalo, 14202	(716) 847-4383
	Mai Tran, Assoc. Rad. Health Spec. (mti02)	Triangle Building, 335 East Main Street, Rochester 14604-2127	(585) 423-8068 Fax (585) 423-8128
	Celeste M. Johnson, Director (CMJ01)	90 Church Street, New York, NY 10007	(212) 268-7185 Fax (212) 268-7212
	Geraldine Neal, Secretary (GXN02)		
	Annette Larke-Griffith, Secretary – for NYC Conf Rooms		
	Patricia Jones, Deputy Director	90 Church Street, New York, NY 10007	(212) 268-7055
	Brian Devine, Reg. Env. Health Program Director (BDD02)	50 North Street, Suite 2, Monticello, NY12701	(845) 794-2045 (Fax (845) 794-3165) Cell 917/841-8306
	Ellen Salovich, Secretary, (ERS04)		
	Field Coordinators		
	Judyth Nicolenko – Prin. Sanitarian (JAN07)	50 North Street, Suite 2, Monticello, NY12701	(845) 794-2045 (Fax (845) 794-3165)
	Anna Stamm - Sr. Sanitary Engineer (AXS06)	90 Church Street, New York, NY 10007	(212) 417-5859 (Fax (212) 417-4909)
	George Philip – Sr. Sanitary Engineer (GXP04)	320 Carlton Ave., #5000, Central Islip, 11722	(631) 851-3082 (Fax (631) 851-4319)
	Regional Environmental Radiation Coordinators		
	Nelson Warren, Assoc. Rad. Health Spec., (NFW01)	145 Huguenot St, 5th Floor, New Rochelle, 10801	(914) 654-7162
	Andrew Bass, Assoc. Rad. Health Spec., (ALB01)	Courthouse Corporate Center, 320 Carleton Avenue, Suite 5000 Central Islip, NY 11722	(631) 851-3083

**NEW YORK STATE DEPARTMENT OF HEALTH
REGIONAL AND DISTRICT OFFICES
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CENTRAL NEW YORK REGION OFFICE (CNY)	Ronald Heerkens – Associate Regional Director (RHH01) Director of Environmental Health Maureen Barr, Secretary (MMB10)	217 S. Salina Street, Syracuse 13202	(315) 477-8484 (Fax (315) 477-8588) Cell (315) 380-1639 (315) 477-8100 (main number)
	Field Coordinators		
	Thomas Okoniewski - Reg. Sanitarian (TEO01)	217 S. Salina Street, Syracuse 13202	(315) 477-8152
	Maggie Deitrich – Reg. Sanitarian (MAD07)	217 S. Salina Street, Syracuse 13202	(315) 477-8144
	John Strepelis - Sr. Sanitary Engineer (JXS06)	217 S. Salina Street, Syracuse 13202	(315) 477-8150 (Fax (315) 477-8581)
	Erin Spier – Assistant Sanitary Engineer (EMS14)	217 S. Salina Street, Syracuse 13202	(315) 477-8149 (Fax (315) 477-8581)
	Gregor Smith – Jr. Engineer (GKS01)	217 S. Salina Street, Syracuse 13202	(315) 477-8515 (Fax (315) 477-8581)
	Regional Toxics Coordinators		
	Henriett Hamel – Public Health Specialist III	217 S. Salina Street, Syracuse 13202	(315) 477-8154 (Fax (315) 477-8581)
	Greg Rys – Public Health Specialist 3 (GAR02)	217 S. Salina Street, Syracuse 13202	(315) 477-8484
	Regional Environmental Radiation Coordinators		
	Gary Baker, Field Supervisor	217 S. Salina Street, Syracuse 13202	(315) 477-8448
	Vidya Goyal	217 S. Salina Street, Syracuse 13202	(315) 477-8452
	William Kelleher	217 S. Salina Street, Syracuse 13202	(315) 477-8451
CAPITAL DISTRICT REGION OFFICE (CD)	Geraldine Bunn, Associate Director (GAB02)	Frear Building, One Fulton Street, Troy12180-3281	(518) 408-5277 (Fax (518) 408-5280)
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	Lynn Schriener (Secretary) (LAS17)		(518) 408-5423 (main number) (Fax 408-5309)
	Field Coordinators		
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	Tim Vickerson - Sr. Sanitary Engineer (TEV01)	Frear Building, One Fulton Street, Troy12180-3281	(518) 408-5423
	Terry Emmitt – Sr. Sanitary Engineer (tle01)	Frear Building, One Fulton Street, Troy12180-3281	(518) 408-5423
	Kristen Sayers – Pub. Health Spec. 3 (Env) (KMS15)	41St. Bernard St., Saranac Lake 12983-1839	(518) 891-1600 (Fax 891-5895) cell (518) 524-1171 (518) 891-7173 (Kristen VoiceMail)
	Regional Toxics Coordinators		
	Dan Geraghty – Program Research Spec. 3 (DRG01)	Frear Building, One Fulton Street, Troy12180-3281	(518) 408-5423
	Kristen Kulow - Public Health Specialist 2 (KKK07)	28 Hill Street, Suite 201, Oneonta, NY 13820-9804	(607) 432-3911 Fax (607) 432-0089

**NEW YORK STATE DEPARTMENT OF HEALTH
REGIONAL AND DISTRICT OFFICES
SUB-SECTION 1045**

DISTRICT OFFICES

DISTRICT	COUNTIES SERVED	ADDRESS	DIRECTOR	TELEPHONE	FAX #
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GLENS FALLS (N) (B0646)	Saratoga, Warren, Washington	77 Mohican Street, Glens Falls 12801-4429	Anita Gabalski (amg02@health.state.ny.us) Kay Bromley (Secretary)	(518) 793-3893 cell (518) 796-7007	(518) 793-0427
HERKIMER (N) (B0640)	Fulton, Herkimer, Montgomery	5665 State Route 5, Herkimer 13350-9721	Donald Van Patten (ddv01@health.state.ny.us) Dawn Hill (Secretary)	(315) 866-6879 cell (315) 866-1687	(315) 866-8192
HORNELL (W) (B0638)	Schuyler, Steuben	107 Broadway, Room 105, Hornell 14843-0430	Tomas Klaseus (tgm02@health.state.ny.us) Denise Lang (Secretary)	(607) 324-8371	(607) 324-5121
MONTICELLO (M) (B0649)	Sullivan	50 North Street, Suite 2, Monticello 12701-1711	Mark Knudsen (mdk02@health.state.ny.us) Virginia Connell (Secretary)	(845) 794-2045	(845) 794-3165
ONEONTA (N) (B0644)	Delaware, Greene, Otsego	28 Hill Street, Suite 201, Oneonta 13820-9804	Robert Pierce (rap02@health.state.ny.us) Carla Huntington (Secretary)	(607) 432-3911	(607) 432-0089
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**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**MEMORANDUM OF UNDERSTANDING
NYS DEPT. OF HEALTH & NYS DEPT. OF AGRICULTURE & MARKETS
SUB-SECTION 1050**

**MEMORANDUM OF UNDERSTANDING
BETWEEN THE NEW YORK STATE DEPARTMENT OF HEALTH AND THE
NEW YORK STATE DEPARTMENT OF AGRICULTURE AND MARKETS
CONCERNING INSPECTION OF FOOD SERVICE ESTABLISHMENTS
AND FOOD PROCESSING ESTABLISHMENT**

I. GENERAL

This Memorandum of Understanding replaces the Memorandum of Understanding dated December 20, 1972, and effective on January 1, 1973, between the New York State Department of Health (Health) and the New York State Department of Agriculture and Markets (Agriculture).

The purpose of this Memorandum of Understanding is to clarify the respective responsibilities of Agriculture and Health in the inspection of food service establishments and food processing establishments, to assure comprehensive food protection for the people of New York State, to maximize the efficient use of the resources of agencies concerned, to avoid gaps in food surveillance, and in furtherance of such purpose, to continue the development of broader cooperative efforts between the two agencies.

Responsible Agencies

Agriculture and Health are the responsible agencies for the implementation of this Memorandum of Understanding. Under the authority of Sections 201(1)(a), 201(1)(m), 206(1)(a), 206(1)(b), 206(1)(f), and Title VIII of Article 13 of the Public Health Law and pursuant to the power granted to the State Commissioner of Health by Article 20-C of the Agriculture and Markets Law to certify and approve service food establishment permit and inspection programs of local health agencies, the State Commissioner of Health, by execution of this instrument, binds all city and county health departments and State district health offices ("Local Health Units") to its terms and conditions.

For purposes of this agreement, the Bureau of Community Sanitation and Food Protection of the State Department of Health at Albany, New York and the Division of Food Inspection Services of the State Department of Agriculture and Markets at Albany, New York will be responsible for its implementation.

Jurisdiction

This Understanding applies to the entire State of New York and includes all city and county health departments.

Effective Date

This agreement will be effective March 1, 1986.

MEMORANDUM OF UNDERSTANDING
NYS DEPT. OF HEALTH & NYS DEPT. OF AGRICULTURE & MARKETS
SUB-SECTION 1050

Legal Authority

The Governor's Executive Order No. 73 of December 1972, which supplements Executive Order No. 3 of 1960, provides requisite authority for Agriculture and Health to enter into this Memorandum of Understanding. Section 206(3) of the Public Health Law and Section 16(24) of the Agriculture and Markets Law also authorize this Memorandum of Understanding.

II. RESPONSIBILITIES AND IMPLEMENTATION

Determination of Responsibility

Health and local health departments will be responsible for the inspection and regulation of places where food is consumed on the premises or sold ready-to-eat for off-premises consumption including the site at which individual portions are provided.

Agriculture will be responsible for the inspection and regulation of places where food is processed or manufactured, food warehouses, wholesale food distributors and retail food stores.

If an establishment has operations that may fall under the jurisdiction of both Health and Agriculture, Agriculture shall have jurisdiction over all operations of the establishment unless sales of food for consumption on the premises or ready-to-eat for off-premises consumption, measured by annual dollar receipts, exceeds fifty percent of total annual dollar receipts in which event Health shall have jurisdiction of the establishment. The field staff of Health and Agriculture shall meet to resolve jurisdictional questions. If such staff does not resolve any jurisdictional issues, the Division of Food Inspection Services of Agriculture and the Bureau of Community Sanitation and Food Protection in Health will meet to resolve the issue and to render a mutually agreed upon decision binding on both departments. In resolving such jurisdictional issue, the representations of the establishment operator shall be dispositive as to whether or not sales of food for consumption on the premises or ready-to-eat for off-premises consumption exceed fifty percent of the total annual dollar receipts of the establishment.

In no instance shall an establishment be required to have a license or permit to operate from both departments or be inspected by both departments, except for retail frozen dessert permits which are issued by the local health unit but may be required in an Agriculture regulated establishment.

Health shall identify and report economic violations under Agriculture's laws and regulations as a routine part of its food service establishment inspections. (See IV. infra).

Determination of Responsibility (cont.)

MEMORANDUM OF UNDERSTANDING
NYS DEPT. OF HEALTH & NYS DEPT. OF AGRICULTURE & MARKETS
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Examples of establishments over which Health normally has jurisdiction include:

Restaurants
Automats
Cafes
Refreshment Stands
Soda Fountains
Carnivals, Circuses, Exhibitions, Fairs and Festivals
Clubs
Organizations
Hamburger Stands
Lunch Bars
Lunch Counters
Lunch Rooms
Catering Kitchens
Industrial Food Services
Mobile Food Establishment and Pushcarts
Food Vending Machine Commissaries
Church Food Services
Oyster and Clam Bars
Fish Fry Places
Dairy Bars
Ice Cream Stands
Frozen Dessert Stands
Carry-out Restaurants
Fast Food Places
Caterers
Drive-in Restaurants
Pizzerias
Convenience Food Preparation Places
Short Order Restaurants
Tea Rooms
Hospital & Nursing Home Food Services
Baby Formula Preparation
Food Vending Machines
Interstate & Intrastate Carrier Food Services
Cafeterias
Coffee Shops
Diners
Sandwich Shops
Taverns
Grills
Cocktail Bars
Night Clubs
Food Services in: Temporary Residences
 Migrant Camp Kitchens
 Children's Camp
 Kitchens

Determination of Responsibility (cont.)

MEMORANDUM OF UNDERSTANDING
NYS DEPT. OF HEALTH & NYS DEPT. OF AGRICULTURE & MARKETS
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Luncheonettes
Mobile Food Vehicle Commissaries
School Food Service Areas
College Food Services
Retail Frozen Dessert Operations
Retail Bakeries
Delicatessens with Food Service Equal to or Greater than 50% of Sales

Examples of establishments over which Agriculture normally has jurisdiction include:

Candy Plants
Frozen Food Plants
Food Warehouses
Fruit and Vegetable Wholesalers
Nut Roasting and Packaging
Spice and Condiment Plants
Soft Drink Bottling Plants
Food Stores
Baby Food Manufacturing
Smoked Fish Plants
Potato and Vegetable Processing and Packaging
Frozen Food Warehouses
Canning Plants
Sugar Refiners
Liquid Sugar (Syrup) Plants
Wineries and Cider Mills
Cream Filling Manufacturing
Wholesale Bakeries
Convenience Food Plants
Delicatessens with Food Service less than 50% of Sales

Other State or federal agencies are responsible for inspection and regulation of certain food processing operations. These include:

Shellfish harvesting, processing and distribution - New York State Department of Environmental Conservation.

Egg Processing (Breaking, Pasteurization, Freezing and Drying) - U.S. Department of Agriculture.

Implementation

Agriculture will inform its field representatives of their areas of responsibility. Health will inform the local health units of their areas of responsibility. Responsibilities of other State and Federal agencies also will be specified. In addition, Health shall not make available State aid to any local health unit for any activity which, under this agreement, is the responsibility of Agriculture.

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Health, Agriculture and local health units will hold or sponsor joint training sessions in the interpretation and application of principles, regulations, standards and techniques of common concern or interest.

III. MECHANISM FOR SETTING OF STANDARDS

In order to provide similar food protection standards in retail food operations, Health shall utilize Part 14 of the State Sanitary Code (10 NYCRR Part 14) as a minimal standard and Agriculture shall use the Retail Food Store Sanitation Regulations (1 NYCRR Part 271) as a minimal standard in performing inspections and requiring compliance.

Agriculture will employ standards of health and sanitation established by the State Commissioner of Health and incorporate these fully in its food inspection programs. In setting such standards, the State Commissioner of Health will solicit comments from Agriculture, particularly as related to the feasibility of implementation. Agriculture will have responsibility for the setting of standards in respect to food adulteration, misbranding and economic factors. In setting such standards, the State Commissioner of Agriculture and Markets will solicit comments from Health.

IV. MECHANISMS FOR INFORMATION EXCHANGE

Health, Agriculture and each local health unit shall maintain current complete listings of all establishments under permit or license by them. Such listings will be available to agencies or units concerned in areas of joint responsibility during normal working hours.

Representatives of Health and Agriculture will meet annually in November to review their respective programs and the implementation of this memorandum. Local health units may be represented at such meetings.

Health, Agriculture and each local health unit shall maintain rosters of regional and local Health officials and Agriculture food program supervisors and make such rosters available to each other.

Health, Agriculture and each local health unit shall review all complaints to determine jurisdiction, and shall acknowledge and forward such complaints to the appropriate office for handling consistent with this Memorandum of Understanding.

If Agriculture becomes aware of actual or suspected cases of foodborne illness it shall report such cases by telephone, without delay, to the local health unit having jurisdiction for that locality. Health and Agriculture will jointly investigate and complete final reports involving illnesses that occur at or due to establishments regulated by Agriculture. These reports will be forwarded to the Division of Food Inspection Services in Agriculture and to the Bureau of Community Sanitation and Food Protection in Health.

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Whenever an economic violation is observed at a food service establishment, the local health unit shall prepare, in duplicate, a Labeling and Advertising Report, FIS-545. One copy shall be left at the establishment at the time of the inspection; the second copy shall be forwarded, as directed by Health, to Agriculture.

If an establishment regulated by Agriculture requires a retail frozen dessert permit as specified in Section 225(5)(s) of the Public Health Law, Agriculture will notify the local health unit of the name and address of the operator of that establishment.

Health shall require the establishment to complete a frozen dessert permit application form, GEN 64. Agriculture shall inspect the operation and require that it meet the requirements of subpart 14-3 of the State Sanitary Code. Upon a determination that the retail frozen dessert operation will meet Subpart 14-3, Agriculture will forward the inspection report form to the local health unit having jurisdiction. The local health unit shall issue the permit when it has received the permit application, the permit fee, and a satisfactory Agriculture inspection report.

Whenever one agency learns of a FDA Class I, or similar recall of food or food products, it shall immediately notify the other agency of such recall. Throughout the recall process, both agencies at all levels will make a maximum effort to keep the other agency informed and cooperate in every way possible to expedite the removal from the marketplace of the food posing the public health hazard.

**V. MECHANISMS FOR EMBARGO/SEIZURE OF FOOD SOURCES IMPLICATED IN
EPIDEMIOLOGIC INVESTIGATIONS**

Epidemiologic Investigation

DOH will investigate foodborne disease outbreaks. These investigations are conducted by county and city health departments and/or State Health Department District Offices following procedures outlined in the "Environmental Health Manual." DOH will notify DA&M of all on-going investigations where a contaminated food source is the suspected cause of a disease outbreak. DA&M will provide assistance in the investigation and may play the lead role in tracing contaminated foods back to their source by visiting retailers, wholesalers and producers to review and obtain records that document the chain of distribution for the products. DOH will analyze the findings of the epidemiologic and source investigations and make a determination as to the likelihood of an association between the illness outbreak and its cause being one or more sources. When warranted, based on the evaluation of the investigation data and analysis, the Commissioner of DOH will certify to the Commissioner of DA&M that food from the source(s) constitute(s) a danger to the health of the people of the State of New York and that such source(s) is/are unapproved source(s) for food service establishments in the state.

Embargo, Seizure, Recall, Public Notification

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After receiving certification from the Commissioner of Health, the Commissioner of Agriculture and Markets shall direct the seizure quarantine and/or destruction of the food in question pursuant to the provisions of Section 202-b of the Agriculture and Market Law, following his or her determination that said food is adulterated within the meaning of Section 200 of the Agriculture and Markets Law and, as such, that the manufacture, processing, possession, sale, offering or exposure for sale of such food would violate Section 199-a(1) of the Agriculture and Markets Law. Where they deem it appropriate, the Commissioners of Health and Agriculture and Markets shall direct that a recall of such adulterated food be implemented and that the public be notified of such recall. The Department of Health shall assist in cases involving such seizures, quarantines, destruction and recalls by assuring the removal of any remaining contaminated food from food service establishments and by making available witnesses for any administrative proceedings and/or litigation associated with such actions.

Nothing herein contained shall be construed to restrict the power of the State Commissioner of Health to take Summary Action under Public Health Law Section 16 to require the discontinuance of conditions or activities constituting a danger to public health when such action is deemed appropriate under the circumstances.

VI. REVIEW OF AGREEMENT

This agreement between the two departments shall be submitted annually to the Governor's Office and the Division of the Budget for their review of effectiveness and to solicit their recommendations to both Agriculture and Health as to changes of policies and procedures with respect to this agreement.

**AMENDMENT TO THE
MEMORANDUM OF UNDERSTANDING
BETWEEN THE NEW YORK STATE DEPARTMENT OF HEALTH**

**MEMORANDUM OF UNDERSTANDING
NYS DEPT. OF HEALTH & NYS DEPT. OF AGRICULTURE & MARKETS
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AND THE

NYS DEPARTMENT OF AGRICULTURE AND MARKETS

**CONCERNING REGULATORY OVERSIGHT OF PUBLIC WATER SUPPLIES
AT AGRICULTURE AND MARKETS LICENSED FACILITIES**

WHEREAS, the parties hereto previously entered in a Memorandum of Understanding, effective March 1, 1986, concerning inspection of Food Service Establishments and Food Processing Establishments; and

WHEREAS, this Memorandum of Understanding was subsequently amended in 1993 to include a mechanism by which Department of Health (DOH) epidemiological findings and recommendations concerning contaminated food sources could be referred to the Department of Agriculture and Markets (DA&M) to enable the DA & M to assure that such food is removed from sale and recalled in an expedient manner; and

WHEREAS, the existing Memorandum of Understanding (as amended) states that the two agencies will cooperate in investigating foodborne illness outbreaks and in food recalls; and

WHEREAS, the parties want to establish a mechanism for inspection of public water supplies at facilities licensed to operate by DA & M along with appropriate follow-up, as may be warranted, to correct any and all identified problems; and

WHEREAS, the parties want to expand the cooperation between the two Departments, as set forth in the existing Memorandum of Understanding, to include public water supply inspections;

NOW, THEREFORE, a new Section VI is added to the Memorandum of Understanding to reflect this additional cooperation, and existing Section VI is renumbered Section VII.

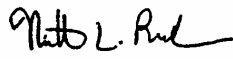
The following items are agreed to:

1. The NYS Department of Health (DOH) or its designated County Health Department (LHD) is responsible for regulatory oversight of public water supplies at DA&M licensed facilities.
2. DA&M will notify their licensed facilities of the DOH/LHD role. DOH will provide to DA&M a pamphlet containing material that would allow prospective DA&M facility operators to easily

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understand the DOH/LHD requirements relative to an on-site public water supply. DA&M would, in turn, provide this material to any new applicant.

3. DOH/LHD will notify DA&M of any potential critical violations of DA&M rules and regulations at DA&M licensed facilities and DA&M will notify DOH/LHD of any potential significant water supply problems they observe within their licensed facilities.
4. DOH/LHD will initiate administrative actions concerning identified public water supply violations in accordance with DOH Administrative Manual Item ADM 2, notifying DA&M of all such actions. Should violations present a public health hazard, DA&M agrees to initiate proceedings to consider revocation of the facility's Article 20-C Food Processing License OR assure that an alternative arrangement for interim water supply is available at the impacted facility until corrections are made to ensure the safety of the water supply.
5. The LHD may charge these DA&M licensed facilities reasonable fees, not exceeding the estimated costs for public water system protection and monitoring services, pursuant to the MOU and consistent with the schedule of fees approved by DOH under Public Health Law Section 606.
6. DA&M will not license facilities with new public water systems until notification is received from DOH/LHD of the approval of a potable source(s) of water.

Signed: 
Nathan L. Rudgers, Commissioner
NYS Department of Agriculture
and Markets
Albany, New York

Dated: November 7, 2000

Signed: 
Ronald Tramontano, Director
Center for Environmental Health
NYS Department of Health
Troy, New York

Dated: Oct 16, 2000

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**MEMORANDUM OF UNDERSTANDING
NYS DEPT. OF HEALTH, NYS DEPT. OF ENVIRON. CONS. & NYS DEPT. OF AG. & MKTS.
SUB-SECTION 1055**

**BETWEEN THE NYS DEPARTMENTS OF HEALTH,
ENVIRONMENTAL CONSERVATION AND
AGRICULTURE AND MARKETS
REGARDING INVESTIGATION OF
SHELLFISH-RELATED FOODBORNE ILLNESS OUTBREAKS
AND EMBARGO/SEIZURE OF IMPLICATED SHELLFISH**

The State of New York recognizes the threat to public health posed by the consumption of contaminated shellfish. In order to further the State's commitment to ensuring the shellfish products shipped and marketed in intra and interstate commerce are safe and wholesome, the New York State Departments of Health (DOH), Agriculture and Markets (DA&M), and Environmental Conservation (DEC) hereby agree to cooperative response for the investigation of shellfish-related foodborne illness outbreaks, to take all necessary and appropriate action to remove contaminated shellfish from commerce and, where necessary, to take enforcement action against parties involved in the illegal sale or shipment of shellfish.

The primary responsibilities of DOH, DA&M and DEC are as follows:

DEC is responsible for sanitary control over shellfish in harvesting and wholesale commerce.

DA&M is responsible for sanitary control over shellfish in retail commerce; and

DOH is responsible for epidemiological investigations and sanitary control over shellfish in food service establishments.

It is understood that these responsibilities may be shared and that interagency cooperation is necessary to best serve the public need. Therefore, it is agreed the investigations of shellfish-related foodborne illnesses shall be conducted according to the attached Interagency (DOH, DEC, AND DA&M) Protocol for Investigation of Shellfish-Associated Foodborne Disease Outbreaks.

**Interagency DOH, DEC, and DA&M Protocol for Investigation of
Shellfish-Associated Foodborne Disease Outbreaks**

POLICY

The New York State Health Department and the local health departments shall investigate shellfish-associated foodborne diseases incident/outbreaks in accordance with procedures contained in the New York State Department of Health's Environmental Health Manual.

The NYS Department of Health (DOH), NYS Department of Environmental Conservation (DEC) and NYS Department of Agriculture and Markets (DA&M) will cooperate in determining the origin of shellfish in all shellfish-associated foodborne disease outbreaks and will take appropriate steps in preventing contaminated shellfish from entering commerce.

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NYS DEPT. OF HEALTH, NYS DEPT. OF ENVIRON. CONS. & NYS DEPT OF AG. & MKTS.
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PROCEDURE

Investigation

DOH and Local Health Department (LHD)	1. Obtains information to verify the incident or outbreak. Interviews people at risk, reviews food preparation, obtains specimens and copies of shellfish tags and invoices indicating shipping dates, reshipper and shipper numbers, harvest waters, description of shellfish and count. Evaluates the data and determines if there is a shellfish association.
DOH	2. Notifies DEC and DA&M, U.S. Food and Drug Administration (FDA) and other states for source tracking verification.
DEC DOH DA&M	3. DEC will assume lead responsibility for source investigation. DEC will communicate with FDA and other states' shellfish regulatory agencies and will investigate intra-state shippers south of, and including, Westchester and Rockland Counties; DA&M will ordinarily conduct source investigations in remainder of state. With support from local health departments, DOH and DA&M, the DEC determines original harvest area, original shipper, and all reshippers of suspect shellfish and whether any state laws were violated.

PROCEDURE (cont'd.)

Investigation

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DEC 4. Relays source information to DOH & A&M.

DOH/DEC/
DA&M 5. Trace shellfish to other points of sale for further case finding and to prevent sale of suspect shellfish.

Response

DEC 6. Confirms source information and determines probable cause for contamination; i.e., poaching, water quality, etc. When out-of-state shipper is involved, requests and reviews report from out-of-state agency. Copies of these reports will be distributed to DOH and DA&M.

DOH 8. Formal certification issued by DOH Commissioner that outbreak is associated with shellfish from DEC identified source. DEC requested to coordinate immediate embargo/seizure/public notification actions.

DEC (Regional Law
Enforcement Unit) 9. Investigate to determine if in-state shipper and/or diggers violated laws or regulations. Assures that additional contaminated shellfish are not served or sold by these parties, and initiates legal action against parties found to have violated the law or regulations.

PROCEDURE (cont'd.)

DOH/DA&M/ 10. Take seizure and/or embargo

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DEC

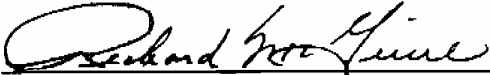
actions as needed to prevent sale
of contaminated shellfish in NYS.

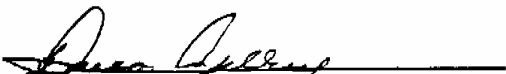
Response

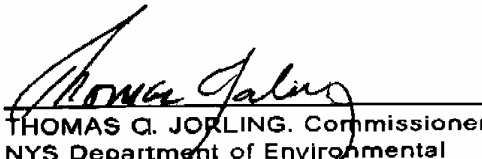
DOH/DA&M/
DEC

11. Takes additional regulatory and enforcement action as is necessary and appropriate to prevent additional contaminated shellfish from being harvested and marketed, consistent with the NSSP (National Shellfish Sanitation Program) Manual of Operations.

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Signed:  Dated: 2/29/91
RICHARD T. MC GUIRE. Commissioner
NYS Department of Agriculture &
Markets
Albany, New York

Signed:  Dated: 1/24/91
DAVID AXELROD. M.D. Commissioner
NYS Department of Health
Albany, New York

Signed:  Dated: 2/8/91
THOMAS C. JORLING. Commissioner
NYS Department of Environmental
Conservation
Albany, New York

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**MEMORANDUM OF AGREEMENT
NYS DEPT. OF AG. & MKTS., NYS DEPT. OF HEALTH, STATE POULTRY INDUSTRY COORDINATED
EFFORT
SUB-SECTION 1060**

**MEMORANDUM OF AGREEMENT
BETWEEN THE NYS DEPARTMENT OF AGRICULTURE AND MARKETS, NEW YORK
STATE DEPARTMENT OF HEALTH, and STATE POULTRY INDUSTRY COORDINATED
EFFORT**

PURPOSE: To provide reasonable assurance to consumers that New York State eggs are a minimal risk to cause foodborne disease caused by Salmonella enteritidis.

The parties to this Agreement are the New York State Department of Agriculture and Markets, hereinafter called NYSA&M and the New York State Department of Health, hereinafter called NYSDOH and the State Poultry Industry Coordinated Effort (hereinafter called SPICE).

WHEREAS, *Salmonella enteritidis* associated with eggs has been determined to be a significant cause of foodborne illness in humans and

WHEREAS, the State Poultry Industry Coordinated Effort and the New York State Departments of Agriculture and Markets and Health wish to assure the safety and quality of eggs and

WHEREAS, the New York State Department of Health has statutory duty to address foodborne threats to human health and

WHEREAS, the New York State Department of Agriculture and Markets has statutory duty to address the safety and quality of eggs and

WHEREAS, the State Poultry Industry Coordinated Effort represents egg producers who wish to market wholesome and safe eggs,

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the parties do mutually agree with each other as follows:

I. New York State Department of Health:

- A. NYSDOH will conduct epidemiological investigations of egg-associated foodborne illness of humans to determine the probable source of the causative agent(s);
- B. NYSDOH will inform NYSA&M of egg-associated foodborne illness and/or food contamination caused by SE and the apparent source of the SE suspect eggs;
- C. NYSDOH will communicate with NYSA&M and SPICE on a regular and ongoing basis regarding ways and means to reduce the risk of egg-associated outbreak of SE disease in humans; and

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D. NYSDOH will promote proper handling, refrigeration and cooking of shell eggs by food establishments and the restriction of shell eggs suspected to be contaminated with SE.

II. New York State Department of Agriculture and Markets:

- A. NYSA&M will facilitate determination of the source of eggs epidemiologically linked with SE illness in humans an/or contamination of food;
- B. NYSA&M will inform owners of the necessity to restrict sale of eggs from flocks epidemiologically linked with SE contamination of food products and/or SE illness in humans according to quality assurance standards set forth by the New York State Egg Quality Assurance Program (NYSEQAP) and Appendix A attached hereto;
- C. NYSA&M will promote proper handling, refrigeration, and storage of shell eggs by food establishments and the restriction of shell eggs suspected to be contaminated with SE as defined in Appendix A, Section IV, Paragraphs I and J;
- D. NYSA&M will communicate with NYSDOH and SPICE on a regular and ongoing basis regarding ways and means to manage the risk of egg-associated outbreaks of SE disease in humans;
- E. NYSA&M will provide, subject to resource limitations, oversight, technical, administrative support to NYSEQAP as outlined in Appendix A; and
- F. NYSA&M will endorse NYSEQAP and permit distinctive labeling recognizing that the eggs were produced from flocks participating in the NYSEQAP.
- G. Information received by the Department pursuant to the program shall be received and accepted by the Commissioner as confidential pursuant to section 23 of the Agriculture and Markets Law, but may be used by the Department in any regulatory action or proceeding involving the failure of any person to comply with the provisions of the program.

III. STATE POULTRY INDUSTRY COORDINATED EFFORT

- A. SPICE will coordinate industry participation in the NYSEQAP via the NYSEQAP Oversight and Planning Committee;
- B. SPICE in concert with Cornell University and NYSA&M will provide technical and professional counsel to NYSEQAP including training and educational services;
- C. SPICE will promote industry participation in NYSEQAP; and

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- D. SPICE will communicate with NYSA&M and NYSDOH on a regular and ongoing basis regarding ways and means to manage the risk of egg-associated outbreak of SE disease in humans.

IV. It is mutually agreed:

- A. That NYSDOH and NYSA&M will be ex-officio members of the NYSEQAP Oversight committee. The Oversight Committee is established according to Appendix A, Section I, 1, B;
- B. That this Agreement shall not preclude or in any way interfere with the exercise of the Departments' of Health and Agriculture and Markets duty to protect human or animal health;
- C. That the attached Appendix A and Appendix B shall be adopted by the parties for investigation and control of SE outbreaks in humans and oversight of NYSEQAP;
- D. That signature of this Agreement does not constitute a financial obligation on the part of a signatory and that each signatory party is to use and manage its own funds by carrying out the purpose of this Agreement; and
- E. That this Agreement will become effective upon date of signature and shall continue for the tenure of the program. Further, this agreement may be amended at any time by mutual agreement of the parties in writing. It may be terminated by any party upon 30 days written notice to the other parties.

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NYS DEPT. OF AG. & MKTS., NYS DEPT. OF HEALTH, STATE POULTRY INDUSTRY COORDINATED
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APPENDIX A
NEW YORK STATE EGG QUALITY ASSURANCE PROGRAM

I. Statement of Purpose

The New York State Egg Quality Assurance Program (NYSEQAP) is a voluntary industry program intended to minimize Salmonella enteritidis (SE) contamination of chicken (shell) eggs. Although this program does not guarantee shell eggs to be free of SE contamination, the program does assure commitment of the producer to implementation of those management and monitoring practices most likely to prevent SE contamination. Basic preventive measures include placement of SE clean chicks, intensive rodent control, cleaning and disinfecting between flocks and environmental monitoring of pullet and layer houses with continuous testing of eggs from any environmentally positive houses. Positive eggs are diverted for pasteurization. Eggs must be kept refrigerated.

The New York State Department of Agriculture and Markets provides oversight and technical advice. The New York State Department of Health provides technical advice regarding public health implications. NYSEQAP participants are assuring the public that they are taking every reasonable precaution to assure the safety of shell eggs.

II. Program Administration

- A. The program is supervised by an oversight committee.
- B. The Oversight Committee will consist of two members from each of the following groups: 1) State Poultry Industry Coordinated Effort, 2) The New York State Department of Agriculture and Markets, 3) New York State Department of Health, and 4) Cornell University. Committee members agree to serve terms of three years.
- C. The program is administered and coordinated by a Program Director who is the chairperson of the Oversight Committee. The Program Director is selected from within the Division of Animal Industry. The State Poultry Industry Coordinated Effort has provided a Liaison Officer who works closely with the Program Director and other appropriate groups and individuals in development and operation of the program.
- D. The Oversight Committee shall meet as frequently as needed but at least twice each year.
- E. Procedures, operating protocols and program standards are established by the Oversight Committee.

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III. Participation

- A. Any poultry producer in New York State may participate in the program. Participation of flocks located outside New York State shall be determined by the Oversight Committee and shall depend upon whether such flocks meet the NYSEQAP program standards or participate in a comparable program that the Oversight Committee has recognized as providing equivalent Salmonella enteritidis protection and control.
- B. Participation in the program is voluntary and any participant may withdraw at any time.
- C. Producer/owner participation in the program may be terminated by the Oversight Committee if the participant does not comply with the "Conditions for Participation".
- D. Flock, egg and premises testing information shall be the property of the flock owner and shall be treated confidentially by NYSEQAP. Such information received by the Department pursuant to the program shall be received and accepted by the Commissioner as confidential pursuant to the section 23 of the Agriculture and Markets Law, but may be used by the Department in any regulatory action or proceeding involving the failure of any person to comply with the provisions of the program.
- E. No evidence of SE contamination of the participant flock, premises or eggs produced thereon shall be withheld from the NYSEQAP Oversight Committee.
- F. Although the poultry house is the basic unit for program operations, the entire complex shall be required to enter the program for bio-security purposes.
- G. Participation in the program offers no warranty by NYSEQAP expressed or implied that eggs produced under this program are free of SE.
- H. Representatives of the State Poultry Industry Coordinated Effort or the Department of Agriculture and Markets may conduct independent spot checking of compliance with program protocols to verify flock status and adequacy of testing.
- I. Nothing in these conditions shall be or become the basis for a claim for damages of any nature whatsoever against representatives of the New York State Egg Quality Assurance Program, the State Poultry Industry Coordinated Effort, the New York State Department of Agriculture and Markets or the New York State Department of Health.

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IV. Program Requirements - Pullets

- A. Chicks shall be obtained from US Sanitation Monitored Salmonella enteritidis negative breeder flocks.
- B. Chick delivery containers shall be swabbed at the time of delivery (every 10th container liner) and submitted to a laboratory for culture for Salmonella enteritidis (SE).
- C. Manure in pullet grower facilities shall be cultured at 10 to 15 weeks of age. A culture will consist of two samples taken from the manure beneath each row of cages.
- D. Houses with positive manure or chick samples must be cleaned and disinfected before new chicks can be placed.

LAYERS

- E. Pullets shall be obtained from an SE monitored flock. Pullets from an unknown or SE positive status house or flock will require that the manure be cultured 7 to 14 days after placement.
- F. The environment (manure and egg belts) shall be sampled within 8 weeks of the date of scheduled flock replacement. Multiage flocks shall be sampled within 8 weeks of the scheduled replacement of an age group.
- G. Houses with positive manure samples must be thoroughly cleaned, disinfected and tested negative prior to the addition of new pullets.

EGGS

- H. Houses with negative manure samples, except flocks and premises implicated in an outbreak of egg-associated human SE or SE contamination of food will not be required to test eggs.
- I. Houses with positive manure samples must test 480 nest run eggs or a combination of all available blood spot eggs plus additional nest run eggs to total 480 eggs every 2 weeks for 4 lots of samples. These eggs will be cultured in pools of 20. If the 4 lots of eggs are negative, a sample of 480 eggs (nest run and blood spot) must be sampled each month for the life of the flock.
- J. If any egg pools are positive, then all eggs must be diverted for pasteurization or hard cooking. To be able to resume sale of eggs as table eggs, 1,000 eggs must be tested in pools of 20 every 2 weeks for 4 lots of samples and test negative. If less than 50% of

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environmentals were positive and only 1 egg pool is positive, owner may elect to test 4,000 eggs at one time. These eggs can be a combination of nest run and blood spot eggs. Following return to the table egg market, 480 eggs (nest run and blood spot) must be sampled each month for the life of the flock.

- K. Houses and flocks determined to be the source of eggs causing egg-associated human SE or SE contamination of food shall be subject to environmental culture and culture of 2,500 eggs in pools of 20 every two weeks for 4 lots of samples or one sample of 10,000 eggs tested in pools of 20 -- samples shall be representative of the building or premises and flocks where the suspect birds are located except when epidemiology indicates a specific flock in which case only the suspect flock and its environment need to be sampled.
- L. Eggs from flocks in SE culture positive environments implicated in an egg-associated outbreak of human SE or SE contamination of food shall, unless determined to be SE culture negative according to the testing requirements of this section, not be marketed for food unless pasteurized or hard-cooked.
- M. Flocks determined to be infected by culture of SE from internal organs shall be subject to the same egg restrictions and testing requirement as an egg culture positive flock.
- N. Egg testing will eliminate the need for further environmental testing.
- O. As additional experience is gained, environmental and egg testing requirements may be modified.

FORCE MOLTED FLOCKS

- P. Manure from force molted flocks shall be tested at five to seven weeks following return to feed. If manure is SE positive, eggs shall be tested as described for a laying flock.

RODENT CONTROL

- Q. The rodent control and monitoring program established by the Oversight Committee must be maintained at all times.

BIO-SECURITY

- R. All participants must maintain bio-security standards established by the Oversight Committee.

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NYS DEPT. OF AG. & MKTS., NYS DEPT. OF HEALTH, STATE POULTRY INDUSTRY COORDINATED
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V. Participant Responsibility

Participants agree that they or their representatives will:

- A. Cooperate with the Oversight Committee and the New York State Department of Agriculture and Markets in carrying out the prescribed monitoring and prevention procedures.
- B. Participate in training sessions on sample collection and SE prevention procedures.
- C. Conduct sample collection in accordance with program protocols covering testing of chicks, pullets, environments and eggs.
- D. Submit required samples to a designated station or processing facility.
- E. Maintain a standard log provided by the New York State Egg Quality Assurance Program for each flock in the program. The log book must include date of sampling and results of laboratory tests.
- F. Maintain an appropriate rodent control program approved by the Oversight Committee.
- G. Divert eggs to pasteurization or hard cooking according to the requirements of this agreement if eggs are positive for SE. Records of diversion must be maintained by the participant for at least six months. Eggs may be returned to the table egg market only by following the appropriate program protocol.
- H. Clean and disinfect environmentally positive (SE) layer or pullet houses between flock placements according to standards set by the Oversight Committee.
- I. Maintain adequate bio-security and practice good poultry management according to standards set by the Oversight Committee.

VI. Department of Agriculture and Markets Oversight and Recordkeeping

- A. An automated record of each NYSEQAP participant activity shall be maintained by the Department that includes identification and location of flock owner(s); identification and description of each flock on premises participating in NYSEQAP; status and outcome of each NYSEQAP prescribed action; disposition of eggs and birds from NYSEQAP participating farms if found to be egg positive; sources of birds, feed and flock services any other information relevant to the SE status of a NYSEQAP participant. This information shall be provided the Department by the flock owner or his designated representative.

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- B. Department representatives shall monitor NYSEQAP activity at every level from flock to Oversight Committee meetings at intervals determined by the Department. Department monitoring will be orchestrated by the Division of Animal Industry which will establish a schedule and protocol attuned to NYSEQAP operations.
- C. The Department shall conduct NYSEQAP quality assurance determinations including but not limited to independent environmental, rodent, bird or egg sampling for microbiological testing.
- D. The Department shall participate in training and program review with NYSEQAP participant flock supervisors.
- E. The Department shall provide NYSEQAP a report each month of NYSEQAP monitoring/oversight results.

APPENDIX B

EGG-ASSOCIATED SALMONELLA ENTERITIDIS OUTBREAKS IN HUMANS

I. Statement of Purpose

The purpose of Appendix B is to establish procedures by which the New York State Department of Health and the New York State Department of Agriculture and Markets can jointly assure that eggs from flocks and premises epidemiologically linked with egg-associated SE contamination are reasonably safe for human consumption. Specific standards for assuring reasonable safety shall be those standards established by the New York State Egg Quality Assurance Program (NYSEQAP) and these standards shall be applicable to non-NYSEQAP participants as well as NYSEQAP participants.

II. Procedure

- A. The Department of Health will conduct epidemiological investigations of egg-associated SE involving New York State residents or foods produced, processed or shipped from or within the state.
- B. The Department of Health will inform the New York State Department of Agriculture and Markets of epidemiological data indicating that eggs produced and/or marketed in New York State are implicated in an egg-associated SE contamination of food or outbreak of SE illness in humans and will provide the Department of Agriculture and Markets documents and records necessary to initiate determination of the egg source.

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- C. Upon notification that shell eggs are the likely source of a human Salmonella enteritidis outbreak originating from shell eggs, the Department of Agriculture and Markets will notify the flock owner of the association. NYSEQAP participating flocks in good standing will operate according to the procedure outlined in Appendix C of this document. Eggs produced from flocks that are not participating in NYSEQAP or equivalent program must be pasteurized or hard cooked before marketing for human consumption until environmental and/or egg tests are SE negative.
- D. The New York State Department of Health and other interested governmental agencies shall be kept informed by the New York State Department of Agriculture and Markets of the response of producers of SE suspect eggs to the requirements of this agreement.
- E. The New York State Department of Agriculture and Markets will monitor and certify that actions required by NYSEQAP to assure the safety of eggs produced by an SE contaminated flock or premises are implemented.
- F. The New York State Department of Health and Agriculture and Markets will collaborate to bring to bear appropriate compliance measures on recalcitrant owners of flocks, premises and/or eggs implicated in egg-associated SE contamination of food or outbreaks of SE illness in humans.
- G. That this Agreement shall not preclude or in any way interfere with the exercise of the Departments of Health and Agriculture and Markets' duty to protect human or animal health.

APPENDIX C

**PROTOCOL FOR INVESTIGATION AND CONTROL
OF
SALMONELLA ENTERITIDIS (SE) OUTBREAKS IN HUMANS**

- I. Investigation and assessment of epidemiological outbreak data.
 - A. Investigations are the responsibility of the local health departments. The Bureau of Community Sanitation and Food Protection coordinates investigations and prepares a report for review by the Director of the Division of Epidemiology (DDE) NYSDOH.
 - B. If DDE determines that eggs are epidemiologically implicated in an SE outbreak, the procedures in Section II and III shall be followed.

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II. Egg trace-back.

- A. If review of epidemiological data associated with an SE outbreak suggests that eggs are the probable source of SE in an outbreak, the DDE will do the following:
 - 1. Request that the New York State Department of Agriculture and Markets (NYSA&M) initiate an egg trace-back to identify the source flock or premise of such eggs.
- B. Upon request of DDE, the NYSA&M will conduct the egg trace-back. NYSA&M will apprise DDE of the name and location of all premises to which the eggs are traced. Information provided verbally shall be confirmed in writing.

III. Action when the egg trace-back reveals a flock or premise as the source of the implicated eggs.

- A. DDE shall send a letter to NYSA&M recommending restriction (retention, diversion to pasteurization or hard cooking) per the provisions of the *1996 SE Protocol* by facsimile with hard copy to follow by mail. The letter shall request that NYSA&M, as the state regulatory agency with jurisdiction over the sale of fresh whole eggs, immediately inform the premise of the public health implications of SE contaminated eggs and ensure that eggs originating from the flock are marketed in accordance with paragraph B of this section.
- B. NYSA&M will ensure that the appropriate number of eggs are collected for culture from all implicated flock(s) according to the New York State Quality Assurance Program (NYSEQAP) protocol for egg positive flocks. In other words, NYSA&M will ensure that four (4) manure drags are obtained from the implicated flock(s) and, at the same time, that either 2,500 eggs from each implicated flock, four times at two week intervals or 10,000 eggs from each implicated flock at one time are cultured for SE. Implicated flocks that are in good standing in the NYSEQAP Program and for which all previous manure drags were third party verified as negative do not need to be placed on restriction prior to positive laboratory results being received. If the laboratory results of the manure drags or the egg culture tests of the implicated NYSEQAP flock are found to be positive, all eggs from that flock will immediately be placed on restriction. Implicated non-NYSEQAP flocks must immediately be placed on restriction until sufficient negative laboratory results are obtained to justify removing the restriction. If the manure drags and all 10,000 eggs are culture negative for *Salmonella enteritidis*, the implicated non-NYSEQAP flock may be released from restriction. Whether or not the implicated flock is in the NYSEQAP program, 480 eggs should be tested each month until the implicated flock is replaced. A positive SE egg identified by the 480 egg test in either a NYSEQAP or non-NYSEQAP flock will be cause for NYSA&M to impose restrictions on the sale of those eggs.

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- C. If an egg trace-back implicates multiple flocks on a single premise, then all eggs produced by the implicated flocks will be subject to the provisions specified in III B of this section.
 - D. If an implicated flock is not participating in NYSEQAP, then the NYSA&M will advise the flock owner of recommended egg testing, rodent control, cleaning and disinfection (C&D) of poultry houses as outlined in the NYSEQAP standards and the NYSA&M will supervise the necessary actions. If a new flock is housed in a poultry house that was deemed inadequately cleaned and disinfected (C&D), based upon the NYSEQAP protocol for environmentally SE positive premises then the replacement flock must be repeat tested with the same frequency and number of eggs cultured as specified for a previously laboratory positive flock under the NYSEQAP protocol.
 - E. If an implicated flock is located outside of New York State then an official state agency in that particular state will be notified that they must verify manure drag testing, egg testing, rodent control, cleaning and disinfection (C&D) of poultry houses as outlined in NYSEQAP standards are accomplished.
 - F. If an implicated flock is located outside of New York State then an official state agency in that particular state will be notified that they must verify manure drag testing, egg testing, rodent control, cleaning and disinfection (C&D) of poultry houses as outlined in the NYSEQAP protocol have been accomplished prior to those eggs being released from restriction for sale in New York State. Implicated out-of-state eggs already located within New York State will be placed on restriction by NYSA&M and no additional eggs from the out-of-state implicated flock will be shipped into New York State until the NYSA&M restriction is lifted. All laboratory results of NYSEQAP egg cultures will be promptly made available to NYSA&M and DDE (upon request), who shall hold that information to be confidential.
- IV. Actions to be taken upon receiving results of manure drag and egg culture tests.
- A. If all manure drags and the eggs cultured from the implicated flock test negative, NYSA&M will immediately inform the flock owner of the negative test results and release the eggs from restriction. However, 480 eggs will still be culture tested each month until the implicated flock is replaced. A positive SE egg identified by the 480 egg test in either a NYSEQAP or non-NYSEQAP flock will be cause for NYSA&M to impose restrictions on the sale of those eggs. In addition, DDE will be notified of the SE test results.
 - B. If any of the manure drags test positive and the eggs cultured from the implicated flock test negative, NYSA&M will immediately inform the flock owner of the test results and release the eggs from restriction. However, 480 eggs will still be culture tested each

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- month until the implicated flock is replaced. A positive SE egg identified by the 480 egg test in either a NYSEQAP or non-NYSEQAP flock will be cause for NYSA&M to impose restrictions on the sale of those eggs. In addition, DDE will be notified of the SE test results.
- C. If any of the non-NYSEQAP flock eggs cultured test SE positive, NYSA&M will immediately inform the non-NYSEQAP flock owner of the positive test results and the need to continue restricting the eggs in a manner approved by NYSA&M until further communication is received from NYSA&M. In addition, DDE will be notified of the SE test results.
- D. If any of the NYSEQAP flock eggs cultured test SE positive, NYSA&M will immediately inform the NYSEQAP flock owner of the positive test results and the need to place the eggs on restriction in a manner approved by NYSA&M until further communication is received from NYSA&M. In addition, DDE will be notified of the test results.
- E. The NYSA&M will monitor compliance of the restricted premises and NYSA&M will apprise Food Safety and Laboratory Services and DDE of the failure to comply. If information on lack of compliance is provided verbally, that communication shall be confirmed in writing with details of non-compliance and names and telephone numbers of persons with first-hand knowledge of the situation.
- F. If NYSA&M advises DDE that a lack of compliance exists, NYSA&M may request the assistance of DOH to seek a court order to compel the premises to exclude its fresh eggs from the fresh egg market. DOH will assist NYSA&M, as needed, to prepare and present the case.
- V. Release of restrictions. Egg restrictions may be removed either by flock depopulation followed by appropriate rodent control, cleaning and disinfection (C&D) of the contaminated poultry house as outlined in the NYSEQAP standards or by subsequent negative SE testing of either 2,500 eggs from the implicated flocks, four times at two-week intervals or 10,000 eggs from the implicated flock at one time. However, 480 eggs will still be culture tested each month until the implicated flock is replaced. A positive SE egg identified by the 480 egg test in either a NYSEQAP or non-NYSEQAP flock will be cause for NYSA&M to again impose restrictions on the sale of those eggs.
- VI. Miscellaneous.
- A. If a poultry house(s) on a premise are determined by a NYSA&M representative to not have adequate bio-security to reasonably prevent the transmission of SE to other poultry

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houses on the same premises, then all of the chickens in all of the houses on that premise shall be treated as if they were a single flock for the purposes of protocol. The definition of flock is either all of the poultry in one poultry house, or on one premises if adequate bio-security between poultry houses is not present. A premises is defined as the property where the poultry house(s) is/are physically located. When sufficient flock management procedures are in place to ensure that there is no significant potential for SE transmission between poultry houses through exposure to chickens, feed, water, manure, rodents, equipment, personnel or any other fomites/vectors deemed important by NYSA&M and/or DOH then the flock has adequate bio-security.

- B. Whenever this protocol provides that an act is to be done by NYSA&M or DDE, it is to be construed to also permit an authorized designee of that entity to perform that act.
- C. The identification of Group D Salmonella is presumptive evidence of SE. For purposes of this protocol, it will be accepted as evidence of SE, unless and until further culture results identify a different Salmonella serotype.
- D. The definition of epidemiologically implicated is that a product (or risk factor) was implicated as the cause of an outbreak of human illness by means of finding a significant association between exposure to the product and illness in humans and also through assessment of other relevant factors which indicate the product to be the cause of the illness. This determination does not require culturing of the causative organism from the product.
- E. A food containing fresh whole eggs is found to be culture positive without epidemiological linkage to a disease outbreak, the fresh whole eggs and/or egg-based foodstuff will be treated as if an epidemiological linkage exists until the threat of human disease can be determined. If the trace-back is successful, eggs from the implicated flock should be appropriately restricted and the procedures in Section II - VI should be followed. For example, if a single SE culture positive egg is identified subsequent to a routine food facility inspection and the trace-back is successful then this protocol should be followed.
- F. The NYSEQAP procedures and standards referenced in this protocol are the most current NYSEQAP procedures and standards in place.
- G. A flock, whose eggs are currently being diverted from the shell egg market because of SE, may be released from this restriction if it meets current NYSEQAP testing guidelines for egg positive flocks, i.e., eggs become SE culture test negative.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
SUPERVISORY REVIEW AND AUDITS
SUB-SECTION 1070**

AUTHORITY

A directive of the Commissioner requires reviews/audits of all Field Employees. Division Directors are responsible for establishing Supervisory Review/Audit procedures within respective Divisions to meet at least the minimum requirements.

The minimum requirements* have been established as follows:

- Food Inspector Trainee 1: 1 Review/Audit per each calendar quarter.
- Food Inspector Trainee 2: 1 Review/Audit per each calendar quarter
- Food Inspector 1: 1 Review/Audit per each calendar year

*Note the above frequencies are the minimum required. Zone Supervisors at their discretion, based upon their knowledge of the inspector's performance, through Supervisory Reports (i.e. Compliance rate data, the quantity and scope of deficiencies written, and other supervisory tools, etc.) may choose to perform additional Supervisory Review/Audits.

** FDA Audits on an inspector will be considered acceptable for meeting the requirements of a Supervisory Review/Audit.

REVIEWERS

A Supervisory Review will consist of a sanitary inspection conducted by the Zone Supervisor within seven working days of an inspection conducted by a subordinate Inspector. An Audit will consist of a sanitary inspection whereby the Zone Supervisor accompanies a Food Inspector Trainee 1, Food Inspector Trainee 2, or Food Inspector 1 or when a Food Inspector 1 accompanies a Food Inspector Trainee 1 or Food Inspector Trainee 2 to critique the employee's inspection technique and knowledge. It is not permissible for a Food Inspector 1 to conduct a Supervisory Review/Audit on another Food Inspector 1.

REVIEW SELECTION

A Supervisory Review or Audit is to be performed on those establishments which have a history of a high level of compliance and on those with a history of serious insanitary conditions. These should also be a selection of establishments according to the IPH Type, generally in proportion to the member of establishments in each IPH Type in the Inspector's assigned area.

SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
SUPERVISORY REVIEW AND AUDITS
SUB-SECTION 1070

SUPERVISORY REVIEW

Prior to making a Supervisory Review inspection, the Zone Supervisor/reviewer should identify themselves to the operator and explain that they are there to perform a Supervisory Review inspection, the purpose of which is to improve effectiveness and uniformity among Food Inspectors.

The Supervisory Review or Audit will concentrate on the presence or absence (and the proper description and scoring, if present) of those critical violative conditions represented on the Sanitary Inspection Report. When the reviewer's inspection results essentially agree with those of the Food Inspector as regards the foregoing criteria, the Supervisory Review or Audit will be considered satisfactory. Where the Supervisory Review or Audit reveals the Inspector failed to report unsanitary conditions in categories other than those covered by the foregoing criteria, the Supervisor may review these verbally or in a separate attached memo.

Sanitary Inspection Reports should not be completed during the Supervisory Review, when the review is deemed to be satisfactory. In the event the Supervisory Review is deemed unsatisfactory, an inspection shall be conducted at the time of the review. A Notice of Inspection shall be left with the establishment operator and an Inspection Report completed by the reviewer. The Supervisor shall complete an FSI-800 which reflects the outcome of the review, and provide a written copy to the inspector within 10 days.

TIME CHECK

An inquiry of the establishment representative's independent recollection of the time and date the Inspector was in the establishment should be made and compared to the times and date entered on the Sanitary Inspection Report and the Inspector's Daily Report. Any discrepancies concerning the reported times or dates shall be reported via a separate memo which names the person interviewed, and immediately forwarded to the Chief Inspector. Copies of this memo are not to be provided to the Food Inspector being reviewed. The Chief Inspector in consultation with the Division Directors will provide guidance on follow-up action.

SUPERVISORY AUDIT

The Zone Supervisor may also permit the Food Inspector, whose work is being reviewed, to be present during a Supervisory Audit. A Supervisory Audit will be performed in conjunction with a full sanitary inspection. The Supervisor shall notify the inspector that a Supervisory Audit is being conducted at the start of the inspection. The Supervisor will let the inspector take the lead and conduct the inspection. After completion of the visual inspection, the inspector shall discuss the deficiencies noted and complete the Notice of Inspection. The Supervisor shall review the Notice of Inspection, and request that the inspector make additional entries if warranted, focusing on critical deficiency items and any other significant unsanitary conditions prior to reviewing the Notice of

SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
SUPERVISORY REVIEW AND AUDITS
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Inspection with the establishment representative. The Supervisor shall discuss the outcome of the review with the inspector after completion of the inspection, including a discussion of the inspector's technique and knowledge displayed during the inspection. The Supervisor shall complete an

FSI-800 which reflects the outcome of the review, and provide a written copy to the inspector within 10 days.

UNSATISFACTORY REVIEWS

The results of every Supervisory Review and Audit must be provided to the Food Inspector whose work is being reviewed or audited within ten days of the Review or Audit via the Notice of Supervisory Review/Audit (FSI-800).

A copy of the unsatisfactory review and the inspector's memo shall be provided to the Chief Inspector immediately.

When a Supervisory Review or Audit is found to be unsatisfactory, the frequency of Supervisory Reviews or Audits for this individual should be increased to at least one per month and continued at this rate for at least one calendar quarter (if all subsequent reviews or audits are satisfactory).

BI-ANNUAL JOINT INSPECTIONS

As a means of promoting uniform inspection techniques and enhancing the knowledge of the strengths and weaknesses of their subordinated, all Food Inspector 2's (Zone Supervisors) should accompany each of their Inspectors during a sanitary inspection on a bi-annual basis.*

The Supervisors Bi-Annual Joint Inspection Log (FSI-801) should be maintained by each Zone Supervisor listing each Inspector in the Zone and the date the Zone Supervisor accompanied him/her on an inspection. The log must demonstrate that each Supervisor has worked with each of their inspectors at minimum of 1x per bi-annual period.

*Not the above frequencies are the minimum required. Zone Supervisors at their discretion, based upon their knowledge of the inspectors performance, through Supervisory Reports (ie. Compliance rate data, the quantity and scope of deficiencies written and other supervisory tools etc.) may choose to perform additional Joint Inspections.

REPORTING

A report shall be submitted to the Chief Inspector by **July 10th and January 10th of each calendar year** as a complete packet containing the following information:

SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
SUPERVISORY REVIEW AND AUDITS
SUB-SECTION 1070

A memorandum which summarizes the Supervisory Review and Joint Inspection activities within the zone, including any discrepancies/concerns, failures to meet minimum requirements, and corrective actions.

A completed Supervisory Review/Audit Bi-Annual Report, with attached Notices of Supervisory Reviews/Audits with attached inspection report reviewed and if applicable (unsatisfactory review) the inspector's written response.

A completed Supervisors Quarterly Joint Inspection Log. The report should document at minimum that the Zone Supervisor has completed an inspection with their Zone Inspectors per each bi-annual period.

Chief Inspectors will compile the information for their respective Regions and submit an Annual Summary Report to the Director of Field Operations by February 1st each year.

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
SUPERVISORY REVIEW AND AUDITS
SUB-SECTION 1070**

FSI-800 (Rev. 3/06)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE, ALBANY, NEW YORK 12235

NOTICE OF SUPERVISORY REVIEW/AUDIT

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TO:	FROM:												
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A Review/Audit was conducted by

 at the cited firm on

(SUPERVISING INSPECTOR) (DATE)

After your ☐ Passing ☐ Failing inspection on

.
(DATE)

The

,

 was interviewed.
(TITLE) (NAME)

The completeness and accuracy of your report, including the time entries reported, were reviewed.

☐ I am in essential agreement with your findings concerning sanitary deficiencies.

☐ I am **not** in agreement with your findings concerning sanitary deficiencies.

☐ Please submit a memo to me within 10 days from the date of this memo explaining why the following deficiencies were not written on your inspection report.

RESPONSE:

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
SUPERVISORY REVIEW AND AUDITS
SUB-SECTION 1070**

FSI-801 (Rev. 3/06)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE, ALBANY, NEW YORK 12235

SUPERVISOR'S BI-ANNUAL JOINT INSPECTION LOG

ZONE:

FOR THE BI-ANNUAL PERIOD STARTING **AND ENDING**

INSPECTOR	ESTABLISHMENT NUMBER	DATE OF INSPECTION
SUPERVISOR:		

FSI-71 (Rev. 7/06)

SUPERVISORY REVIEW/AUDIT QUARTERLY REPORT

SUPERVISORY REVIEWS FOR THE ☐1ST ☐2ND ☐3RD ☐4TH QUARTER OF

P/F – PASS/FAIL, R/A – REVIEW/AUDIT, S/U – SATISFACTORY/UNSATISFACTORY

SUPERVISOR:

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
INSPECTOR'S DAILY REPORT-ELECTRONIC
SUB-SECTION 1075**

GENERAL INSTRUCTIONS

The Inspector's Daily Report shall be completed each normal work day and on days when leave credits are used.

COMPLETION OF THE INSPECTOR'S DAILY REPORT

In reviewing these instructions, please refer to the "Electronic Daily Report," (attachment # 1), at the end of this section.

All time entries shall be in quarter-hour decimal intervals, e.g., 0.25, 0.50, 0.75, 1.0, etc.

- Starting in the upper left-hand corner of this report screen, verify the CURRENT DATE, NAME, START TIME, and STARTING LOCATION.
- "Worked With": If accompanied by another Department employee, even if only for part of a day, enter that person's name.
- "Leave Used – Hrs.": The amount of time taken for vacation, sick, personal or other types of leaves shall be entered in this section.
- In the "Type of Leave" section, indicate the type of leave taken. A daily report must be submitted for each day of leave. The "Remarks Section" at the top of the daily is to indicate overtime used, excused time, worker's compensation, military leave (not active duty) and administrative employee and organizational leave (EOL).
- Enter time of arrival at first stop in "Arrive" box. Indicate name and location of first stop if not an establishment. If first stop is an establishment, enter the establishment number in the appropriate box. Click enter. Click on the "Activities" button. Food inspectors will normally use Activity Codes 101 through 602. Farm Products Inspectors will normally use Activity Codes 801 through 893, unless assigned to cross utilization activities. (Attachment #2).

Most of the Daily Activity Codes are self-explanatory. See Pages 4 and 5. If assistance or clarification is needed, first review the appropriate Inspector's manual sections then, if necessary, consult your immediate supervisor.

DEFINITIONS

Miscellaneous Activity Codes used by all Division field staff members:

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
INSPECTOR'S DAILY REPORT-ELECTRONIC
SUB-SECTION 1075**

701. Training (Classroom): All field staff members who are either providing or receiving training in a classroom setting will enter this Activity Code. A brief notation, e.g., "Conducted training class" or "Attended training class" or other appropriate notation should be entered in the Itinerary section. (See No. 15 re: Non-Classroom Training).
702. Zone Conference: All field staff members, including supervisory personnel, attending Zone, Regional or District meetings, will enter this Code.
703. Office Work - Admin.:
- Field Inspectors - Time spent at Official Station *preparing reports, reviewing handbooks and planning work schedules.
- *Note:** Office work - Administration time will not include the preparation of Sanitary Inspection Reports or Reports of Investigation.
704. Professional Conference: Attending meetings or conferences with other regulatory agencies or industry groups at the direction of the Central Office.
705. State Car Repair: Use this Code when having a State vehicle repaired or emergency repairs on a personal vehicle used on official business.
706. Jury Duty: Enter the number of hours spent on jury duty. Submit a Daily Report for each day so spent.
707. Disaster Preparedness: Enter the amount of time devoted to planning and participating in disaster preparedness exercises.
708. Desk Assignment: For Farm Products Inspectors **only**.
709. On Call - Non-Contract: Standby time for the sole purpose of a Farm Products Inspector being available to respond rapidly to requests for inspections. Standby time which is being charged to an applicant as the result of a contractual agreement should be listed under the specific activity code for that type of inspection activity, e.g., "820 Shipping Point-Contract" and not to "709 On Call-Non-Contract."

Number: Enter the total number of each specific type of activity conducted, e.g., number of sanitary inspections or the number of seed potato field inspections conducted, etc.

Hours: Enter the number of hours spent on the noted activity.

Travel Hours: Enter the number of hours of travel time. Only travel time incurred on an activity shall be charged to that Activity Code.

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
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Training Hours: Supervisory personnel will predetermine if a given situation is a joint work effort, a supervisory evaluation, a peer review or an on-the-job training activity (non-classroom). If it is deemed a training activity, the trainee will enter the number of hours spent while on-the-job training with a field Inspector or field Supervisor.

Similarly, while performing food safety activities, the trainer claims credit only for the food safety work activity codes. If the situation is not an on-the-job training activity, all field Inspectors involved will claim time for the appropriate farm products or food safety tasks.

Mileage: Complete this section with the actual mileage between stops when using a state or private vehicle.

Remarks: Enter any additional pertinent information such as Seizure or Sample Numbers, etc.

Expense: Enter the total official expenses incurred during the visit at this establishment.

Note: Any information entered in one section of the Daily Report form, e.g., mileage or expenses, need not be duplicated in another section of the report unless needed for clarity and understanding.

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
INSPECTOR'S DAILY REPORT-ELECTRONIC
SUB-SECTION 1075**

DAILY ACTIVITY CODES

Sanitary Inspections	Investigations	Miscellaneous	
101 Type 1 Inspection Inspection	301 Consumer Complaints	701 Training (Classroom)	823 Seed Potato Field
102 Type 1 Reinspection Contract	302 Refrig. Warehouse Ext.	702 Zone Conference	824 Shipping Point Insp.
103 Type 2 Inspection Fee	303 Food Seizure/Disaster	703 Office Work - Admin.	825 Shipping Point Insp.
104 Type 2 Reinspection	304 Food Seizure/Other	704 Professional Conference	826 State Institution
105 Type 3 Inspection	305 Disaster Investigation	705 State Car Repair	828 Terminal Contract
106 Type 3 Reinspection	306 5-C Disposal/Transporter	706 Jury Duty	829 Terminal Fees
107 Type 4 Inspection	307 Operation Change Report	707 Disaster Preparedness	830 Terminal Market Relief
108 Type 4 Reinspection	308 Miscellaneous Investigation	708 Desk Assignment	831 Resident Egg Grading
109 Type 5 Inspection	309 Vehicle Inspection	709 On Call	832 Consulting Service
110 Type 5 Reinspection	310 Feed/Pet Food Investigations		833 WIC Program
Investigations	311 Food Security Investigations		
111 Type 6 Inspection Service)	Recalls	Product Grading/Testing	835 HACCP (Fee for
112 Type 6 Reinspection	401 Recall - USDA	805 EPIA Surveillance	837 PQAP
113 Limited Inspection Program	402 Recall - FDA	811 Egg Product Inspection	840 State Processing
114 HACCP Inspection	403 Recall - A & M	812 Meat Grading	841 GAP
		813 Ornamental Tabulation	880 FDA Domestic Sample
Economics	Sampling	814 Poultry/Egg Fees	881 Controlled Atmosphere
201 Labeling Enforcement/Regulations	501 Scheduled Sample	815 Processed Commodities	882
202 Advertising	502 Non-Scheduled Sample	816 Processing Contract (Fed/State)	883 Market Order
203 Availability/Price Check	503 Feed Sample	817 Quality Control Contract	884 Shipping Permit
204 Unit Pricing	504 Seizure Sample	818 Milk Price Survey	885 SOQ Promotion
205 Item Pricing	505 Pesticide Residue Sample	819 Seafood Inspection	887 Consumer Pack
206 Scanner Check	506 Microbiological Residue Sample		
	507 Food Security Sample	820 SOQ Egg Contract	889 Pride of New York

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
INSPECTOR'S DAILY REPORT-ELECTRONIC
SUB-SECTION 1075**

Compliance Action

	821 SOQ Egg Hourly	890 Plant Industry
601 Industry Conference	822 SOQ Shipping Point Inspection	891 USDA Custom Slaughterhouse
602 Hearing		893 Triazole Sampling Project

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
INSPECTOR'S DAILY REPORT-ELECTRONIC
SUB-SECTION 1075**

[Daily Form]

File Edit Insert Records Window Help

FOOD INSPECTOR'S DAILY REVIEWING SCREEN

Date Name

Remarks

Leave Used Type of

Start Time Leave Used Worked With

Starting Location

ITINERARY

Arrive	Leave	Est #	Tradename/Address	Non Est Addr	Remarks	Activities	Travel Time
			Non Est #				Miles Trvld
Lunch/Personal ☐							

Arrive	Leave	Est #	Tradename/Address	Non Est Addr	Remarks	Activities	Travel Time
			Non Est #				Miles Trvld
Lunch/Personal ☐							

Arrive	Leave	Est #	Tradename/Address	Non Est Addr	Remarks	Activities	Travel Time
			Non Est #				Miles Trvld
Lunch/Personal ☐							

Total Hrs incl Trvl Activity Hours Total Expenses Total Miles Total Travel Leave Used

☐ Main Screen ☐ Daily Report ☐ Reviewed

Record: 1 of 1

Form View NUM

ATTACHMENT 1

**NYS Department of Agriculture and Markets
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Field Operations Manual**

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
ZONE MEETING GUIDELINES
SUB-SECTION 1080**

ZONE MEETING GUIDELINES

Zone meetings may only be held upon request. The FI 2 should demonstrate a need for such a meeting in a memo or by E-mail to the FI 3 outlining the purpose, the proposed date and location. If the FI 3 concurs, he/she should forward the request to the office of the Food Inspection Manager for final approval.

Zone meetings should be held at least bi-annually. Such meetings are especially useful when scheduled after statewide FI 2 / FI 3 or FI 3 meetings.

The Zone meeting request should specify the time and place of the meeting and the proposed agenda.

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**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
EMPLOYEE CONDUCT
SUB-SECTION 1085**

OVERVIEW

As a government employee of the New York State Department of Agriculture and Markets, the Agency places as few limits as possible on your interests and activities, but certain limitations are necessary to protect the interest of the government. These limitations are briefly covered in the various subsections of the *Employees' Manual*.

As you work to advance the health and welfare of the public, seek to maintain the highest standards of ethical conduct. The essence of good government is the personal responsibility that each public servant feels for the public trust he/she holds. You are responsible for complying with the regulations, obtaining advice from your supervisor or personnel office, and when required, obtaining advanced approval for certain outside activities.

To assure that the business of the Department is conducted effectively, objectively, and without improper influence or the appearance thereof, all employees must be persons of integrity and observe the highest standards of conduct. Because of the Department's special regulatory responsibilities to both the consumer and industry, its employees must avoid real, or the appearance of, conflict to their private interests with their public duties. Their actions must be unquestionable and free of suspicion.

You are the eyes and ears of the Department of Agriculture and Markets and to most of the public you are the only contact. Your actions will be the basis upon which they judge the entire Department. The public expects exemplary behavior and conduct from the government employee. This responsibility applies to both on-the-job and off-the-job activities. As you inspect or appraise individuals, you are, in turn, being appraised. Both the industries we regulate and the public at large are keenly aware of and are quick to report what they consider to be improper actions by government employees. This surveillance generally works to the public good and is welcomed by the Department.

INTEGRITY

This is the assurance that a person can be relied upon to do the right thing; a deep-seated honesty that gives rise to dependability; that quality that makes a person's word better than his/her bond. It assumes a devotion to accuracy, objectivity, and fairness. You are entrusted with equipment and operational latitude under minimum supervision and have a positive responsibility to protect and conserve all government property, including equipment and supplies.

Employees may not use or permit others to use official information not available to the general public for gain or to advance a private interest. You are expected to conduct yourself in a prudent

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
EMPLOYEE CONDUCT
SUB-SECTION 1085**

manner so that the work of the Department is effectively accomplished. Your job is to gather and present the facts. Accuracy and objective observation are absolutely essential.

ATTITUDE

You must be dignified, tactful, courteous, and diplomatic. Your approach must be firm but not unresponsive. At no time must you display strong-arm tactics, an air of superiority, an attitude of special authority, or an over-bearing posture. It is not necessary to apologize or justify your request for necessary and authorized information.

ATTIRE

Good public relations and practical common sense require that you dress appropriately for the activity in which you are engaged.

PROHIBITIONS, GIFTS, LUNCHEONS AND SNACKS

An employee shall not, directly or indirectly, solicit or accept a gift:

1. From a prohibited source; or
2. Given because of the employee's official position

Furthermore, an employee shall not:

1. Accept a gift in return for being influenced
2. Solicit or coerce the offering of a gift; or
3. Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee is using his public office for private gain

PROFESSIONAL PERSONNEL CONTACTS

During inspections and investigations your activities often involve discussions, conferences, and interviews with professional people. Credentials must always be presented during these activities.

When dealing with top management officials and other professional persons, your presence may often be disruptive to their activities. Many times you may be squeezed into already crowded schedules and your interviews or investigations may, of necessity, be conducted in offices, waiting rooms, or other areas where customers or employees are present and are aware of the investigation. If you find yourself in this type of situation, as always, proceed with tact and diplomacy, being especially conscious that any of your conversations or activities may be overheard by other individuals.

**SUPERVISORY AND ADMINISTRATIVE ACTIVITIES
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If it is necessary to review records which are located in a public area of the office, or to interview persons in that area, try to have the person in charge arrange that this be done in a more private area at a mutually agreeable time. If this cannot be done and it becomes a fact that you must work in an area with other persons present, conduct your activities in a quiet and dignified manner. If the person becomes unreasonable, and it is impossible to continue the assignment, terminate the interview and consult your supervisor.

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**SANITARY INSPECTIONS
SANITARY INSPECTION REPORT GUIDELINES
SUB-SECTION 2000**

ESTABLISHMENT INSPECTION PRACTICES AND PROCEDURES

Establishment inspection objectives include the documented observation of conditions under which food products are processed, packed, shipped or stored. This involves the determination of whether or not the conditions found contribute to the product becoming contaminated or adulterated.

These observations include, but are not limited to, the physical plant, equipment, raw materials, ingredient storage and handling, processing procedures, employees' health and hygiene, water supply, waste disposal, and product storage, distribution and display.

The Rules and Regulations Relating to Human Foods: "Current Good Manufacturing Practice" (GMP's - Circular 933) shall be applied to all food processors, food storage warehouses and vehicles transporting food (excluding common carriers in transit through the state). Exempt from these regulations are animal food manufacturers, growers and packers of raw agricultural commodities not subject to further processing and maple syrup and honey producers who use only their own product. Part 271 (Circular 962) applies only to retail food stores.

The GMPs set a criteria for determining whether the facilities, methods, practices and controls used in the manufacture, processing, packing, shipping or holding of food are in conformance with or are operated or administered in conformity with good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, shipped and held under sanitary conditions.

REPORTING DEFICIENCIES

The deficiencies noted during an inspection are scored as "critical" or "general" by the Inspector on the Sanitary Inspection Report. See Sub-Sections 2010, Critical Deficiencies and 2015, General Deficiencies.

Reporting critical deficiencies does not mean the establishment will automatically be referred for legal action nor does reporting only general deficiencies mean the establishment will not be referred for legal action.

Inspectors should not use the terms "pass" or "fail" when reviewing inspection results with an establishment representative. Instead, use the terms "Critical" and/or "General" deficiencies. A Critical Deficiency is a food safety condition or sanitary practice that is a violation of New York State Department of Agriculture and Markets requirements and which is likely to contribute to food contamination, illness or an environmental health hazard.

The reporting of each deficiency, whether critical or general, will be based on the guidelines in this Manual, the New York State Agriculture and Markets Law, the regulations and policies derived from the Law and the guidance and instructions of your Supervisors.

SANITARY INSPECTIONS
SANITARY INSPECTION REPORT GUIDELINES
SUB-SECTION 2000

Sanitary inspection reports are reviewed by the Food Safety and Compliance Unit (FSCU) to determine field staff compliance with completion and scoring guidelines and to assess trends and patterns and severity of violations reported.

Legal action may be taken against an establishment when a reinspection reveals numerous or repeated general deficiencies.

All Sanitary Inspection Reports, with critical or general items, are reviewed to determine the appropriate action to follow. The “appropriate action” may be based on an assessment of:

1. The kind of deficiencies reported	3. The severity of the deficiencies
2. The number of deficiencies	4. The establishment history

“Appropriate action” may include:

1. No action	6. Hearing
2. Warning letter	7. Summary Suspension
3. Penalty	8. Injunction
4. Legal Letter	9. Restraining Order
5. Conference/Food Safety Course	10. A combination of these actions

It is imperative that Inspectors understand one of the most important parts of the Central Office assessment of field reports is the review of the Inspector's narrative on the Sanitary Inspection Report. The narrative section of the sanitary inspection report and the Inspector's verbal description of the deficiencies found is very important to the establishment operator who must understand and use the narrative section to initiate corrective action. It is also important to every administrative level for law enforcement purposes. Each Inspector has a responsibility to ensure the written narrative, as well as the rest of the report, is completed to the very best of their ability.

RECORDING DEFICIENCIES

While the method of recording deficiencies differs from paper and electronic reports, the required content is the same. Detailed instruction for electronic reporting is provided in Sub-Section 2006. For the purpose of content, the following Guidelines for recording deficiencies should be followed:

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SANITARY INSPECTION REPORT GUIDELINES
SUB-SECTION 2000

Critical Deficiencies: Circle the appropriate number and letter on the FSI-894 and provide a complete narrative description on the FSI-898.

General Deficiencies: Circle the appropriate number and letter on the FSI-894 and provide a complete narrative description on the FSI-898.

In all cases: A complete verbal description of all the deficiencies noted during the inspection (both Critical and General) should be provided to the most responsible establishment representative present.

A well-written narrative describing deficiencies is:

1. Neat, legible and concise with short, simple words and sentences
2. Accurately related to a Law, regulation or policy
3. Objectively professional in tone
4. Based on observable fact
5. Complete, where required

SANITARY REPORT FORM INTEGRITY

Any alteration, modification, addition or deletion of information in a completed Sanitary Inspection Report (or any report where a copy is left with the establishment) without a corresponding change in the establishment copy, casts doubt on the integrity of the report and may alter its effectiveness as a legal document. Therefore, whenever a report needs changing, these guidelines will apply.

1. A field Supervising Inspector will not alter, add to, delete from, or mark any Sanitary Inspection Report, except in the "Field Review" box on Form FSI-894.
2. Paper Inspection Reports FSI-894 & 898 - Changing a general deficiency to a critical deficiency: The assigned Inspector will return to the establishment, change all copies and advise management why the change is required. Submit a Report of Investigation (ROI) documenting this activity. The inspector will provide a photocopy of the amended report to the establishment management if their original copy is not available.
3. Electronic Inspection Report - Changing a general deficiency to a critical deficiency: Changes are to occur only upon approval/notification of the Food Safety and Compliance Unit. The assigned Inspector will return to the establishment, change all copies of the FSI-890 Notice of Inspection Report and advise management why the change is required. The inspector will notify the Food Safety

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SANITARY INSPECTION REPORT GUIDELINES
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and Compliance Unit of the change. The Food Safety and Compliance Unit will facilitate deletion of the errant original report, then instruct the inspector to resubmit the report.

Any and all other changes: When using paper reports the Inspector will make necessary changes and attach a note or memo, directed to the Food Safety and Compliance Unit, describing what addition, deletion or alteration is required and why. The Food Safety and Compliance Unit will send modified copies with cover letters to the establishment, as necessary. When using electronic reports, the Inspector will call the Food Safety and Compliance Unit for further instructions.

ESTABLISHMENT INSPECTIONS

Inspections of establishments should be scheduled so that plant operations are in progress and processing procedures and employee sanitary practices are reviewed as a part of the inspection. There is no objection to a portion of the inspection being performed during non-operating periods if this is necessary to properly inspect ingredients or equipment to detect possible adulteration such as insect infestation in flour handling systems in bakeries. This is particularly applicable to large, complex operations and to U.S. Food and Drug Administration Contract Inspections.

LIMITED INSPECTIONS

Limited inspections are only to be conducted before a new establishment is officially open. See Limited Inspection Guidelines, Sub-Section 2005, Page 3, 7-C.

TEAM INSPECTIONS

As a rule, sanitary inspections are conducted by one Inspector. When an establishment's size or condition requires more than one Inspector, the Zone Supervisor should participate in the inspection. On those rare occasions when more than two Inspectors are needed to perform an inspection, prior approval shall be received from the Regional Chief or from the Director of Field Operations.

The only other exception to the one Inspector rule would be the possible need for team inspection in high crime areas. In such cases, the Zone Supervisor should clearly identify these high crime areas and closely control the extent of such team inspections. Team inspections for training purposes are, of course, exempt from these restrictions.

SPECIAL INSPECTIONS

Maple Syrup Producers: Inspect on a complaint basis only. Discuss these, as well as repackaging and blending operations, with your Supervisor first.

Honey Producers (Apiaries): Inspect on a complaint basis only. Discuss these, as well as repackaging and blending operations, with your Supervisor first.

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Non-FDA Contract Feed Mill Inspections: Confine deficiencies reported to the General Deficiencies, No.'s 9 through 16 and critical deficiencies, No. 2 and No. 4 using the FSI-894 and FSI-898.

FDA Contract Medicated Feed Mill Inspections: Inspect these establishments only at the specific direction of your supervisor. The FSI-894 and FSI-898 will not be used when conducting an FDA contract medicated feed mill inspection. The FDA forms provided by the Central Office will be used exclusively.

VEHICLE INSPECTIONS

Food vehicles are subject to many of the same deficiencies found in other food establishments. See Sub-section 2025, Vehicle Inspections, for information and instructions for inspecting food vehicles.

HOME PROCESSORS

Home processors may be exempt from normal inspection procedures. See Sub-Section 2030, Home Processors, for more information.

FARM WINERY

Wineries licensed by the State Liquor Authority as a Farm or Special Farm Winery are exempt from licensing under Article 20-C if no other licensable processing activities are being conducted on the premises. Establishment Type (W) has been assigned these exempt Farm Winery operations. Annual inspections are still to be conducted.

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SANITARY INSPECTION REPORTS - FSI-894 AND FSI-898
SUB-SECTION 2005**

LEGAL AUTHORITY

THE DIVISION OF FOOD SAFETY AND INSPECTION OPERATES UNDER THE AUTHORITY OF THE NEW YORK STATE DEPARTMENT OF AGRICULTURE AND MARKETS LAW, ARTICLES 4-D, 5-A, 5-B, 5-C, 17, 17-A, 17-B, 19, 20, 20-C, AND 28 AS WELL AS 1NYCRR; PARTS 245, 246, 256, 257, 261, 262, 265, 266, 267, 271, 272, 275, 276, 277 AND 301. ALL QUESTIONS RELATING TO SPECIFIC APPLICATIONS OF THE LAW SHOULD BE DIRECTED, THROUGH YOUR SUPERVISING INSPECTOR, TO THE FOOD SAFETY AND COMPLIANCE UNIT.

OVERVIEW

The Sanitary Inspection Report consists of:

1. The Cover Sheet (FSI-894), which is used to report:
 - A. Establishment ownership information and related statistical data
 - B. The critical and general deficiencies used to indicate conditions found in establishments inspected
 - C. Establishment representative/Inspector activity information
2. The Sanitary Inspection Guidelines (FSI-894-back) lists specific categories of Critical and General deficiencies primarily relating to insanitary conditions.
3. The Supplemental Sanitary Inspection Report (FSI-898) is used in conjunction with the Sanitary Inspection Report (FSI-894) to submit descriptive, written reports of violations found in an establishment as well as other supportive information such as an establishment's license status, products sold or processed, etc.
4. The Specialized Inspection Guidelines (FSI-898-back) lists specific categories of Critical and General deficiencies relating to the manufacturing, processing and record keeping of potentially hazardous foods and salvaged food products.
5. The Notice of Inspection Report (FSI-890) (Refer to Sub-Section 2006).

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Each of these forms, the FSI-894 and FSI-898, are provided in sets of four. The Notice of Inspection Report (FSI-890) is provided in bound pads. Distribution of the completed reports is as indicated at the bottom margin of each report form. All information entered in these reports is to be printed or written neatly, legibly and concisely.

SANITARY INSPECTION REPORT COMPLETION PROCEDURES - FSI-894

1. **Date:** Enter the date of the sanitary inspection activity. If the inspection is of more than one day's duration, retain the FSI-894 and FSI-898. Do not send in the sanitary inspection report until the inspection is completely done. An e-mail to the Zone Supervisor and the Compliance Unit, explaining the circumstances, should be submitted daily.

A separate cover sheet (FSI-894) must be completed for each subsequent day of the inspection. All deficiencies, regardless of the day found, shall be circled only on the last page of the FSI-894 Cover Sheet. This last page shall be placed on top of all the prior FSI-894 cover sheets. In the space above the date box on each page of the FSI-894, prominently indicate the page number and the total FSI-894 pages, i.e., Page 1 of 3, 2 of 3, 3 of 3, etc. The following information **MUST** be included on each of the FSI-894's for each subsequent day:

- A. The applicable date
 - B. The establishment number
 - C. The owner's name
 - D. The Inspector's I.D. Number
 - E. The time in, time out and total hours and minutes worked each day
 - F. The inspector(s) name(s), printed
2. **Establishment Number:** Place the establishment number in the spaces provided. If unknown, enter the County Code in the first two boxes. Leave the remaining four boxes blank.
 3. **OCR:** Check the "Reviewed" box to indicate establishment information has been reviewed and no changes were made. Check the "Reviewed" box if the establishment information was reviewed and an OCR was submitted to report establishment information changes.
 4. **Establishment Information:** Enter the owner's name, trade name, street, city and ZIP code in the spaces provided.

Note: See Sub-Section 2045, Operation Change Report, for entry procedure information.

5. **Type:** Refer to the electronic Operation Change Report instructions, Sub-Section 2045, to determine the establishment type(s).
6. **IPH (Indicator of Potential Hazard):** Refer to Sub-Section 2050, IPH Categories and Inspection Rate Guidelines. Determine the IPH category and enter the number in the box.

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7. Inspection Type:

- A. Inspection: Check this box if this is a new business inspection or if the previous inspection did not result in “critical deficiencies” as noted in Sub-Section 2000, Sanitary Inspection Report Guidelines.

Note: An Inspector may be asked to return to an establishment where many general deficiencies had previously been reported. In this case the report would be marked as an “inspection”.

- B. Reinspection: Check this box if the prior reinspection revealed the presence of critical deficiencies.

“Limited in scope” reinspections, in lieu of a complete reinspection, can be performed when an establishment has failed the previous inspection as a result of one readily identifiable and easily remedied critical deficiency item (i.e., no hot water, inadequate hand wash facilities, inadequate equipment cleaning and sanitizing facilities, improper hot holding, improper cooking or re-heating, improper cooling or refrigeration, unclean food contact surfaces, bare hand contact with ready-to-eat foods.).

Establishment operators can be asked for a target date by which they plan to have the deficiency corrected and a limited reinspection restricted to a review of that one deficiency item can be scheduled for that time or within the normal reinspection frequency. This report should be identified as “Reinspection” and the memo/narrative section of the report should state as follows: “Limited-in-scope Reinspection” - follow-up to inspection dated _____ regarding _____ (deficiency).

- C. Limited: Check this box if the inspection is a “limited”.

Limited inspections may be conducted at a new business not yet operational but requiring a sanitary inspection prior to being issued a Department License. This limited inspection may be conducted at a time prior to the operation opening for business and when facilities (i.e., equipment wash facilities, toilet facilities, handwash facilities, etc.) have been installed and functional. A full sanitary inspection of the business would follow within three months after the establishment has opened for business.

- D. Hazard Analysis (Hazard Analysis Critical Control Points):

All sanitary inspections should be conducted using HACCP principles as much as possible. However, this box should be checked only when conducting a complete hazard analysis inspection and only with your Supervising Inspector’s specific instructions. See HACCP forms FSI-892 (page 14) and FSI-893, (page 16) in Sub-Section 2035. A

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SANITARY INSPECTION REPORTS - FSI-894 AND FSI-898
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program for reporting HACCP inspections is not available for the electronic reporting system at this time.

8. FDA Contract: Check the “Yes” box if you are conducting an FDA Contract inspection. Check the “No” box if you are not. See Sub-Section 5020, Federal-State Inspection Contract for procedural information.
9. Photos Taken: If photographs were taken check the “Yes” box. If not, check the “No” box. If possible, photographs should be taken of all critical deficiencies found during any inspection activity. See Sub-Section 2065 for photographic reporting instructions.
10. Consumer Complaint:
 - A. If the subject establishment is due for an inspection or reinspection, a full inspection or reinspection is to be conducted, along with the investigation of the complaint. Check on the appropriate complaint box; and report in the “Memo” section of the electronic report/narrative of FSI-898 as follows: “consumer complaint investigated regarding _____” (list issue).
 - B. If the establishment is not due for inspection or reinspection, conduct an inspection restricted to the investigation of the alleged deficiencies. This inspection should be identified as an inspection and the Memo/898 narrative should include the following: “Limited in scope inspection conducted pursuant to the consumer complaint regarding _____” (list issue). If during the course of this “limited in scope” inspection one or more critical deficiencies are noted, a full sanitary inspection is to be conducted.
 - C. Consumer complaints involving pre-packed food products, and where establishment inspection is not necessary, are to be reported on the appropriate consumer complaint report only (no sanitary inspection report is to be submitted).
11. FL-Number: If sample(s) are taken, enter the FL-number(s) in the boxes provided.
12. Seizure Number: If a food seizure is executed during an inspection, enter the six-digit number and the alpha character in the boxes provided, i.e., 123456Z.
13. Explanation of Sample/Seizure: Enter a brief, concise description of the samples taken and the analyses requested, why products were placed under seizure and weight of seized products (excluding pet foods).
14. License Information: Must be entered manually on the paper FSI-894. For the electronic report this is a default entry made by the AS400. Inspector’s need not make any changes in

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license information. Any incorrect license information should be noted in the memo section of the sanitary inspection report.

- A. None: A License is not required by the establishment.
- B. Article 5-A: Slaughterhouse license
- C. Article 17-B: Food Salvagers
- D. Article 19: Refrigerated Warehouses and Locker Plants (includes fruit and produce warehouses)
- E. Article 20-C Exempt: Home processors, honey and/or maple syrup producers and Farm Wineries
- F. Article 20-C: Food Processing Operations, wholesale and retail, not regulated by a Health Department or a Federal Agency or exempt
- G. Article 28: Retail food store that do not process food. Warehouses that distribute food
- H. License Expiration Date: For electronic inspection reports, the expiration date is a default entry made by the AS400. On the FSI-894 paper report form, enter the expiration date from the current valid license. If the establishment license is expired or not available, leave this space **blank** and document on the FSI-898 the processes or operations you observed or are said to be conducted by the management. If a license is pending for the current year, write "Pending" and the license expiration date. Do this only if confirmed by a telephone call to the License Unit or by a printout that shows the pending license and date.
- I. Operating Without Required License: Check this box if the establishment is observed conducting licensable operations either with an expired license or without a license.

Note: Refer to Sub-Section 4065, Licensing and Permits, and Sub-Section 2010, Critical Deficiencies - Item 5-B and Sub-Section 2015, General Deficiencies - Item 13-A for additional information.

15. Critical Deficiencies: A Critical Deficiency is a condition that does not conform to this Department's sanitary requirements and is an immediate threat to the public health and welfare. Immediate corrective steps should be taken by the establishment operator(s).

To report a critical deficiency circle both the appropriate number and letter(s) on the FSI-894 cover sheet and write the narrative on the FSI-898.

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SANITARY INSPECTION REPORTS - FSI-894 AND FSI-898
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The establishment operator should be advised to initiate immediate corrective action on all critical deficiencies. Corrective action should be fully described on the FSI-898.

A reinspection will be scheduled by supervisory personnel based on the reinspection rate for the IPH category of the establishment. (See Sub-Section 2050, IPH Categories and Inspection Rate Guidelines).

16. General Deficiencies: A General Deficiency is a condition which does not conform to the Department's sanitary requirements but is not severe enough to be an immediate hazard to the public health or immediately contribute to product contamination or adulteration.

Note: To report a general deficiency, circle both the appropriate number and letter(s) on the FSI-894 cover sheet as well as writing a description of the deficiency on the Supplemental Sanitary Inspection Report (FSI-898). The establishment operator should be advised to initiate prompt corrective action.

17. Inspector No. and Time: Enter your I. D. number, the time you entered the establishment, the time you left and the total amount of inspection time. Do not include lunch periods, coffee breaks, time spent on economic inspections, telephone calls and other interruptions unrelated to the sanitary inspection of the establishment.

Time spent during the inspection on seizures or sampling shall be included along with sanitary report preparation and discussions of findings with management.

The I. D. and time section must also be completed by each additional Inspector and Supervising Inspector who helped conduct the inspection or was present during any part of the inspection.

This portion of the report must be completed, clearly and accurately, on all four copies of the FSI-894 cover sheet, including the copy left with the establishment.

This information must also be entered on each additional FSI-894 cover sheet prepared when the inspection takes more than one day.

18. Person Receiving Report - Title: Print the full first name, the last name and title of the establishment representative receiving the report. Non-specific titles such as "in charge" are not acceptable. Examples of acceptable titles might be: Proprietor, president, manager, treasurer, assistant manager, acting manager, clerk, etc.
19. Inspector(s): Print the name(s) of the Inspector(s), and/or Supervising Inspector(s) who were present during any part of the inspection on the date cited.

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20. Field Review: The field Supervising Inspector should review every sanitary inspection report for completeness, accuracy, legibility and conformance with Department regulations and policies. If a reinspection is indicated, the number of days to the reinspection date, measured from the date of the inspection, should be entered in the “Reinspect” box. The reviewer should legibly enter their initials in the “Rev. By” box and enter the “Review Date”.

Note: Field Supervisory personnel shall not use the “Office Use Only” section.

SANITARY INSPECTION REPORT COMPLETION PROCEDURES - FSI-898

The Supplemental Sanitary Inspection Report (FSI-898) is used in conjunction with the Sanitary Inspection Report (FSI-894) to submit descriptive, written reports of violations found in an establishment as well as other supportive information such as an establishment’s license status, products sold or processed, etc.

All entries on an FSI-898 shall be neat, clearly written or printed in black ink.

See Recording Deficiencies, page 3, Sub-Section 2000 for additional information on completing the FSI-898.

SANITARY INSPECTIONS
SANITARY INSPECTION REPORTS - FSI-894 AND FSI-898
SUB-SECTION 2005

FSI-894 (REV. 7/05)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
 DIVISION OF FOOD SAFETY AND INSPECTION
 10 B AIRLINE DRIVE, NY 12235

DATE:

OCR
 REVIEWED: ☐
 SUBMITTED: ☐

SANITARY INSPECTION REPORT

EST. NO:

OWNER:		EST. TYPE:												
TRADE NAME:		IPH:												
STREET:	CITY:	ZIP CODE:												
INSPECT TYPE: ☐ 1- INSPECTION ☐ 2- REINSPECTION ☐ 3- LIMITED ☐ 4- HAZARD ANALYSIS		LICENSE INFORMATION												
FDA CONTRACT: YES ☐ NO ☐ PHOTOS TAKEN: YES ☐ NO ☐ CONSUMER COMPLAINT: YES ☐ NO ☐		NONE ☐ 5a ☐ 17b ☐ 19 ☐												
SAMPLE NUMBERS		20-C EXEMPT ☐ 20-C ☐												
FL- <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>							S- <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>							LICENSE EXPIRATION DATE:
FL- <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>							S- <table border="1" style="display: inline-table; width: 100px; height: 20px;"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>							OPERATING WITHOUT THE REQUIRED LICENSE ☐
EXPLAIN SAMPLES/SEIZURES:														

CRITICAL DEFICIENCIES				GENERAL DEFICIENCIES			
1	FOOD RECEIVED FROM UNAPPROVED SOURCES A B C D E F	9	IMPROPER OR INADEQUATE SANITARY FACILITIES OR CONTROLS A B C D E F G H				
2	FOOD PRODUCTS OR INGREDIENTS ADULTERATED OR UNFIT A B C D	10	INADEQUATE SANITARY DESIGN, CONSTRUCTION AND MAINTENANCE A B C D				
3	FOOD NOT PROTECTED FROM CONTAMINATION BY WORKERS A B C D E	11	POOR HYGIENE AND ACTIVITIES OF FOOD HANDLERS A B C D				
4	FOOD NOT PROTECTED FROM CONTAMINATION BY OTHER SOURCE A B C D E F G H	12	INADEQUATE FOOD STORAGE AND PROTECTION A B C D E F				
5	CRITICAL PROCESSING OR SALVAGING PARAMETERS ARE NOT MET A B	13	REQUIRED PROCESSING OR SALVAGING PROCEDURES ARE NOT FOLLOWED A B C D E				
6	POTENTIALLY HAZARDOUS FOOD IMPROPERLY COOLED OR REFRIGERATED A B	14	INSECT, RODENT OR VERMIN ACTIVITY A B C				
7	POTENTIALLY HAZARDOUS FOOD NOT ADEQUATELY COOKED OR REHEATED A B C D E	15	ADEQUATE EQUIPMENT, UTENSILS AND MATERIALS UTILIZED AND MAINTAINED A B C D E F G H				
8	IMPROPER HOT HOLDING PROCEDURES FOR POTENTIALLY HAZARDOUS FOOD A B	16	OTHER SANITATION A B C D E				

ITEMS MARKED ABOVE IDENTIFY SERIOUS DEFICIENCIES WHICH MAY RESULT IN THE ASSESSMENT OF CIVIL PENALTIES AND OTHER ACTION PROVIDED BY LAW INCLUDING ADMINISTRATIVE HEARING OR COURT ACTION. THE DEFICIENCIES MUST BE CORRECTED IMMEDIATELY.

ITEMS MARKED ABOVE IDENTIFY INSANITARY DEFICIENCIES THAT MUST BE CORRECTED WITHOUT DELAY. THE PRESENCE OF THESE CONDITIONS MAY RESULT IN THE ASSESSMENT OF CIVIL PENALTIES

INSPECTOR NO:	TIME IN:	TIME OUT:	TOT. HRS:	TOT. MIN:
INSPECTOR NO:	TIME IN:	TIME OUT:	TOT. HRS:	TOT. MIN:
INSPECTOR NO:	TIME IN:	TIME OUT:	TOT. HRS:	TOT. MIN:
PERSON RECEIVING REPORT:			TITLE:	
INSPECTOR(S):				
KEYPUNCH DATE:				

FIELD REVIEW	
REINSPECT DATE:	REV. DATE:
REV. BY:	REV. DATE:
OFFICE USE ONLY	
ACTION CODE:	
REV. BY:	REV. DATE:
B/O DATE:	
DATE SENT TO LEGAL:	

SANITARY INSPECTIONS

SANITARY INSPECTION REPORTS - FSI-894 AND FSI-898

SUB-SECTION 2005

FSI-894 Back (REV. 7/04)

SANITARY INSPECTION GUIDELINES

Critical Deficiencies

1. Food Received From Unapproved Sources
 - A. *Unpasteurized milk/milk products used
 - B. *Water or ice is not potable
 - C. Foods or ingredients from unapproved source
 - D. Meat, poultry, or game products are not from officially inspected plants
 - E. *Shellfish from unapproved source
 - F. Liquid eggs, frozen eggs, or dried milk products are not from USDA inspected plants
2. Food Products or Ingredients Adulterated or Unfit
 - A. Rodent defiled foods or ingredients
 - B. Insect infested foods or ingredients
 - C. Food products contain unidentified sulfiting agents or other unapproved additives
 - D. *Other adulterated/unfit foods or ingredients
3. Food Not Protected From Contamination By Workers
 - A. *Food handlers handle foods when ill with a disease transmissible by foods
 - B. *Food handlers have infected cuts or burns on their hands
 - C. *Food handlers do not wash hands thoroughly after contaminating them
 - D. Employee handwashing facilities inadequate for establishments handling exposed foods
 - E. *Employees handling exposed, ready-to-eat foods without an acceptable protective barrier
4. Food Not Protected From Contamination By Other Sources
 - A. *Food contact equipment, utensils or conveyances for potentially hazardous foods: contact surfaces unclean or not properly sanitized and likely to contribute to contamination
 - B. *Food contact equipment, utensils, or conveyances are not cleaned or sanitized between use on different species or between raw and ready-to-eat foods
 - C. *Ready-to-eat foods are subjected to cross contamination from raw foods, or cross contamination between species is likely to occur
 - D. *Toxic chemicals are improperly labeled, stored, or used so that contamination of food is likely to occur
 - E. Food contact equipment condition, design or location is likely to contribute to contamination
 - F. Insect, rodent, bird or vermin activity likely to result in product contamination
 - G. Evidence of leakage or backup in sewage lines
 - H. Equipment cleaning or sanitizing facilities inadequate for establishments handling potentially hazardous foods
5. Critical Processing Or Salvaging Parameters Are Not Met
 - A. *Pork products, which may be eaten without further cooking, are not treated to kill trichina
 - B. *(Refer to Specialized Inspection Guidelines)
6. Potentially Hazardous Foods Improperly Cooled or Refrigerated
 - A. *Potentially hazardous foods are not cooled by an approved method where the product temperature can be reduced to 70°F or less within two hours and 41°F (45°F) or less within an additional 4 hours
 - B. *Potentially hazardous foods are not stored at safe temperatures
7. Potentially Hazardous Foods Not Adequately Cooked or Reheated
 - A. *Poultry, poultry stuffings, stuffed meats, or stuffings containing meat are not heated to 165°F or above
 - B. *All pork or any food containing pork is not heated to 150°F or above
 - C. *Other potentially hazardous foods requiring cooking are not heated to and/or held at required temperatures
 - D. *Potentially hazardous foods that have been cooked and then refrigerated are not rapidly reheated to 165°F or above (whole roast beef may be reheated to adequate time/temperature requirements)
 - E. *Equipment used for heating or reheating potentially hazardous foods is inadequate
8. Improper Hot-holding Procedures for Potentially Hazardous Foods
 - A. *Potentially hazardous foods are being kept below 135°F during hot-holding (rare roast beef may be served at 130°F or above)
 - B. *Hot-holding equipment improperly designed, maintained, or operated to keep hot foods at 135°F or above.

General Deficiencies

9. Improper or Inadequate Sanitary Facilities and Controls
 - A. Handwashing facilities improperly installed or maintained
 - B. Suitable water temperature or adequate pressure for food processing; equipment, utensil or container cleaning; or handwashing in establishments that do not handle exposed foods, not available
 - C. Toilet facilities improperly installed, equipped or maintained
 - D. Plumbing or sinks not properly sized, installed or maintained: equipment or floors not properly drained
 - E. Lighting or ventilation is inadequate
 - F. Cleaning or sanitizing equipment, materials or agents are not available, suitable or properly stored
 - G. Sanitizing test devices not in use where required
 - H. Lack of certification of water potability or record for disinfection
10. Inadequate Sanitary Design, Construction and Maintenance
 - A. Exterior of unsuitable construction or not in good physical repair
 - B. Establishment has insufficient space to accommodate operations
 - C. Interior floors, walls, ceilings or fixtures are not of suitable construction, clean or well maintained
 - D. Refuse containers not clean, covered, in good repair or removed at sufficient intervals
11. Poor Hygiene and Activities of Food Handlers
 - A. Not maintaining a high degree of cleanliness or taking precautions to prevent contamination of foods from perspiration, cosmetics, chemicals or medicants, etc.
 - B. Not wearing clean outer garments, effective hair restraints or secure jewelry
 - C. Eating, drinking or use of tobacco in exposed food areas
 - D. Locker or dressing rooms are not segregated from food areas, clean or orderly
12. Inadequate Food Storage and Protection
 - A. Food not stored, conveyed or displayed in a manner that prevents contamination including marginal temperature deficiencies
 - B. Food or ingredient storage containers are not clean, covered or properly identified
 - C. Bulk food displays are improperly constructed, displayed or handled
 - D. Street clothing or soiled linen stored unsegregated from exposed food or food-contact surfaces
 - E. Food displays are improperly constructed, maintained or supervised
 - F. Improper thawing procedures are utilized
13. Processing Procedures/Educational Requirements Are Not Met
 - A. (See Specialized Inspection Guidelines)
 - B. Other required records/certifications are not maintained
 - C. Other coding requirements are lacking or inadequate
 - D. Article 28 posting requirements are not met
 - E. Consumer advisory requirements are not met
14. Insect, Rodent or Vermin Activity
 - A. Evidence of rodents observed (not likely to result in product contamination)
 - B. Insect, birds or other vermin observed within the establishment (not likely to result in product contamination)
 - C. Evidence of pets or other domestic animals in establishment
15. Equipment Utensils and Materials Adequately Utilized and Maintained
 - A. Food contact equipment, utensils or conveyances: contact surfaces unclean or not properly sanitized
 - B. Non-contact food equipment, utensils or conveyances are not clean or in good repair
 - C. Food equipment improperly designed, constructed or maintained
 - D. Thermometers not provided where required
 - E. Unused equipment or materials improperly stored or in an unclean condition
 - F. Storage cabinets or shelves are not clean or in good repair
 - G. Packaging materials unclean, improperly stored or handled in an insanitary manner
 - H. Air system or transfer lines are not clean, properly constructed or in good repair
16. Other Sanitation
 - A. Chemicals or pesticides improperly labeled, stored or handled
 - B. Outside premises or loading zones improperly maintained
 - C. Vehicles are not clean or in good repair
 - D. Morgue area or bottle return area improperly maintained
 - E. Shellfish tags or records improperly maintained

CRITICAL DEFICIENCIES PRECEDED BY AN ASTERISK (*) ARE LEADING CONTRIBUTING FACTORS WHICH CAUSE FOODBORNE DISEASE.

FSI-898 (Rev. 07/05) pm5

Date _____

Est.
No.

Item No's:
Gen. &
Spec. Lists

[illegible]

If any employee of the Department of Agriculture and Markets asks for or accepts any benefit, thing or money from you, you should report that conduct to the Inspector General of New York State by writing to the Inspector General, State Capitol, Albany, New York, 12224, or by phone at 1-800-367-4448. You may also report that conduct to your local police or sheriff's department.

Signature of Establishment Representative

Title

Date

1 - CENTRAL OFFICE

SANITARY INSPECTIONS
SANITARY INSPECTION REPORTS - FSI-894 AND FSI-898
SUB-SECTION 2005

FSI-898 (REV. 2/04) Back

SPECIALIZED INSPECTION GUIDELINES

17. Manufacturers of Thermally Processed, Low-Acid Foods, Packaged in Hermetically Sealed Containers
- A. *Processing and production records not maintained or do not indicate product code, processing system number, container size, number of containers per coding interval, minimum initial temperature, actual processing time and temperature, mercury-in-glass and recording thermometer readings and other critical factors specified in the scheduled process
 - B. *Records not maintained for retort, aseptic processing or flame sterilization
 - C. *Recording thermometer charts do not identify lots processed. Entries during processing not signed by designated person. Record not signed by reviewer prior to release of product for distribution or within 24 hours of process, whichever is sooner.
 - D. *Container closure examination records not maintained or do not indicate product code, date and time of inspection, measurements, corrective actions, signed or conducted at sufficient intervals
 - E. *Processing systems, container closure, etc., not under supervision of certified individual
 - F. Blanching operation: product not handled properly or unclean
 - G. Fillers not providing sufficient equal fills without overflows. Vacuum is not achieved in filled containers
 - H. *Scheduled food processes: not established by qualified individuals; not posted or available to retort or processing system operator and inspector
 - I. *Processing time and temperature do not meet scheduled processes
 - J. *All baskets and other containers of unretorted food products not marked with a heat sensitive indicator
 - K. *Retorts, aseptic processing and flame sterilization equipment does not meet requirements contained in Section 277.6 of NYCRR
 - L. Container cooling water is not adequately chlorinated or equivalently treated
 - M. Each container of product not coded with establishment where packed, product name, year packed, day packed, packing period
 - N. *Deviations from scheduled process not identified and evaluated with corrective action recorded
18. Acidified Foods (and Tomato Products and other Potentially Low-Acid Products)
- A. *Product does not achieve and maintain a finished equilibrium pH of 4.6 or lower
 - B. *Thermal processing or permitted preservatives not used in accordance with the scheduled process
 - C. *Production not done under operating supervision of qualified individual
 - D. *Sufficient control, including frequent testing and recording not exercised
 - E. *Acidification procedures not adequate
 - F. Containers not tested or examined at sufficient intervals and/or marked with coding
 - G. *Scheduled process not established by qualified individual
 - H. *Deviations from scheduled process not identified or evaluated with corrective action recorded
 - I. *Adequate pH testing methods not performed to insure proper acidification
 - J. *Processing and production records not properly maintained
19. Water Activity Reduced Foods
- A. *Water activity level of .85 or less not achieved
 - B. *Water activity testing procedures not performed to insure proper water activity level
20. Salvage Dealers
- A. Records not kept or available for damaged merchandise, merchandise found to be unfit and salvaged merchandise. Receipt of damaged foods not properly reported to Commissioner's representative.
 - B. Storage of products and removal of unfit foods: All unfit foods not frequently removed; products not stored off floor, 12" from wall and/or with 18" aisles between double rows of merchandise
 - C. 1. Receiving room, 2. Sorting and cutting room, 3. Storage area for reconditioned merchandise, 4. Waste room, 5. Separate cleaning room (if cleaning of merchandise performed), 6. Separate retail sales area (if retail sales provided), 7. Refrigerator and/or freezer (if refrigerated and/or frozen foods are handled) not provided where required
 - D. *Reconditioning and Labeling: unfit merchandise is offered for sale including but not limited to: metal cans; rust pitted or with rim, seam or sharp body dents, springers, flippers and swells; food containers with press caps or screw caps having been immersed in water; unlabeled merchandise; single-service items
21. Licensable Food Operations
- A. *Processing of potentially hazardous foods not authorized
 - B. Operation not licensed
22. Vacuum or Modified Atmosphere Packaging at Retail
- A. *Foods packaged not restricted to those which will not support the growth of Clostridium botulinum
 - B. *Vacuum packaged foods not maintained at proper temperatures or not conspicuously labeled with the temperature requirements
 - C. *Refrigerated vacuum packaged products not given a maximum 14-day use by date and not so labeled. This expiration date exceeds the manufacturer's expiration date as indicated on the original container
 - D. *Conspicuous signs listing products which may be vacuum packaged and warning against packaging any other products not posted in vacuum packaging area
 - E. *Compliance with Clostridium botulinum control parameters not verified via written certification from the manufacturer or independent laboratory analysis on products purchased for vacuum packing
 - F. *Access to the vacuum packaging equipment not restricted to qualified persons
 - G. *Written product purchase specifications not utilized when procuring products to be vacuum packaged
 - H. *Detailed written in-store HACCP Plan which includes steps to minimize opportunities for product adulteration and cross-contamination not developed, not adhered to or not monitored
 - I. Other vacuum packing requirements not met
23. Cured, frozen and/or Smoked Fish Processors
- A. *Unwholesome, unsound, adulterated or organoleptically detectably spoiled fish are processed
 - B. *Fish processed not free of viscera
 - C. *Evisceration of fish not conducted in a safe, sanitary manner or segregated from other processing operations
 - D. *Brining procedures not properly conducted
 - E. *Curing, freezing or smoking of fish not conducted by a controlled process whereby the safety and wholesomeness of the fish is not adversely affected
 - F. *Processed fish not held or distributed at safe temperatures
 - G. *Labeling for processed fish does not indicate the perishable nature of the product
24. Specialized food processing requiring a HACCP Plan
- A. *Specialized food processing is being conducted without the required HACCP Plan
 - B. *Critical requirements of the HACCP Plan not met
 - C. Other HACCP requirements not met

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT
NOTICE OF INSPECTION - FSI-890
SUB-SECTION 2006**

OVERVIEW

The Electronic Sanitary Inspection Reporting System consists of:

1. The Notice of Inspection Report (FSI-890), which is used to report:
 - A. Establishment ownership, name and address
 - B. The critical and general deficiency categories used to indicate conditions found in the establishment
 - C. Establishment representative/Inspector information and signatures
2. The Electronic Sanitary Inspection Report, which is used to report:
 - A. Descriptive, typed violations found in the establishment
 - B. Supportive information such as license status, sample information, etc.

NOTICE OF INSPECTION COMPLETION PROCEDURES – FSI-890 (Front and Back)

The Notice of Inspection report (NOI) is always used when reporting an inspection electronically. The NOI is validation that the Inspector conducted an inspection at the establishment on the given date. The NOI's are available in bound paper pads. The NOI is completed at the end of the inspection and a carbon copy given to the establishment representative upon departure. The original copy is to be maintained in the Zone file.

NOTICE OF INSPECTION - FSI-890 (Front Page)

1. Date: Enter the date of the sanitary inspection activity. If the inspection is of more than one day's duration, enter all activity dates and complete the report at the end of the inspection (last day).
2. Establishment Number: Enter the establishment number in the space provided. The firm must have an establishment number to enter the inspection **ELECTRONICALLY**. In the case of a new business, follow the procedures set forth in Sub-Section 2045, OCR – Operation Change Report.
3. Establishment Information: Enter the owner name, trade name, street, city and zip code in the space provided. This information must be verified at each inspection.

SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT
NOTICE OF INSPECTION - FSI-890
SUB-SECTION 2006

4. Deficiency Check Boxes: Place an 'X' in the appropriate box:

- A. The establishment is in substantial compliance in that no critical deficiencies were observed - Check this box if no deficiencies or only general deficiencies were noted.

A GENERAL DEFICIENCY is a condition, which does not conform to the Department's sanitary requirements, but is not severe enough to be an immediate hazard to the public health or immediately contribute to product contamination or adulteration.

A General Deficiency does not generally warrant a follow-up inspection. Under certain conditions supervision may request a follow-up inspection. Establishment operators should be advised to initiate prompt corrective action regarding General Deficiencies.

- B. Critical Deficiencies which were corrected at time of inspection – Check this box if one or more critical violations were noted AND corrected at the time of inspection.

A CRITICAL DEFICIENCY is a condition that does not conform to this Department's sanitary requirements and is an immediate threat to the public health and welfare. The establishment operator should be advised to initiate immediate corrective action on all Critical Deficiencies, during the inspection wherever possible.

A Critical Deficiency will warrant a follow-up, or reinspection. Reinspections will be scheduled by supervision based on the reinspection rate for the IPH category and/or the severity of the violation.

- C. Critical Deficiencies – Check this box if one or more critical violations were noted and were not corrected at the time of inspection.

If Critical Deficiencies which were corrected at time of inspection and Critical Deficiencies were both noted, check only the Critical Deficiencies box. Refer to Sub-Section 2010 – Critical Deficiencies and Sub-Section 2015 - General Deficiencies to determine severity of violations.

5. Establishment Representative's Name and Title: Print the full first name and last name of the representative receiving the report. Non-specific titles such as "In Charge" are not acceptable. Examples of acceptable titles are owner, manager, president, clerk, etc.
6. Inspector Signature and I.D.#: Enter the signature and corresponding I.D. number for each Inspector participating in the inspection.

NOTICE OF INSPECTION - FSI-890 (Back Page)

The back of the Notice of Inspection shows the Critical and General Deficiency checklists, "SANITARY INSPECTION GUIDELINES". The guidelines are used to categorize or "score" establishment violations. Prior to leaving the establishment, the Inspector shall assign each violation the appropriate number and letter category. The category for each deficiency is to be circled (number and letter) on

SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT
NOTICE OF INSPECTION - FSI-890
SUB-SECTION 2006

both Notice of Inspection copies. Every deficiency is to be discussed with the establishment representative before leaving the establishment. The original copy is to be maintained by the Supervising Inspector in the Zone file. The carbon copy is to be left with the establishment representative.

ELECTRONIC INSPECTION REPORT COMPLETION

The Notice of Inspection Report (FSI-890) states in part: “A written report summarizing the results of today’s inspection will be mailed to you within five working days.” To facilitate this commitment, every effort should be made to complete electronic report composition and transmission the same day as the inspection. When this is not possible, the reports should be transmitted immediately the next working day. **Note:** Legal inspections must be uploaded the same day as the inspection.

Once the electronic inspection is uploaded to the AS/400 computer in Albany the Inspector cannot access the report to make changes or corrections. A critical error (date, times, etc.) affecting the integrity of the report can only be corrected by deleting the report in Albany and then resubmitting the corrected version. The deletion of reports from the AS/400 is a time-consuming task. Reports must be closely reviewed before transmission. If the Inspector is aware of a critical error on an uploaded report, the Zone Supervisor and the Food Safety and Compliance Unit are to be notified immediately.

This Sub-Section has addressed the electronic Sanitary Inspection Report. For additional information regarding inspection practices, reporting, integrity and legal authority, refer to Sub-Sections 2000-2070.

**SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT
NOTICE OF INSPECTION - FSI-890
SUB-SECTION 2006**

FSI-890(Rev. 7/04)



NOTICE OF INSPECTION

New York State Department of Agriculture and Markets
Division of Food Safety and Inspection
10B Airline Drive, Albany, NY 12235

DATE: _____ **EST. NO.:** _____

OWNER NAME: _____

TRADE NAME: _____

EST. ADDRESS: _____

An inspection of your establishment was made today pursuant to provisions of the New York State Agriculture and Markets Law relating to food.

A report of the Department's findings will be mailed to you within five working days.
The results of the inspection show:

- ☐ The establishment in substantial compliance in that no critical deficiencies were observed
- ☐ Critical deficiencies which were corrected at time of inspection
- ☐ Critical deficiencies

EST. REP'S NAME (Please print) _____

TITLE _____

EST. REP'S SIGNATURE _____

INSPECTOR'S SIGNATURE _____ **I.D. #** _____

PLEASE NOTE:

A critical deficiency is a sanitation or food safety condition that must be corrected immediately. It may result in the assessment of civil penalties and other action provided by law, including administrative hearing or court action.

Article 28 of the New York State Agriculture and Markets Law requires a retail food store to post a copy of the date and results of its most recent sanitary inspection in a conspicuous location near each public entrance. A retail food store may comply with this requirement by posting a copy of this Notice of Inspection.

If you offer to give any benefit, thing or money to any employee of the Department of Agriculture and Markets, your conduct will be reported to your local police or sheriff's department.

SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT
NOTICE OF INSPECTION - FSI-890
SUB-SECTION 2006

FSI-890 Back (REV. 7/04)

SANITARY INSPECTION GUIDELINES

Critical Deficiencies

1. Food Received From Unapproved Sources
 - A. *Unpasteurized milk/milk products used
 - B. *Water or ice is not potable
 - C. Foods or ingredients from unapproved source
 - D. Meat, poultry, or game products are not from officially inspected plants
 - E. *Shellfish from unapproved source
 - F. Liquid eggs, frozen eggs, or dried milk products are not from U.S.D.A. inspected plants
2. Food Products or Ingredients Adulterated or Unfit
 - A. Rodent defiled foods or ingredients
 - B. Insect infested foods or ingredients
 - C. Food products contain unidentified sulfiting agents or other unapproved additives
 - D. *Other adulterated/unfit foods or ingredients
3. Food Not Protected From Contamination By Workers
 - A. *Food handlers handle foods when ill with a disease transmissible by foods
 - B. *Food handlers have infected cuts or burns on their hands
 - C. *Food handlers do not wash hands thoroughly after contaminating them
 - D. Employee handwashing facilities inadequate for establishments handling exposed foods
 - E. *Employees handling exposed, ready-to-eat foods without an acceptable protective barrier
4. Food Not Protected From Contamination By Other Sources
 - A. *Food contact equipment, utensils or conveyances for potentially hazardous foods: contact surfaces unclean or not properly sanitized and likely to contribute to contamination
 - B. *Food contact equipment, utensils, or conveyances are not cleaned or sanitized between use on different species or between raw and ready-to-eat foods
 - C. *Ready-to-eat foods are subjected to cross contamination from raw foods, or cross contamination between species is likely to occur
 - D. *Toxic chemicals are improperly labeled, stored, or used so that contamination of food is likely to occur
 - E. Food contact equipment condition, design or location is likely to contribute to contamination
 - F. Insect, rodent, bird or vermin activity likely to result in product contamination
 - G. Evidence of leakage or backup in sewage lines
 - H. Equipment cleaning or sanitizing facilities inadequate for establishments handling potentially hazardous foods
5. Critical Processing Or Salvaging Parameters Are Not Met
 - A. *Pork products, which may be eaten without further cooking, are not treated to kill trichina
 - B. *(Refer to Specialized Inspection Guidelines)
6. Potentially Hazardous Foods Improperly Cooled or Refrigerated
 - A. *Potentially hazardous foods are not cooled by an approved method where the product temperature can be reduced to 70°F or less within two hours and 41°F (45°F) or less within an additional 4 hours
 - B. *Potentially hazardous foods are not stored at safe temperatures
7. Potentially Hazardous Foods Not Adequately Cooked or Reheated
 - A. *Poultry, poultry stuffings, stuffed meats, or stuffings containing meat are not heated to 165°F or above
 - B. *All pork or any food containing pork is not heated to 150°F or above
 - C. *Other potentially hazardous foods requiring cooking are not heated to and/or held at required temperatures
 - D. *Potentially hazardous foods that have been cooked and then refrigerated are not rapidly reheated to 165°F or above (whole roast beef may be reheated to adequate time/temperature requirements)
 - E. *Equipment used for heating or reheating potentially hazardous foods is inadequate
8. Improper Hot-holding Procedures for Potentially Hazardous Foods
 - A. *Potentially hazardous foods are being kept below 135°F during hot-holding (rare roast beef may be served at 130°F or above)
 - B. *Hot-holding equipment improperly designed, maintained, or operated to keep hot foods at 135°F or above.

General Deficiencies

9. Improper or Inadequate Sanitary Facilities and Controls
 - A. Handwashing facilities improperly installed or maintained
 - B. Suitable water temperature or adequate pressure for food processing; equipment, utensil or container cleaning; or handwashing in establishments that do not handle exposed foods, not available
 - C. Toilet facilities improperly installed, equipped or maintained
 - D. Plumbing or sinks not properly sized, installed or maintained: equipment or floors not properly drained
 - E. Lighting or ventilation is inadequate
 - F. Cleaning or sanitizing equipment, materials or agents are not available, suitable or properly stored
 - G. Sanitizing test devices not in use where required
 - H. Lack of certification of water potability or record for disinfection
10. Inadequate Sanitary Design, Construction and Maintenance
 - A. Exterior of unsuitable construction or not in good physical repair
 - B. Establishment has insufficient space to accommodate operations
 - C. Interior floors, walls, ceilings or fixtures are not of suitable construction, clean or well maintained
 - D. Refuse containers not clean, covered, in good repair or removed at sufficient intervals
11. Poor Hygiene and Activities of Food Handlers
 - A. Not maintaining a high degree of cleanliness or taking precautions to prevent contamination of foods from perspiration, cosmetics, chemicals or medicants, etc.
 - B. Not wearing clean outer garments, effective hair restraints or secure jewelry
 - C. Eating, drinking or use of tobacco in exposed food areas
 - D. Locker or dressing rooms are not segregated from food areas, clean or orderly
12. Inadequate Food Storage and Protection
 - A. Food not stored, conveyed or displayed in a manner that prevents contamination including marginal temperature deficiencies
 - B. Food or ingredient storage containers are not clean, covered or properly identified
 - C. Bulk food displays are improperly constructed, displayed or handled
 - D. Street clothing or soiled linen stored unsegregated from exposed food or food-contact surfaces
 - E. Food displays are improperly constructed, maintained or supervised
 - F. Improper thawing procedures are utilized
13. Processing Procedures/Educational Requirements Are Not Met
 - A. (See Specialized Inspection Guidelines)
 - B. Other required records/certifications are not maintained
 - C. Other coding requirements are lacking or inadequate
 - D. Article 28 posting requirements are not met
 - E. Consumer advisory requirements are not met
14. Insect, Rodent or Vermin Activity
 - A. Evidence of rodents observed (not likely to result in product contamination)
 - B. Insect, birds or other vermin observed within the establishment (not likely to result in product contamination)
 - C. Evidence of pets or other domestic animals in establishment
15. Equipment Utensils and Materials Adequately Utilized and Maintained
 - A. Food contact equipment, utensils or conveyances: contact surfaces unclean or not properly sanitized
 - B. Non-contact food equipment, utensils or conveyances are not clean or in good repair
 - C. Food equipment improperly designed, constructed or maintained
 - D. Thermometers not provided where required
 - E. Unused equipment or materials improperly stored or in an unclean condition
 - F. Storage cabinets or shelves are not clean or in good repair
 - G. Packaging materials unclean, improperly stored or handled in an insanitary manner
 - H. Air system or transfer lines are not clean, properly constructed or in good repair
16. Other Sanitation
 - A. Chemicals or pesticides improperly labeled, stored or handled
 - B. Outside premises or loading zones improperly maintained
 - C. Vehicles are not clean or in good repair
 - D. Morgue area or bottle return area improperly maintained
 - E. Shellfish tags or records improperly maintained

CRITICAL DEFICIENCIES PRECEDED BY AN ASTERISK (*) ARE LEADING CONTRIBUTING FACTORS WHICH CAUSE FOODBORNE DISEASE.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT – FSI-894 & FSI-898
SUB-SECTION 2007**

OVERVIEW

The Electronic Sanitary Inspection Reporting System is to be used for all routine sanitary inspections and reinspections except the following:

1. Home Processor Inspections
2. Vehicle Inspections

The following instructions are intended to guide the Inspector regarding the input of appropriate information in the sanitary inspection report. User guides for navigating the sanitary inspection and electronic mail programs are available from the Division of Food Safety and Inspection Central Office upon request (and provided upon appointment).

ELECTRONIC INSPECTION REPORT – COMPLETION PROCEDURES(See Attachments 1-3)

1. Date: The computer will automatically enter (default) the present date in this slot. If the inspection report is being composed the day after the actual inspection was conducted, the date can be deleted and changed by the Inspector (backspace or delete key).

In the case of a multi-day inspection, the last day of the inspection will be used for the report date.

Note: If unable to compose an inspection report the same day as the inspection, it is advisable to at least start the report by entering the inspection type (see Step 2) and closing the program. This process will lock in the current date. The properly dated report can be retrieved from the “Inspections to Complete” file the next day.

2. Inspection Type: Click in the appropriate inspection type box:
 - A. Inspection: Check this box if this is a new business inspection or if the previous inspection did not result in “critical deficiencies” as noted in Sub-Section 2000, Sanitary Inspection Report Guidelines.

For new business inspection procedures, see Sub-Section 2045, OCR – Operation Change Report.
 - B. Reinspection: Check this box if the prior inspection revealed the presence of “critical deficiencies”.
 - C. Limited: Check this box for limited pre-operational new business inspections.

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ELECTRONIC SANITARY INSPECTION REPORT – FSI-894 & FSI-898
SUB-SECTION 2007

D. Hazard Analysis: Check this box for HACCP inspections. Supporting documents such as flow charts will need to be submitted in addition to electronic sanitary inspection report. (See Sub-Section 2008).

3. License Information:

- A. Article 5-A: Slaughterhouse license
- B. Article 17-B: Food Salvagers
- C. Article 19: Refrigerated Warehouses and Locker Plants
- D. Article 19-A: Refrigerated Produce Warehouses
- E. Article 20-C: Food processing operations, wholesale and retail, and not regulated by a Health Department or a Federal Agency or otherwise exempt
- F. Article 28: Retail food stores that do not process food. Warehouses that distribute food
- G. None: No license required
- H. Article 20-C Exempt: Home processors, honey and maple syrup producers and farm wineries
- I. Expiration Date: Default entry
- J. Operating Without the Required License: Check this box if the establishment is observed conducting licensable operations with an expired license or without a license.

License information will automatically fill in upon clicking in the inspection type. If any of the license information is incorrect, the Inspector should notify the License Unit.

Note: Refer to Sub-Section 4065, Licenses and Permits; Sub-Section 2010, Sanitary Inspections - Critical Deficiencies, Item 5-B, and Sub-Section 2015, Sanitary Inspections - General Deficiencies – Item 13-A for additional information.

- 4. FDA Contract: Click on this box when reporting an FDA contract inspection.
- 5. Photos Taken: Check box if photos are taken in conjunction with the inspection. Instructions for photo submission are found in Sub-Section 2065, Photographic Report – (FSI-825).
- 6. Consumer Complaint: Check box if the Sanitary Inspection is submitted in conjunction with a Consumer Complaint Report (FSI-550) or an Illness Investigation Report (FSI-551).
- 7. Sample No./Explanation: If sample(s) are taken:
 - A. Enter the six-digit FL-number(s) in the first cell. Tab to the second cell and:
 - B. Enter a brief, concise description of the sample(s) and requested analysis.
- 8. Seizure No.: Whenever a food seizure is executed during an inspection:

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ELECTRONIC SANITARY INSPECTION REPORT – FSI-894 & FSI-898
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A. Enter the six-digit number and corresponding alpha character in the first cell and:

B. Enter the total weight, a brief description of the products and reason for seizure.

9. Inspector Information/Time:

A. InspNo./Inspector: Click in the right end of the ‘InspNo’ cell and enter the appropriate Inspector number and name from the scroll list. Enter each Inspector present during the inspection.

B. TimeIn: Enter the time each Inspector enters the establishment. Time is reported in quarter-hour increments, i.e., 9:00am, 9:15am, 9:30am, 9:45am.

C. TimeOut: Enter the time each Inspector leaves the establishment.

D. Total: Enter the total amount of inspection time spent at the establishment. Do not include lunch periods, coffee breaks, telephone calls or other interruptions unrelated to the sanitary inspection of the establishment. Time spent during the inspection on seizures or sampling shall be included along with completion of the Notice of Inspection (FSI-890) and discussions of findings with management.

In the case of multi-day inspections, the combined inspection times from each day will be entered in the total column and each day’s separate date and time noted in the “Memo” section of the Electronic Sanitary Inspection Report. The final day of the inspection will be the date used in the heading of the Sanitary Inspection Report.

10. Person Contacted/Title: Type in the full first name, last name, and title of person identified on the Notice of Inspection (FSI-890).

11. Critical: This tab opens the Critical Deficiency checklist screen. Instructions for composing Critical (and General) Deficiencies on the electronic program are provided in the Field Laptop User Guide. Refer to Sub-Section 2010 for guidance on Critical Deficiencies.

12. General: This tab opens the General Deficiency checklist screen. Refer to Sub-Section 2015 for guidance on General Deficiencies.

13. Preview: This tab allows a view of the finished Electronic Sanitary Inspection Report in the final printed version. Electronic Sanitary Inspection Reports must be carefully reviewed for errors before submission.

14. Memo: The memo section is reserved for pertinent inspection information only. This section is not to be used for personal or interagency notes. Information entered in the memo section becomes part of the finished Sanitary Inspection Report. Unless otherwise directed by supervision, the memo field shall be used for the following statements only:

SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT – FSI-894 & FSI-898
SUB-SECTION 2007

- A. Confirmation of licensable operations is to be entered on all Sanitary Inspection Reports, i.e., “Article 20-C operations as noted during inspection: heat soups and make sandwiches”. See Sub-Section 4065, Licenses and Permits.
- B. Limited In-Scope/Reinspection conditions are to be reported in the memo section according to instructions in Sub-Section 2005, Sanitary Inspection Reports.
- C. All Variances from Required Facilities and Controls shall be entered in the memo section according to instructions in Sub-Section 2040, Variance from Required Facilities and Controls.
- D. Timekeeping details of multi-day inspections are to be recorded in the memo section. The following example shows acceptable memo section entries for a two-day inspection:

This inspection was conducted over a two-day period:

Day 1 – 02/29/00 – 2:00pm to 4:00pm

Day 2 – 03/01/00 – 9:00am to 11:00am

Refer to Item 9-D in this Sub-Section for additional multi-day timekeeping instructions.

- E. Consumer complaint information.
 - F. The statement “OCR reviewed” or “OCR updated” is to be entered in the memo section for all sanitary inspections.
- 15. Back: This tab closes the Sanitary Inspection Report screen and reopens the Establishment List (see Field Laptop User Guide).
 - 16. Complete: This tab completes the Sanitary Inspection Report making the report ready for uploading to the database in Albany.

SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT – FSI-894 & FSI-898
SUB-SECTION 2007

Attachment #1

Electronic Sanitary Inspection Report (top of page):

The screenshot shows the 'Sanitary Inspection - [Inspection Information]' window. It contains several sections: 'Inspection Information' with fields for Date (05/24/2002), Estab. No. (015821), Owner Name (TEST ESTABLISHMENT), and Trade Name (TEST RECORD); 'Inspection Type' with checkboxes for 1-Inspection, 2-Reinspection, 3-Limited, and 4-Hazard Analysis; 'License Information' with checkboxes for 5a, 17b, 19, 19a, 20c, and Operating Without the Required License; and a section for 'Sample No.' and 'Seizure No.' with 'Explain' fields. There are also buttons for 'Critical', 'General', 'Preview', 'Back', and 'Complete'. A 'Memo' section is at the bottom left, and a 'Critical Deficiencies' section is at the bottom right. A status bar at the bottom shows 'Record: 1 of 1 (Filtered)' and 'Form View'.

1: Date field (05/24/2002)

2: Estab. No. field (015821)

3: Owner Name field (TEST ESTABLISHMENT)

4: Trade Name field (TEST RECORD)

5: Inspection Type section

6: License Information section

7: Sample No. field

8: Seizure No. field

9: Memo field

10: Critical Deficiencies section

(Scroll to view page bottom)

SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT – FSI-894 & FSI-898
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Attachment #2

Electronic Sanitary Inspection Report (bottom of page):

The screenshot shows the 'Sanitary Inspection - [Inspection Information]' window. It features a menu bar (File, Edit, Insert, Records, Window, Help) and a toolbar. The main interface includes:

- 11:** 'Critical' and 'General' buttons for selecting the inspection type.
- 12:** 'Preview' button.
- 13:** 'Memo:' label above a large text area.
- 14:** The memo text area, which contains the placeholder text: 'Everything here will appear on the printed report'.
- 15:** 'Person Contacted' and 'Title' input fields.
- 16:** 'Back' and 'Complete' buttons.

Below the memo area, there are two sections for deficiencies:

Critical Deficiencies:

DefNo	DefDesc
06A	I Store made potato salad is not prepared from chilled ingredients and is 75°F after 8 hours in cooling phase. 20 lbs of product destroyed under signed waiver during inspection.

Record: 1 of 1

General Deficiencies:

DefNo	DefDesc
09A	I Handwash facility in deli food preparation area is observed to lack hand soap.

Record: 1 of 1 (Filtered)

The taskbar at the bottom shows the Start button and several open applications, including 'Sent Items - Microsoft O...', 'Session A - [24 x 80]', 'Sanitary Inspection...', and 'Microsoft Word - Docum...'. The system clock shows 2:28 PM.

SANITARY INSPECTIONS
ELECTRONIC SANITARY INSPECTION REPORT – FSI-894 & FSI-898
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Attachment #3

FSI-894 (Rev. 9/98)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION SERVICES
10B AIRLINE DRIVE, ALBANY, NY 12235

Page 1 of 1

Date: 05/11/2006

SANITARY INSPECTION REPORT

Estab. No.: 015821

EST. TYPE: JAL

IPH: 3

TEST ESTABLISHMENT
TEST RECORD
TEST
TEST NY 12205

INSPECTION TYPE: Inspection

LICENSE TYPE: 19a

LIC. EXP. DATE: 09/30/2001

Consumer Complaint Operating Without the Required License

Sample No.	Explanation

Seizure No.	Explanation

Critical Deficiencies ITEMS LISTED BELOW IDENTIFY SERIOUS DEFICIENCIES WHICH MAY RESULT IN THE ASSESSMENT OF CIVIL PENALTIES AND OTHER ACTION PROVIDED BY LAW INCLUDING ADMINISTRATIVE HEARING OR COURT ACTION. THE DEFICIENCIES MUST BE CORRECTED IMMEDIATELY.

04F ☐ 100-200 fresh appearing mouse droppings are present on the retail shelves.

General Deficiencies ITEMS LISTED BELOW IDENTIFY INSANITARY DEFICIENCIES THAT MUST BE CORRECTED WITHOUT DELAY. THE PRESENCE OF THESE CONDITIONS MAY RESULT IN THE ASSESSMENT OF CIVIL PENALTIES.

13A ☐ 21B. The establishment conducts food processing activities and does not have a valid Article 20-C License. Licensable operations, as observed, are listed in the memo section of this report. License application and instructions left with management.

Memo

20C operations noted: slice cold cuts, make sandwiches

Consumer complaint states that firm has rodents.

Insp. No.	Inspector Name	Time In	Time Out	Total Time
980	SEMO	10:00 AM	12:00 PM	2:00

Person Interviewed: Michael Hill **Title:** President

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SANITARY INSPECTIONS
HACCP INSPECTION REPORT-FSI-893
SUB-SECTION 2008**

COMPLETION OF HACCP FORMS

Sanitary Inspection Forms

Every HACCP inspection will require the completion of the electronic Sanitary Inspection Report and the Notice of Inspection forms (FSI-894 and FSI-890).

Hazard Analysis Report Forms

The Hazard Analysis Report, which shall be completed on a ROI (FSI-30), and the Product Flow Diagram Chart (FSI-893) emphasize the complete review of the food product manufacturing process and will assist in identifying conditions and practices most likely to contribute to foodborne outbreaks.

Completing the Product Flow Diagram Chart (FSI-893)

See the form (FSI-893) on Page (2) of this sub-section.

SANITARY INSPECTIONS
HACCP INSPECTION REPORT-FSI-893
SUB-SECTION 2008

FSI-893 (5/06)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE
ALBANY, NEW YORK 12235

Process Flow Chart

DATE:

OWNER:	EST. NO.:	

NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual

SECTION 8054-B
CRITICAL DEFICIENCIES
SUB-SECTION 2010

OVERVIEW

THE FOLLOWING PAGES CONTAIN A LISTING OF EACH CRITICAL DEFICIENCY AS PRINTED ON THE BACK OF THE SANITARY INSPECTION REPORT FORM (FSI-894) AND ON THE BACK OF THE NOTICE OF INSPECTION REPORT FORM (FSI-890). ALSO INCLUDED IS BASIC BACKGROUND INFORMATION FOR SPECIFIC DEFICIENCIES, DEFICIENCY EXAMPLES AND SCORING GUIDELINES.

THE BACKGROUND INFORMATION AND SCORING GUIDELINES ARE PROVIDED TO GUIDE YOU IN MAKING ACCURATE DECISIONS. THEY ARE NOT INTENDED TO BE COPIED VERBATIM, NOR TO LIMIT YOUR FREEDOM IN EVALUATING VARIOUS DEFICIENCIES. AS ALWAYS, CONTACT YOUR SUPERVISING INSPECTOR FOR ASSISTANCE, IF NEEDED.

CRITICAL DEFICIENCY CATEGORIES, ITEMS 1 THROUGH 8
INFORMATION NOTES AND EXAMPLES

1. Food Received From Unapproved Sources

1-A. *Unpasteurized milk/milk products used

Information Note

Seize and retain any unpasteurized milk or milk products (unless it is a cheese product aged for 60 days and so labeled, or if the firm has a Raw Milk Retail Permit). Call and advise the Division of Milk Control immediately.

Deficiency Examples

Critical/General

1. Establishment has milk or milk products from unapproved sources.

X

1-B. *Water or ice is not potable

Information Note

Potable water is required in all food handling establishments whether or not they handle exposed foods. Food establishments categorized as “non-community public water supplies” by NYS Department of Health, or as a retail food store under the Retail Food Store Sanitation Regulations, must have a quarterly certificate of water potabilities and an annual certificate of nitrate analysis on file on the premises. Food establishments with private water

**SECTION 8054-B
CRITICAL DEFICIENCIES
SUB-SECTION 2010**

supplies not categorized as “non-community public water supplies” or retail food stores must have an annual certificate of water potability on file on the premises. All establishments are required to have a one-time certificate of analysis for nitrites. Classification of these water supplies is on file at regional FSI offices. Close communication with state and county Departments of Health is required for updating status of categories and categorizing new businesses. Additionally, seasonal operations such as cider mills and Passover bakeries shall obtain a certificate of potability prior to resuming seasonal operation.

See Sub-Section 5080, Water Emergency Procedures.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Water potability certificate unavailable or misplaced. (See Item 9-H)	X
2. Water is not potable(and firm is not following emergency water procedures).	X
3. Chlorine residual test records for a private water supply are not current. (See Item 9-H)	X
4. Sanitary survey conducted by NYS/County Dept. of Health reveals system is inadequate/unacceptable.	X
5. Test kit indicated no chlorine residual in water system requiring chlorination.	X
6. UV light not operating for system requiring Sterilization/disinfection.	X
7. Chlorine test kit not available. FSI field test kit indicates acceptable residual is present. (See Item 9-G).	X

Information Note

Chlorine tests should be taken at time of inspection. If the test is found to be negative, then it shall be treated as a non-potable supply.

1-C. *Foods or ingredients from unapproved source

Information Note

All foods or ingredients sold or used by establishments under FSI jurisdiction must come from establishments or sources inspected or regulated by New York State Department of

**SECTION 8054-B
CRITICAL DEFICIENCIES
SUB-SECTION 2010**

Agriculture and Markets, U. S. Food and Drug Administration, U. S. Department of Agriculture or other recognized regulatory authority.

Deficiency Examples

Critical/General

1. Non-potentially hazardous foods (cookies, bread, rolls, etc.) offered for sale are from an unapproved source.
(See Specialized Inspection List, Sub-Section 2020).

X

Information Note

If management refuses to remove this product from sale, it should be placed under food seizure and scored as a critical deficiency.

Critical/General

2. Potentially hazardous foods (cooked roast beef, cream-filled pastries, etc.), low acid canned foods, potentially low-acid foods, fermented foods, or other particularly hazardous foods, offered for sale from an approved source.

X

Information Note

These products shall always be placed under seizure.

1-D. *Meat, poultry or game products are not from officially inspected plants

Information Note

Meats and poultry sold within New York State shall come from plants supervised by the Meat and Poultry Inspection Service of the United States Department of Agriculture (USDA) or are licensed under the New York State Department of Agriculture and Markets Poultry and Small Animal Slaughterhouse Program (Article 5-A) or the New York State Department of Environmental Conservation.

Any of the above foods coming from a non-inspected or non-approved source may be a vehicle for pathogenic organisms or may result in economic fraud. If you encounter meats, poultry or game products that you suspect are from a non-inspected or non-approved source, the products shall be placed under food seizure. Consult with your Supervising Inspector for further guidance.

Deficiency Examples

Critical/General

**SECTION 8054-B
CRITICAL DEFICIENCIES
SUB-SECTION 2010**

1. Meat, poultry and game products not from an approved source.	X
-

1-E. *Shellfish from unapproved source

Information Note

Shellfish distribution has become increasingly regulated because of the number of food poisoning cases related to the consumption of raw or improperly cooked contaminated shellfish. To help control these outbreaks, the Division of Food Safety and Inspection cooperates with the Department of Environmental Conservation in a joint enforcement program.

During each (re)inspection examine the fresh or frozen shucked and unshucked shellfish in the establishment.

Place the shucked or unshucked shellfish under seizure if critical deficiencies are found. Promptly notify the nearest NYS DEC Office. Complete an ROI which includes the establishment information, type of shellfish, any pertinent tag information, an explanation of the violation, and the name and phone number of the person at DEC who was given the information.

The following guidelines include fresh or frozen shucked shellfish (oysters, clams or mussels) and unshucked shellfish (oysters, clams or mussels), as appropriate.

*(See **Sub-Section 2015, General Deficiencies, Item 16**).*

Deficiency Examples

Critical/General

1. Shellfish from unapproved sources offered for sale	X
2. Untagged lots of shellfish offered for sale	X
3. Tags and records of current shellfish purchases and sales are not available for review	X
-

1-F. *Liquid eggs, frozen eggs, or dried milk products are not from U.S.D.A. inspected plants

Information Note

The cited items will readily support the growth of pathogenic organisms, notably, salmonella. These ingredients, used by bakeries and other food manufacturing operations, must be processed under the supervision of the United States Department of Agriculture.

**SECTION 8054-B
CRITICAL DEFICIENCIES
SUB-SECTION 2010**

The product must have a U.S.D.A. Shield, with a plant number on the container. Original containers holding these products without the U.S.D.A. Shield shall be seized. Notify the nearest U.S.D.A. Office. Document the action on the Sanitary Inspection Report.

Deficiency Examples

Critical/General

1. Liquid, dried or frozen eggs or dried milk products not from an approved source. **X**

Information Note

Small amounts of product in unmarked containers is not a deficiency.

2. Food Products or Ingredients Adulterated or Unfit

2-A. *Rodent defiled foods or ingredients

(See Sub-Section 5055, Insects and Rodents, for useful information).

Deficiency Examples

Critical/General

1. A mouse was seen running from a hole in a five pound bag of flour on a display shelf. **X**
2. Rat droppings were seen on and around exposed loaves of bread on the pre-bagging storage shelf. **X**
3. Rodent droppings, gnaw marks and/or urine stains noted on food packages. **X**
4. Rodent defiled pet foods. **X**

Information Note

Seizure action is warranted in these examples. Write this deficiency along with deficiency 4F if evidence of rodents is observed in establishment.

2-B. *Insect infested foods or ingredients

(See Sub-Section 5055, Insects and Rodents, for useful information).

Information Note

SECTION 8054-B
CRITICAL DEFICIENCIES
SUB-SECTION 2010

The examples listed below would include all types of insects in food or ingredients, i.e., flour weevils, Egyptian meal moths, cockroaches, flies or fly larvae, wasps, bees, grasshoppers, etc. Write the deficiency to fully describe the specific infestation. Seizure action is warranted in these cases.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Insect (describe as alive/dead) infested foods or ingredients	X
2. Pet foods found to contain live/dead insects and/or webbing	X
3. Live/dead flour beetles in bulk flour	X

2-C. *Food products contain unidentified sulfiting agents or other unapproved additives

Information Note

Sensitive consumers, primarily asthmatics, react to the ingestion of sulfites by suffering shock, respiratory distress, coma and sometimes death.

Sulfites are legitimately used, at the producer-packer level, as stabilizers and color fixatives in cooked or processed fruits and vegetables. It is also used as a bactericide to inhibit spoilage organisms in seafood and as a dough conditioner. Sulfites also have other acceptable uses in food products or ingredients, such as wines or vinegar.

Sulfites are illegally used to enhance the appearance of meat, meat products and fresh fruits and vegetables by slowing the interaction between oxygen and the hemoglobin in meats and meat products and the chlorophyll in fruits and produce. This interaction may conceal putrefaction.

Sulfiting agent means potassium bisulfite, potassium metabisulfite, sodium bisulfite, sodium metabisulfite and sulfur dioxide. These are normally found in the form of a white or pinkish granular powder.

It is legal to sell, offer to sell or serve at retail dried fruits treated with sulfur dioxide provided they are properly labeled.

All references to fruit or produce offered for sale at retail shall include produce displays and salad bars.

**Raw grapes containing less than 10 ppm of sodium sulfite applied by the producer-packer may be offered for sale in New York State retail stores.*

**SECTION 8054-B
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Deficiency Examples

Critical/General

1. It is suspected the establishment is using sulfites in fresh meats:
 - A. If field test positive, seize and sample. X
 - B. If negative, consider sampling. **No deficiency.**
2. It is suspected sulfites are being applied to produce by the wholesaler or retailer to be sold at retail: Sample produce. **No deficiency.**
3. The Inspector determines sulfites are being applied to produce, by the wholesaler or retailer. X
4. It is suspected produce being sold at retail has been treated with sulfites by the producer/packer but, the master container does not so state: Sample product. **No deficiency.**
5. The Inspector determines produce being sold at retail has been treated with sulfites by the producer/packer although the master container does not so state: Seize and sample X
6. Foods, other than raw fruits and vegetables, treated with sulfites by a producer/packer are offered for sale at retail without conspicuous, easily readable signs, placards or menu statements at the display location. X
Information Note
Score this deficiency Critical if not corrected before the inspection ends.)
7. A suspected sulfiting agent has been found in a retail store. Sample the suspected sulfiting agent. **No deficiency.**
8. The Inspector determines a sulfiting agent has been found in a store. X
Seize and sample.

Information Note

The foregoing does not include added ingredients, at the retail level containing incidental levels of sulfites, i.e., glazed ham. The inadvertent addition of sulfites under these circumstances would not constitute a violative condition provided any finished product which contains more than 10 ppm of sulfites was properly labeled. Sulfites are most often used to illegally enhance fresh meats and produce. Other chemicals and agents are also used; e.g.,

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- A. *Blood, with citric acid added as an anti-coagulant, enhances the color of ground meat and will color fat. The colors will range from bright red to purplish red.*
- B. *Red coal tar dye: Imparts a long lasting, bright red color to meats.*
- C. *Niacin (Nicotinic Acid): Prolongs color retention in meats.*
- D. *Ascorbic Acid (Vitamin C): Retards color loss in fresh meat.*

Deficiency Examples

Critical/General

1. It is suspected the establishment is adding blood, niacin or ascorbic acid to fresh meats. Submit samples of the product and suspected additives. No deficiency.	
2. The Inspector determines blood, niacin, ascorbic acid, dye, etc., is being added to fresh meats. Seize and sample product and suspected additives.	X
3. FD & C Yellow No. 5, a color additive, is not specifically identified as an ingredient on the label of bulk foods being offered for sale.	X

Information Note

Score deficiency Example #3 Critical if not corrected before the end of the inspection.

2-D. *Other adulterated/unfit foods or ingredients

Any critical deficiency relating to adulterated and/or unfit foods or ingredients that cannot be specifically and appropriately categorized in items numbered 3 through 8 shall be described and scored under this item.

Deficiency Examples

Critical/General

1. Food products contain undeclared allergens. Products not immediately removed from circulation, relabeled or other corrective action <u>not</u> taken during the inspection.	X
2. Food products defiled/contaminated by birds.	X
3. Multiple canned foods on retail shelves exhibit extensive seam dents, swells or leaks.	X
4. Food packages exhibit smoke, water or container seal integrity damage.	X
-

**SECTION 8054-B
CRITICAL DEFICIENCIES
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3. Food Not Protected From Contamination By Workers

Information Note

Most foodborne illnesses are caused by ill or contaminated food handlers inoculating food or food contact surfaces with pathogenic bacteria such as Staphylococcal aureus or viruses like Hepatitis A and others.

These pathogens predominantly involve fecal/oral transmission by food handlers who are asymptomatic carriers or who are in the early stages of an illness prior to symptoms becoming evident.

Because of this, Inspectors must carefully observe whether direct hand contact of foods, which do not subsequently receive heat treatment during processing or prior to consumption, is minimized.

An establishment may minimize cross contamination by removing personnel from food handling duties who have:

- A. Been exposed to a communicable disease*
- B. Show symptoms of an illness or respiratory distress*
- C. Have infected cuts or burns on their hands*

The establishment management should ensure all food handling employees wash their hands thoroughly after contaminating them and regularly during the workday.

They should also provide a handwashing facility with potable water at proper temperatures, soap and acceptable hand drying devices.

Other methods to minimize contact of food is through the proper use of utensils, deli paper, napkins or disposable gloves. Caution should be taken that these items do not become sources of cross contamination.

In some cases the use of disposable plastic gloves may create a hazard for the wearer. For example, deep fat fryers, stoves, etc., can cause the gloves to melt, injuring the worker. In these cases alternative methods to avoid cross contamination should be utilized.

During every inspection, look very closely at food handling practices in each establishment and be assured every effort is being made to comply with these foregoing precautions.

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3-A. *Food handlers handle foods when ill with a disease transmissible by foods

Deficiency Examples

Critical/General

1. A food handling employee has a communicable disease or is a carrier of a disease that can be transmitted by food, or has an acute respiratory disease. **X**

Information Note

Establishment management should immediately remove this person from food contact activities until the violative condition no longer exists.

Consider seizure of food or ingredients possibly contaminated by an ill food handler.

3-B. *Food handlers have infected cuts or burns on their hands

Information Note

Boils, cuts and burns on the hands of food handlers are a prime source of food contamination.

Deficiency Examples

Critical/General

1. Food handling employee has an unprotected/improperly protected boil, cut, sore on hand(s). **X**

Information Note

Establishment management should immediately remove such a person from food contact activities until the violative condition has been resolved.

Consider seizure of foods or ingredients possibly contaminated by a food handler with open sores, wounds or burns.

3-C. *Food handlers do not wash hands thoroughly after contaminating them

Information Note

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Washing hands thoroughly and completely, with soap or detergent and warm water (105°F) is one of the best and easiest ways to reduce the bacteria load on one's hands to prevent contamination.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Food workers not washing hands and exposed part of arms before starting work.	X
2. Food workers not washing hands after smoking, eating, drinking, using the toilet, touching their hair, nose or mouth.	X
3. Food workers not washing hands before and after handling equipment, raw meat, poultry or seafood or between raw and ready-to-eat foods or as necessary during the workday.	X

3-D. *Employee handwashing facilities inadequate for establishments handling exposed foods

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Handwash sinks are not available for food handlers.	X
2. Handwash sink is inaccessible. <u>Not</u> corrected during inspection.	X
3. There is no hot water available in the establishment.	X

3-E. *Employees handling exposed, ready-to-eat foods without an acceptable protective barrier

Information Note

An "acceptable protective barrier" may include plastic or rubber gloves, plastic or metal tongs, spoons, forks, patty paper or any other material or properly designed device that is clean and sanitary and is disposable or is in good repair and easily cleanable that provides an effective sanitary interface between the employee's hand(s) and the exposed ready-to-eat food.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Food handling employee(s) was/were observed handling exposed ready-to-eat foods without using an adequate protective barrier system.	X

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Information Note

The misuse of protective barriers should be weighed regarding the impact of the event/violation in relation to the overall operations of the establishment. Examples to consider:

- 1. A food worker in the bakery of a multi-department retail food store is noted to handle a roll with bare hands. Thirty food workers in various departments are noted properly handling exposed foods during the inspection. This violation can be viewed as isolated, described as “incidental bare hand contact...” and entered under general deficiency Item 11-A.*
- 2. A food worker in a small establishment with few food workers is noted handling ingredients and making a sandwich with bare hands and the establishment has no control system in place. This violation represents extensive bare hand manipulation of the food (not incidental) and a higher impact on overall store operations. This deficiency would be scored under critical Item 3-E.*

Less obvious situations require additional considerations, such as: properly equipped handwash facilities, actual use of hand wash facilities, extent of bare hand manipulation of food, availability of gloves and/or utensils and overall hygienic practices of food workers.

4. Food Not Protected From Contamination By Other Sources

4-A. *Food contact equipment, utensils or conveyances for potentially hazardous foods: contact surfaces unclean or not properly sanitized and likely to contribute to contamination

Information Note

Unclean equipment is a major source of contamination of potentially hazardous foods and is likely to contribute to contamination if:

- 1. There are food and soil particles large enough to be seen without magnification adhering to food contact surfaces.*
- 2. The food contact surfaces are not sanitized.*

Food and soil particles may be effectively removed by applying a combination of a warm detergent solution and vigorous scrubbing with an appropriate tool. This will also remove up to 90% of surface bacteria.

A sanitizer is required to eradicate remaining bacteria. However, sanitizing agents will not be effective unless food and soil particles and especially, grease and oils are removed from the contact surfaces.

To ensure sanitization is properly done the Inspector should determine, by observation, that:

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1. *Food contact surfaces are properly cleaned.*
2. *An approved sanitizer is being used.*
3. *The correct amount of sanitizing solution at proper temperatures is used.*
4. *The method of application is appropriate.*

Deficiency Examples

Critical/General

1. More than one day's accumulation or an excessive amount of food waste and soil noted on potentially hazardous food contact surfaces.	X
2. The sanitizer solution for the wipe cloth seen being used on a potentially hazardous food prep board is unclean and testing shows no chlorine residual.	X
3. An accumulation of dark, dried, hardened food residues are noted on food contact surfaces of equipment used for the preparation of potentially hazardous foods.	X
4. The top surface of the white plastic sandwich prep board has a dark, gummy, scrapable buildup of food residues.	X
5. The meat bandsaw has a buildup of dark dried meat shavings on blade and blade clean-off areas.	X
6. Knives used for potentially hazardous foods have accumulation of dried food residues and are stored between table and soiled wall in food prep area.	X

Information Note

A statement from establishment personnel concerning cleaning or sanitization practices is not sufficient to document the foregoing deficiencies.

4-B. *Food contact equipment, utensils, or conveyances are not cleaned or sanitized between use on different species or between raw and ready-to-eat foods

Information Note

Many food poisoning cases originate in the meat, deli or fish departments of a store or in a food processing facility. This is often due to inadequate cleaning and sanitizing of food contact equipment, utensils or conveyances on which different species or raw or ready-to-eat foods are processed, held or transported.

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The terms “different species” means the raw flesh of pork, chicken, beef, fish and other raw meat and seafood. A “raw” food is one requiring further cooking or processing before consumption. A “ready-to-eat” food is one that can be consumed without further cooking or processing.

Because of the high probability of cross contamination between different species and/or raw and ready-to-eat foods it is especially important that contact equipment, utensils and conveyances be properly cleaned and sanitized when required. The Inspector should determine by observation and investigation that:

- A. An approved sanitizer for the task is being used.*
- B. The correct amount of sanitizer, with proper water temperatures, are used.*
- C. The method of application is appropriate.*
- D. Cleaning and sanitizing are done at required times and intervals.*

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Raw chicken is noted being cut on meat table, then beef is noted being cut on same table without proper cleaning and sanitizing of table between species.	X
2. A fully cooked ham is noted being split on meat band saw previously used to cut raw pork ribs. Saw not cleaned and sanitized as required.	X
3. Meat lugs are noted improperly cleaned and sanitized between alternate use for raw chicken, pork and beef.	X

Information Note

Clean-in-place (C.I.P.) procedures must follow those outlined in the Rules and Regulations Relating to Retail Food Stores, Section 271-5.4. Also, see the Information Note, relating to the manual cleaning and sanitizing of equipment, Section 271-5.3, in Item 4-H.

4-C. *Ready-to-eat foods are subjected to cross contamination from raw foods, or cross contamination between species is likely to occur

Information Note

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Most ready-to-eat potentially hazardous foods are easily contaminated by contact with raw foods or other species. Examples of these potential situations are: Raw shrimp displayed on a bed of ice above a quantity of cooked read-to-eat shrimp or, raw chickens stored next to and in contact with raw ground beef in storage or on display.

The possibilities for these types of violative situations in food processing and manufacturing establishments are endless. The Inspector must be continually alert to recognize these conditions.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Potentially hazardous foods are stored, displayed or handled whereby cross contamination with raw foods is likely to occur.	X
2. Foods of one specie are stored, displayed or handled whereby cross contamination of a different specie is likely to occur.	X
3. Uncovered ground beef is displayed in contact with uncovered raw chicken in meat service cooler.	X

4-D. *Toxic chemicals are improperly labeled, stored or used so that contamination of food is likely to occur

Information Note

The poisonous and toxic material section noted in Circular 926, Rules and Regulations Relating to Retail Food Stores, Section 271-7.19 through 271-7.24 covers the major aspects of toxic chemical and toxic material hazards found in retail stores. It also has application in the food processing, manufacturing, storage and sales establishments under this Division's jurisdiction.

Most toxic chemicals and materials will be handled in a manner consistent with proper practices. However, you will observe instances where a potential problem exists. Please note, the key phrase in this deficiency is "likely to occur." You should familiarize yourself with the cited regulation sections, weigh the conditions noted against the key phrase and if, in your opinion, contamination is "likely to occur," score the deficiency as critical.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Toxic chemicals and/or toxic materials are improperly labeled, stored or used. Direct or indirect contamination of foods is <u>likely to occur</u> .	X
<u>Critical/General</u>	
2. Tracking powder is noted on floor perimeters of the food preparation area.	X

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4-E. *Food contact equipment condition, design or location is likely to contribute to contamination

Information Note

Food contact equipment must be in good condition, i.e., free of breaks, open seams, cracks, chips, pits and similar imperfections. Food contact equipment must be installed, set up or operated in a location wherein it will be free from possible contamination by the physical surroundings or traffic.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Whole chickens were observed being sectioned on a meat cutting block with a rough, worn, undulating surface with gaping side seams.	X
2. Five whole chickens were observed laying, unprotected, on the shelves of a walk-in cooler storage rack. The rack was assembled with pressure-treated wooden 2 x 4's.	X
3. Food contact equipment design is likely to contribute to product contamination.	X
4. Food contact equipment location is likely to contribute to product contamination.	X
5. The inside walls and ceiling of the ice machine have a heavy accumulation of rust and mold.	X
6. The interior of bakery mixing bowls have metal burrs and areas of rough welded repairs.	X
7. Exposed foods are stored directly on non-food grade cardboard used to line shelves in walk-in cooler.	X
8. Water is dripping from condensation pans on top inside of deli cooler onto deli meats and shelves below.	X
9. Foods are likely to contain undeclared allergens due to cross-contact caused by equipment condition, design or location. <u>Not</u> corrected during inspection.	X

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Information Note

New York State has received allergen threshold data from academia for peanut (10 ppm) and eggs (150 ppm). These are the exposure levels at which allergic individuals are believed to have a reaction. Until further data on other allergenic materials becomes available, we should concentrate our inspection efforts on clear, visible cross contact issues concerning peanut and eggs. These should be dealt with in a similar fashion that we address sulfiting agents. If the cross contact is corrected during the inspection, it will be scored as a general deficiency. If it is not corrected, it will be scored as a critical deficiency.

4-F. *Insect, rodent, bird or vermin activity likely to result in product contamination

Information Note

The examples listed below do not mention, but shall include, insects such as grain beetles, weevils, moths and other insects known to infest foods. Not to be included are incidental insects not normally associated with food product contamination such as bees, wasps, etc., unless they are found within the food or ingredient. Vermin would include, but is not limited to, dogs, cats, turtles, etc., or other “pets” whose presence is likely to result in product contamination.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Evidence of an active rodent infestation (fresh droppings, rub marks, entryways, etc.) with evidence of inadequate pest control efforts.	X
2. Evidence of an active cockroach infestation (live roaches, viable egg sacs, fresh excreta) in exposed food area.	X
3. Fly activity noted on exposed food contact surfaces (the observed fly activity and the described establishment fly control measures are the prime evaluators for this deficiency, not the number of flies present).	X
4. Evidence of an active cockroach infestation in non-exposed food areas of the establishment with evidence of inadequate pest control efforts.	X
5. Live bird(s) noted in the establishment and packages of food/food equipment defiled/contaminated by birds.	X

Information Note

“Inadequate” pest control may include:

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1. *Lack of trapping devices, bait, or pesticides*
2. *Existence of insect and rodent attractants, i.e., harborages, poor sanitation*
3. *Open doors or other entryways*

4-G. *Evidence of leakage or backup in sewage lines

Information Note

Sewage and liquid wastes will be disposed of by means of a public sewer system or a private system constructed and operated in compliance with all applicable laws and regulations.

Non-water carried sewage disposal systems shall not be used unless prior permission is granted by this agency.

Deficiency Examples

Critical/General

1. Evidence of sewage line drainage noted on the ground outside of the establishment.	X
2. Evidence of sewage on floors or leaking from cracks, joints or breaks in interior lines.	X
3. Evidence of cross connections between sewage lines and potable water systems.	X

4-H. *Equipment cleaning or sanitizing facilities inadequate for establishments handling potentially hazardous foods

Information Note

Section 271-5.3, Clean-in-Place procedures of the Rules and Regulations Relating to Retail Food Stores requires that facilities and/or equipment are available to provide proper cleaning and sanitizing of all food contact surfaces. This requirement may be satisfied by a system for manually cleaning and sanitizing in-place equipment which is too large to be properly cleaned and sanitized by immersion in a two or three-bay sink.

This system, which involves rinsing, spraying, or swabbing with a chemical sanitizing solution can be used for large or non-moveable equipment. Food establishments, which utilize limited amounts of equipment, such as one meat slicer in a small delicatessen

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operation, may utilize this system in lieu of installing a two or three-bay equipment wash sink. In such cases, it is important that operators are aware of the proper sanitizing strengths required.

This alternate procedure is not an acceptable option for retail food establishments that merely prefer to avoid the expense of sink installation. In order to support and confirm field Inspector approval of the alternate cleaning and sanitizing procedures described above, we will require that these decisions be reviewed and approved by supervisory personnel. It is not necessary for supervisory personnel to visit the affected establishments, but Supervisory Inspectors and Inspectors must concur with all such allowances made in their respective areas. This may be done by attaching a Report of Investigation to an inspection report detailing the circumstances and indicating the Supervisor agrees with the Inspector's decision.

All establishments, other than retail food stores are not explicitly required by Law to have two or three-bay equipment washing facilities. However, the installation of adequate equipment wash facilities may be necessary to achieve an adequate level of equipment sanitation.

The regulations for food salvage establishments, bakeries, food processing plants, etc. should be reviewed prior to inspecting these establishments.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Establishment handling potentially hazardous foods lacks adequate cleaning and sanitizing facilities.	X
2. There is no hot water available in the establishment (not corrected by end of inspection).	X
3. The ware-wash sink is cross-utilized as a mop sink (as witnessed or observed by evidence).	X
4. The faucet for the 3-basin sink does not extend to reach the outer basins.	X
5. The final rinse for the single tank, stationary rack, dual temperature pan washer in the prep kitchen reaches only 150°F. No sanitizer in use.	X
6. The automatic pan washer in the bakery lacks a rinse water pressure gauge. (See Item 9-B)	X
7. Establishment handling non-potentially hazardous foods lacks adequate cleaning and sanitizing facilities (See Items 9-B, D, F, G, H).	X

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8. Sanitizing solution strength was found to be superpotent.	X
9. Sanitizing test devices are not available or used (See Item 9-G).	X
10. Wiping cloths are not stored in a sanitizing solution (See Item 9-F).	X

Information Note

When such unclean or soiled cloths are observed being used on food contact equipment, this shall be scored as a critical deficiency.

5. Critical Processing or Salvaging Parameters Are Not Met

5-A. *Pork products, which may be eaten without further cooking, are not treated to kill trichina

Information Note

Trichinella spiralis is a microscopic, parasitic, worm-like creature which lodges and lives in the striated musculature of an animal. Infections occur by consuming contaminated raw or improperly cooked or cured meats. Pork is the most common infectious source for humans although the parasite may be found in almost all warm-blooded animals.

The organism may cause diarrhea, fever, nausea, vomiting, anorexia, emaciation, malaise, laryngitis, hard, swollen and painful muscles and in some cases, death.

Trichina organisms may be destroyed by proper heating, freezing or curing. However, all forms of fresh pork, including fresh unsmoked pork sausage or pork bacon or pork jowls are customarily well cooked in the home and, therefore, treatment to kill trichina before sale is not required.

Conversely, all establishments selling any pork or pork product which may be eaten without further cooking must properly heat, freeze, cure or otherwise process the pork or pork product using approved procedures as outlined in 1NYCRR, Sections 271 and 318 before the product is offered for sale. Also, see Sub-Section 4095, Trichinae Control for Ready-To-Eat Pork Products.

Deficiency Examples

Critical/General

1. Pork or pork products are not treated to kill trichina.	X
-

5-B. *(Refer to Specialized Inspection Guidelines)

Information Note

This item covers critical deficiencies of specialized establishments and operations such as:

Item #17 Manufacturers of thermally processed low-acid foods, packaged in hermetically sealed containers.

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Item #18 Acidified foods (and tomato products and other potentially low acid products)

Item #19 Water activity reduced foods

Item #20 Salvage dealers

Item #21 Licensable food operations

Item #22 Vacuum or modified atmosphere packaging at retail

Item #23 Cured and/or smoked fish processors

Item #24 Specialized food processing requiring a HACCP plan

Item #25 Slaughterhouse

To promote clarity and avoid confusion when reporting and writing deficiencies related to “Specialized Inspection” critical deficiencies both the “Sanitary Inspection Guidelines” item number and “Specialized Inspection” item number must be entered on the FSI-898, Supplemental Sanitary Inspection Report, in the following manner:

<i>The 5-B “Sanitary Inspection Guidelines” Item Number is entered on the left side of the column</i>	<i>Item No. From General & Specialized Reports</i> <i>5-B - 17-A</i> <i>5-B - 17-K</i> <i>5-B - 18-C</i> <i>5-B - 21-A</i> <i>5-B - 22-B</i>	<i>The “Specialized Inspection” Critical Deficiency (Red) Item Number is entered on the right side of the column</i>

See Sub-Section 2020, “Specialized Inspection Guidelines.”

6. Potentially Hazardous Foods Improperly Cooled or Refrigerated

6-A. *Potentially hazardous foods are not cooled by an approved method wherein the product temperature can be reduced to 70°F or less within two hours and 41°F (45°F) or less within six hours

Information Note

Improper cooling of potentially hazardous foods is one of the major causes of food poisoning situations in retail stores.

Some acceptable methods of rapid cooling are by the use of shallow pans, agitation, quick chilling or water circulation external to the food container.

Deficiency Examples

Critical/General

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1. Potentially hazardous foods are not being cooled by an approved method.	X
2. The temperature of a potentially hazardous food was not reduced from 135°F or above to 70°F or less within 2 hours, and 41°F (45°F) or less within 6 hours.	X
3. In-store made potato salad is not made from pre-chilled ingredients and has internal temperature of 80°F after four hours in cooling phase.	X

Deficiency Examples

Critical/General

4. In-store made soup is allowed to cool in covered 8" deep crock in walk-in cooler and has internal temperature of 100°F after three hours in cooling phase.	X

Information Note

These deficiencies must be corrected immediately by the implementation of an approved method and rapidly bringing the temperature to an acceptable level. Failure to do so will result in product seizure and destruction.

6-B. *Potentially hazardous foods are not stored at safe temperatures

Information Note

All potentially hazardous food must be maintained at temperatures below 41°F(45°F) or at 135°F or above, except during a combined preparation or holding for service time, not to exceed 4 hours measured from the time the internal temperature reaches and goes below 135°F or reaches and goes above 41°F(45°F).

Potentially hazardous food held at unsafe temperatures for more than four hours must be discarded.

Smoked Fish guidelines: See 1NYCRR, Part 262.4 (c) (1) & (2) and Sub-Section 6010.

Important: Potentially hazardous food held under inadequate refrigeration constitutes gross temperature abuse and is an imminent health hazard.

Any potentially hazardous food held under inadequate refrigeration and found to be 70°F or over, and without supporting documentation, shall be placed under seizure and destroyed under signed waiver even if no signs of spoilage are evident via organoleptic examination.

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Any potentially hazardous food held at temperatures between 46°F and 69°F may be returned to refrigeration in lieu of seizure action if there is good evidence the food has been in the unsafe temperature range for less than 4 hours.

This policy pertains only to potentially hazardous food which would ordinarily be displayed at proper refrigeration temperatures. It does not include those in a cooling stage following processing.

Deficiency Examples

Critical/General

1. Potentially hazardous foods held at unsafe temperatures for more than four hours.	X
2. Potentially hazardous foods held at temperatures of 70° F or over and not in a cooling stage or displayed for < four hours with supporting records.	X
3. Cut and wrapped melon wedges are displayed without refrigeration with internal temperature of 65°F. Product prepared and packed > four hours prior.	X
4. Egg and cheese breakfast sandwiches are displayed without refrigeration or hot holding unit and have an internal temperature of 75°F. No records are maintained to show product is displayed < four hours.	X

Information Note

Potentially Hazardous Foods at Abused Food Temperature Guidelines:

Cold food at temperatures greater than 10°F above required temperatures - CRITICAL

Hot food at temperatures greater than 15°F below required temperatures - CRITICAL

All others will be scored as -

GENERAL

When time is used as a public health control for potentially hazardous foods, records shall be maintained to indicate the time that is 4 hours past the point in time when the food is removed from temperature control. If the food is past the four hour period and records are not available or are incomplete the product shall be seized and destroyed under signed waiver. Discuss evidence of possible fraudulent record keeping with your Supervising Inspector.

7. Potentially Hazardous Foods Not Adequately Cooked or Reheated

- 7-A. *Poultry, poultry stuffing's, stuffed meats, or stuffing's containing meat are not heated to 165°F or above**

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Information Note

Because of the nature of their ingredients, these products are very supportive of the rapid growth of pathogenic bacteria. Strict adherence by the establishment to the cooking and heating requirements is necessary.

Deficiency Examples

Critical/General

1. Poultry and/or poultry stuffing are not cooked to an internal temperature of 165°F or above with no interruption of the cooking process.	X
2. Stuffed meats or stuffing containing meat are not cooked to an internal temperature of 165°F, or above, with no interruption of the cooking process.	X
3. In-store prepared meatloaf is not cooked to an internal temperature of 165°F, or above, with no interruption of the cooking process.	X
4. Stuffed peppers containing beef are not cooked to an internal temperature of 165°F, or above, with no interruption of the cooking process.	X

Information Note

These deficiencies must be corrected immediately by recooking to the proper temperatures, or the product should be placed under seizure.

7-B. *Pork or any food containing pork is not heated to 145°F for 15 seconds.

Information Note

This deficiency refers to the cooking of fresh pork and pork products for the purpose of killing trichina (trichinella spiralis) in a retail store (see Item No. 5-A).

All fresh pork and any food containing fresh pork cooked within the store must be cooked to an internal temperature of 145°F for 15 seconds..

Deficiency Examples

Critical/General

1. Pork and food containing pork is not heated to an internal temperature of 145°F or greater for 15 seconds.	X

Information Note

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This deficiency must be corrected immediately by recooking to the proper temperature or the product should be seized and destroyed under signed waiver.

7-C. *Other potentially hazardous foods requiring cooking are not heated to required temperature

Deficiency Examples

Critical/General

1. All potentially hazardous foods (except those noted in 7-A, 7-B or rare roast beef) are not cooked to an internal temperature of 145° F or greater for 15 seconds.

X

Information Note

This deficiency must be corrected immediately by recooking to 165°F or the product should be placed under seizure.

7-D. *Potentially hazardous foods that have been cooked and then refrigerated are not rapidly reheated to 165°F or above

Information Note

It is acceptable to cook potentially hazardous foods to various temperatures ranging from 130°F for roast beef (plus time requirements) to 145°F for most foods. However, all potentially hazardous foods that have been cooked, then refrigerated, must always be rapidly reheated to an internal temperature of 165°F or above. This period is not to exceed 2 hours. The foods may then be brought down to no less than 135°F for storage or display (See Item No. 8A).

Deficiency Examples

Critical/General

1. Cooked, then refrigerated, potentially hazardous foods not rapidly reheated to 165°F or above.

X

Information Note

This deficiency must be corrected immediately by reheating to 165°F or the product should be seized.

7-E. *Equipment used for heating or reheating potentially hazardous foods is inadequate

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Information Note

The equipment used for heating, cooking or re-heating potentially hazardous foods must be designed and maintained to rapidly reach and/or hold the required temperature for the time needed to heat or reheat the food to the proper temperature.

Deficiency Examples

Critical/General

1. The equipment used for heating/reheating potentially hazardous foods does not raise the food to the required temperatures as evidenced by(<u>explain</u>)	X
2. Food warmers or other hot holding units that cannot rapidly raise the internal temperature of potentially hazardous foods are used.	X
-

8. Improper Hot-holding Procedures for Potentially Hazardous Foods

8-A. *Potentially hazardous foods are being kept below 135°F during hot-holding (rare roast beef may be served at 130°F or above)

Information Note

Potentially hazardous foods, if not stored refrigerated at 41°F (45°F) or below, must be stored, displayed or held at 135°F or above (except for rare roast beef). Rare roast beef may be held at temperatures of 130°F and above only on the first day of service. On subsequent days the holding temperature range must be 41°F (45°F) or below or 135°F and above after being rapidly reheated to 165°F. The establishment must have enough hot holding devices, of adequate capacity, to maintain all potentially hazardous foods at the required temperatures.

Deficiency Examples

Critical/General

1. The internal temperature of hot, potentially hazardous foods are not being held at 135°F or above.	X
-

8-B. *Hot-holding equipment improperly designed, maintained or operated to keep hot foods above 135°F

Information Note

This deficiency covers a broad area of requirements relating to equipment design, materials used, the quality of construction and installation.

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Other important factors are equipment maintenance, the accuracy of the temperature controls on the equipment and the ability of the staff to operate the equipment.

The adequacy of all these factors should be considered when evaluating hot-holding equipment.

Deficiency Examples

Critical/General

1. Potentially hazardous hot foods not being maintained at an internal temperature of 135°F or, above because of design, maintenance or operational faults.

X

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SANITARY INSPECTIONS
GENERAL DEFICIENCIES
SUB-SECTION 2015**

OVERVIEW

THE FOLLOWING PAGES CONTAIN A LISTING OF EACH GENERAL DEFICIENCY AS PRINTED ON THE BACK OF THE SANITARY INSPECTION REPORT FORM (FSI-894). ALSO INCLUDED IS BASIC BACKGROUND INFORMATION FOR SPECIFIC DEFICIENCIES AND SCORING GUIDELINES.

THE BACKGROUND INFORMATION AND SCORING GUIDELINES ARE PROVIDED TO GUIDE YOU IN MAKING ACCURATE DECISIONS. THEY ARE NOT INTENDED TO BE COPIED VERBATIM NOR TO LIMIT YOUR FREEDOM IN EVALUATING VARIOUS DEFICIENCIES. AS ALWAYS, CONTACT YOUR SUPERVISING INSPECTOR FOR ASSISTANCE, IF NEEDED.

DEFINITION: GENERAL DEFICIENCIES

A GENERAL DEFICIENCY IS A CONDITION WHICH DOES NOT CONFORM TO THE DEPARTMENT'S SANITARY REQUIREMENTS BUT IS NOT SEVERE ENOUGH TO BE AN IMMEDIATE HAZARD TO THE PUBLIC HEALTH OR IMMEDIATELY CONTRIBUTE TO PRODUCT CONTAMINATION OR ADULTERATION.

GENERAL DEFICIENCY CATEGORIES, ITEMS 9 THROUGH 16, INFORMATION NOTES AND EXAMPLES

9. Improper or Inadequate Sanitary Facilities and Controls (See Item 3-D)

9-A. Handwashing facilities improperly installed or maintained

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. The handwash facility lacks a mixing valve or combination faucet.	X
2. The self-closing, slow closing or metered faucet does not provide a flow of water for at least 15 seconds without reactivation.	X
3. Access to handwash sink filled with utensils and/or covered by food prep board. Corrected during inspection.	X

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	<u>Critical/General</u>
4. A handwash sink for food handlers lacks soap and/or hand drying devices and/or waste receptacles.	X
5. Changes to food preparation area/operations now requires an additional handwash sink (additional, fully functional handwash sinks are located in other areas of the establishment).	X
6. The hot water system in the establishment is in disrepair. Corrective action initiated during inspection.	X
7. Hot water is not available at every sink in the establishment.	X

9-B. Suitable water temperature or adequate pressure for food processing; equipment, utensil or container cleaning; or handwashing in establishments that do not handle exposed foods, not available

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. The temperature of the food processing equipment rinse water was less than 75°F.	X
2. The hot and/or cold water pressure at the handwash sink and/or the equipment wash facility was not adequate to foster and/or ensure adequate cleaning.	X
3. Hot water is not provided at hand wash sinks in establishments that do not handle exposed foods.	X
4. The temperature of the food processing equipment sanitizer solution is less than 75°F.	X

9-C. Toilet facilities improperly installed, equipped or maintained

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. The toilet and/or urinal does not function properly and/or is in disrepair.	X
2. Toilet tissue was not provided.	X
3. Waste receptacles are not provided, or are unclean or are not covered (where required).	X

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	<u>Critical/General</u>
4. The toilet room is not adequately enclosed and/or is in disrepair.	X
5. The toilet room is not accessible to employees.	X
6. The toilet and/or the urinal and/or the room is unclean.	X
7. The toilet room and/or facilities are not easily cleanable.	X
8. The toilet room opens into an exposed food area and lacks a double door or a positive air flow system.	X

9-D. Plumbing or sinks not properly sized, installed or maintained: equipment or floors not properly drained (See Items 4-G, 4-H)

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. The equipment wash sink is not in good repair.	X
2. The plumbing system is not sized to adequately provide or remove the volume of water and/or waste generated by the establishment.	X
3. Back flow prevention devices are not adequate or are not where required.	X
4. Grease traps and/or garbage grinders are not adequately installed or maintained.	X
5. Floor drains inadequately installed or maintained.	X
6. Floors not sloped to drain, allowing pooled wastewater.	X
7. Firm processing only non-potentially hazardous foods fails to have a 2 or 3 basin equipment wash sink.	X

9-E. Lighting or ventilation is inadequate

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Adequate lighting is not provided at required areas within the establishment.	X
2. Lamps are not shielded against breakage where required.	X
3. Adequate ventilation is not provided within the establishment where required.	X
4. The ventilation system is not adequate or is in disrepair.	X

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9-F. Cleaning or sanitizing equipment, materials or agents are not available, suitable or properly stored

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Cleaning and/or sanitizing equipment or agents are not present where required.	X
2. Cleaning equipment and/or sanitizing agents are not properly stored.	X
3. Sanitizer solution is not provided for food equipment wipe cloths.	X

Information Note

See Items 4-H and 9-G for related information.

9-G. Sanitizing test devices not in use where required

<u>Deficiency Example</u>	<u>Critical/General</u>
1. Sanitizing test devices are not available or used.	X

9-H. Lack of certification of water potability or record for disinfection (See Item 1-B)

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Water potability certificate unavailable, misplaced or not current.	X
2. Chlorine residual test records for a private water supply are not current.	X
3. A spare bulb is not available for the ultra-violet water disinfection unit.	X

10. Inadequate Sanitary Design, Construction and Maintenance

10-A. Exterior of unsuitable construction or not in good physical repair

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<u>Deficiency Example</u>	<u>Critical/General</u>
1. The exterior walls, ceiling, doors and/or windows are in disrepair or not of a suitable material for the intended purpose.	X

10-B. Establishment has insufficient space to accommodate operations

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Aisles and the working space between equipment and between equipment and walls is congested and obstructed.	X
2. Employees do not have sufficient space to work and/or clean without contaminating foods or food-contact equipment.	X

10-C. Interior floors, walls, ceilings or fixtures are not of suitable construction, clean or well maintained

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. The floors, walls or ceilings are not smooth, non-absorbent or easily cleanable.	X
2. The floors, walls and ceilings are not clean and/or in good repair.	X
3. Wall, ceiling and floor fixtures (to include: service lines, utility lines, pipes, vent covers, fans, decorative materials, light fixtures, etc.) are not properly installed, clean or cleanable or in good repair.	X
4. Floors or floor coverings are not made of an acceptable material.	X
5. Prohibited floor spillage absorbency materials are improperly used or stored.	X

10-D. Refuse containers not clean, covered, in good repair or removed at sufficient intervals

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Refuse containers not in good condition, or covered, or clean, or cleanable or properly stored.	X

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	<u>Critical/General</u>
2. Trash and garbage is not stored or removed or disposed of properly.	X
3. Refuse containers provided are not suitable for the purpose or in adequate numbers.	X
4. Refuse rooms, areas and enclosures are not clean, cleanable, vermin resistant, large enough, in good repair, or free of spillage or odor.	X

11. Poor Hygiene and Activities of Food Handlers

11-A. Not maintaining a high degree of cleanliness or taking precautions to prevent contamination of foods from perspiration, cosmetics, chemicals or medicants, etc.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Food workers are perspiring or using or storing cosmetics, chemicals or medicants in a way that may contaminate foods or food contact surfaces.	X
2. Food worker is noted to handle a roll with bare hands. An effective control system is noted throughout the rest of the establishment.	X

11-B. Not wearing clean outer garments, effective hair restraints or secure jewelry

<u>Deficiency Example</u>	<u>Critical/General</u>
1. Food workers are not wearing clean outer garments or effective hair restraints or secure jewelry.	X

11-C. Eating, drinking or use of tobacco in exposed food areas

<u>Deficiency Example</u>	<u>Critical/General</u>
1. Food workers were observed eating, drinking or using tobacco over or near exposed foods or in a manner that may contaminate food, equipment or utensils.	X

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11-D. Locker or dressing rooms are not segregated from food areas, clean or orderly

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Foods, food contact equipment, utensils, or single service items are stored in locker or dressing rooms.	X
2. Locker or dressing rooms are not segregated from food storage, processing or sales areas.	X
3. Locker or dressing rooms are not clean or orderly.	X

12. Inadequate Food Storage and Protection

12-A. Food not stored, conveyed or displayed in a manner that prevents contamination including marginal temperature deficiencies (See 6-A & 6-B)

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Non-potentially hazardous foods are subjected to conditions whereby they may become contaminated with/by airborne contamination or customer handling.	X
2. Foods are subjected to temperature ranges whereby the product quality may be adversely affected.	X
3. Ready-to-eat foods are subjected to conditions whereby they may become contaminated by raw foods.	X
4. Foods are likely to be contaminated with allergens due to cross contamination caused by equipment condition, design or location. Corrected during Inspection.	X

12-B. Food or ingredient storage containers are not clean, covered or properly identified

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Old, dry, hardened or discolored non-potentially hazardous food or ingredients are adhering to the outer surfaces of storage containers.	X
2. Food or ingredient containers are not covered (except those in active use).	X
3. Legible signs, labels or other marks, in English, do not identify the contents of containers with their common name. Submit an Economic Report, if appropriate.	X

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12-C. Bulk food displays are improperly constructed, displayed or handled

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Bulk food containers are not made of acceptable materials or constructed to prevent contamination of the contents or adjacent containers or are not in good repair or are not easily cleanable.	X
2. Bulk food containers are without appropriate individual lids or covers which are clean, non-absorbent, impervious and in good repair.	X
3. Human bulk foods are not segregated from animal foods and other items not for human consumption.	X
4. Manual dispensing utensils are not protected from contamination.	X
5. Manual dispensing utensils are not properly tethered or stored between uses.	X
6. Liquid foods are not dispensed by gravity feed or pressurized tops.	X
7. Bulk foods are not protected from mishandling or contamination by consumers.	X
8. Bulk food containers or modules are not cleaned or filled in a servicing area or in a manner to avoid contaminating the product or container.	X
9. Foods are likely to be contaminated with allergens due to cross contamination caused by equipment condition, design or location. Corrected during inspection.	X

12-D. Street clothing or soiled linen stored unsegregated from exposed food or food-contact surfaces

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Soiled clothing or soiled linen is not kept in non-absorbent containers or washable laundry bags.	X
2. Soiled clothing, soiled linen or their containers are not stored away from food or food-contact surfaces.	X
3. Street clothing (including shoes, purses and other items) is not properly stored in a locker area, dressing room or other suitable facility or away from foods, food storage and food-contact areas.	X

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12-E. Self-service food displays are improperly constructed, maintained or supervised

Information Note

This deficiency refers to all hazardous and non-hazardous self-serve retail displays of exposed foods including salad bars, but, excluding bulk food displays which are covered under deficiency 12-C. The examples listed below are generalized in content because of the difficulty in describing the many conditions that may be encountered by an Inspector. Part 271-4 of Title 1, NYCRR (Circular 962, Retail Food Store Regulations) contains an excellent overview of this subject and should be thoroughly reviewed and applied, as appropriate, by every Inspector.

Deficiency Examples

Critical/General

1. Self-serve food displays are not constructed with safe or acceptable materials.	X
2. Self-serve food displays are not designed or constructed to facilitate proper cleaning and maintenance.	X
3. Self-serve food displays are not designed, constructed or maintained to prevent consumer, airborne, vermin or product cross contamination.	X
4. Non-potentially hazardous foods are not displayed at temperatures or in a manner adequate to maintain the food in sound condition.	X
5. Foods are likely to be contaminated with allergens due to cross contamination caused by equipment condition, design or location. Corrected during inspection.	X
-

12-F. Improper thawing procedures are utilized

Information Note

This deficiency refers to the improper thawing of only potentially hazardous foods in all establishments under this Department's jurisdiction.

It will be enforced whenever an Inspector observes or determines improper thawing procedures are being used even if the food or ingredient will be subjected to further cooking or processing that may destroy potentially harmful organisms.

Other appropriate critical deficiency guidelines will be applied when potentially hazardous frozen foods, thawed in any manner, are found to exceed time and temperature parameters.

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<u>Deficiency Example</u>	<u>Critical/General</u>
1. Frozen, potentially hazardous foods are not being thawed in refrigerated units at temperatures of 41 ⁰ F(45 ⁰ F) or less; under potable running water at a temperature of 70 ⁰ F or below with sufficient velocity to remove food particles; for a reasonable time period; in a microwave oven, within proper parameters; as part of a conventional cooking process or by other approved methods.	X

13. Required Processing or Salvaging Procedures Are Not Followed

13-A. (See Specialized Inspection Guidelines)

Information Note

This item covers general deficiencies of specialized establishments and operations.

13-B. Other required records are not maintained

Information Note

This deficiency relates to any potentially hazardous food processing or manufacturing operation's record keeping requirements not specifically covered in the Specialized Inspection Guidelines.

<u>Deficiency Example</u>	<u>Critical/General</u>
1. Cooking records not (properly) maintained	X
2. Person in charge of food establishment has failed to attend a Department approved food safety course as directed.	X

13-C. Other coding requirements are lacking or inadequate

Information Note

This deficiency also relates to the absence of (adequate) coding or product labeling on food products not specifically covered in the Specialized Inspection Guidelines. (Label or coding content violations are economic violations and are reported as such).

<u>Deficiency Example</u>	<u>Critical/General</u>
1. Shellfish tank logs not (adequately) maintained	X

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Information Note

For additional information regarding the use of 13-A, B or C, consult your Supervising Inspector.

13-D. Article 28 posting requirements are not met.

<u>Deficiency Example</u>	<u>Critical/General</u>
1. The date and results of the most recent inspection are not posted and management fail to correct during inspection.	X
2. The posted results of the most recent inspection are not accurate and management failed to correct during inspection.	X

14. Insect, Rodent or Vermin Activity

14-A. Evidence of rodents observed (not likely to result in product contamination)

Information Note

*See **Sub-Section 5055, Insects and Rodents**, for useful information. This deficiency refers to: 1. Evidence of an inactive (prior) rodent infestation (dried, decayed rodent carcass(es), hard, dust covered droppings, old gnaw marks, rub marks or nesting sites, etc.) 2. Evidence of a current infestation which does not represent a direct threat of product contamination and is accompanied by a properly designed and applied control program.*

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. A dried, decomposed mouse carcass and about 12 dried, hardened mouse droppings were seen on the floor of the cellar compressor room.	X
2. A freshly killed mouse was observed on a glue board along a wall of the produce trimming room. A satisfactory rodent control program is in effect.	X

14-B. Insect, birds or other vermin observed within the establishment (not likely to result in product contamination)

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Information Note

This deficiency refers to those insects, birds, or other vermin not normally implicated in the transmission of foodborne diseases, e.g., ants, fruit flies, grain insects, yellow jackets, etc., all birds and assorted vermin, provided there is no evidence of adulterated food or ingredients.

Deficiency Examples

Critical/General

1. About 12 small, black ants were seen on the floor of the cased, canned food storeroom.	X
2. What appeared to be old, dry grayish squirrel droppings were observed on the floor of an unused upper storeroom.	X
3. One live bird is noted in the establishment. No evidence of contaminated food or food equipment. Corrective action has been instituted.	X
4. A live cockroach is noted on the floor of the bottle return room.	X

Information Note

Corrective action for bird control may include:

- 1. Netting, glueboards or other traps*
- 2. Evidence of professional extermination efforts*

14-C. Evidence of pets or other domestic animals in establishment

Information Note

Service animals, e.g., guide dogs for the blind or the hearing impaired are allowed in the sales area of food establishments and are not subject to regulatory action (if there is evidence of product contamination by these animals appropriate action should be taken).

Pets of any kind or other domestic animals, whether owned by the establishment or its customers, are not allowed in any food storage or handling area. This exclusion does not apply to edible fish, crustacea, shellfish or fish in aquariums.

Patrol dogs are allowed free access to all enclosed areas outside of the building housing the establishment. While with a police or security officer, they are allowed access to offices, storage areas and outside premises. Employees, on duty in food areas, shall not care for or touch any pet or patrol dog.

Live or dead fish bait shall be stored separately from food or food products.

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<u>Deficiency Examples</u>	<u>Critical/General</u>
1. A cat was seen sleeping on a chair by the checkout counter.	X
2. A customer was observed with a small dog in her shopping cart.	X
3. A large patrol dog was observed roaming loose in the main warehouse area.	X

15. Equipment Utensils and Materials Adequately Utilized and Maintained

15-A. Food contact equipment, utensils or conveyances: contact surfaces unclean or not properly sanitized

Information Note

This deficiency refers to equipment, utensils or conveyances contacting only non-potentially hazardous foods.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. The interior of the mixing bowl and the paddle of the vertical mixer was lightly encrusted with a yellowish colored, dried, hardened dough paste.	X
2. The white plastic fish filleting board has moderate yellow-brown staining across top.	X
3. Bakery trays have a light buildup of scrapable baked on dough residues on outer edges.	X
4. The bench top can opener has buildup of dark scrapable matter on plunger areas.	X
5. Foods are likely to be contaminated with allergens due to cross contamination caused by equipment condition, design or location.	X

15-B. Non-contact food equipment, utensils or conveyances are not clean or in good repair

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. The outer surfaces of the large horizontal mixer electrical control button box had accumulations of heavy, dark, dried dough on it.	X

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	<u>Critical/General</u>
2. Hand contact surfaces of food equipment have a buildup of dark grime and/or dried on food residues.	X
3. Tracks of deli cooler access windows have an accumulation of dried food residues.	X

15-C. Food equipment improperly designed, constructed or maintained

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Non-food contact areas of food equipment are repaired with rough, uncleanable tape.	X
2. Food preparation boards exhibit moderate knife scoring.	X
3. Exterior housing of the meat bandsaw exhibits rust.	X

15-D. Thermometers not provided where required

Information Note

This general deficiency encompasses only potentially hazardous foods. The lack of a thermometer may subsequently lead to the rapid growth of pathogenic or spoilage organisms in foods not properly heated or refrigerated. If this spoilage should occur, it would, of course, be a critical deficiency. However, the lack of thermometers, where required, is a general deficiency.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Thermometer is not provided in coolers/freezers.	X
2. Thermometer is not provided to monitor hot food temperatures.	X
3. Thermometer is not graduated in $\leq 3^{\circ}\text{F}$ increments.	X
4. Thermometer is not calibrated/accurate to within $\leq 3^{\circ}\text{F}$.	X

15-E. Unused equipment or materials improperly stored or in an unclean condition

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Information Note

Equipment or utensils stored improperly or in an unclean condition may interfere with proper housekeeping, provide a harborage or be an attractant for rodents, insects or other vermin.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Seasonal displays and decorations intermingled with broken shelving, shopping carts and other unused equipment were piled haphazardly in a small outer room off the main food storage area.	X
2. An unused meat cuber, a grinder and a slicer, all covered with soiled rags were observed in the rear storage area.	X

15-F. Storage cabinets or shelves are not clean or in good repair

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Food storage shelves are constructed of untreated/uncoated wood (porous/uncleanable).	X
2. Food storage shelves are covered with cardboard, crumpled metal foil or other uncleanable material.	X
3. Food storage shelves are rusted or have peeling coating.	X

15-G. Packaging materials unclean, improperly stored or handled in an insanitary manner

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Food packaging is stored in restroom.	X
2. Food packaging is stored uncovered and exposed to dust, food spillage or other contamination source.	X
3. Food packaging is stored on floor.	X
4. Clear plastic salad containers for takeout use were stored on open shelves at the base of the salad bar. Dried particles of various vegetation and dried salad dressings were noted inside the top trays of the six stacks of trays.	X

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15-H. Air system or transfer lines are not clean, properly constructed or in good repair

Information Note

The regulations covering this deficiency are general in nature, i.e., suitable for the purpose, designed and constructed to be cleanable and properly maintained, etc. However, good industry practice dictates that: 1. Air supply systems have a functioning automatic pressure control unit; 2. A check valve to prevent water from entering the air lines be present; 3. Air to be used in direct contact with exposed foods or for food contact surfaces be filtered to prevent dust, oil, grease, water and other pollutants from causing contamination; 4. All air systems be kept clean and well maintained.

Deficiency Example

Critical/General

1. Air system and/or transfer lines not clean, properly constructed or in good repair.	X
-

16. Other Sanitation

16-A. Chemicals or pesticides improperly labeled, stored or handled

Information Note

Item No. 4-D states "Toxic chemicals are improperly labeled, stored or used so that contamination of food is likely to occur." If the Inspector determines that contamination is not likely to occur, score the situation as a general deficiency.

See Item 9-F for related information.

Deficiency Examples

Critical/General

1. Sealed cans of motor oil (10+) were stacked on a retail display shelf over boxes of cereal.	X
2. An unlabeled, tightly sealed, quart sized clear plastic bottle containing chlorine was noted on a shelf over a deli section work table.	X

Critical/General

3. An unauthorized store employee was observed spraying pesticide from an aerosol can into the air in the rear stockroom. No exposed foods present.	X
4. An uncovered box of rodenticide pellets is noted on floor under bread display.	X
-

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16-B. Outside premises or loading zones improperly maintained

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Outside area abutting the establishment has extensive growth of tall vegetation.	X
2. Outside area abutting the establishment is heavily littered with refuse.	X
3. Outside loading area ground surface is worn and uneven causing flooded areas.	X

16-C. Vehicles are not clean or in good repair

Information Note

*See **Sub-Section 2025**, Vehicle Inspections, for proper inspection and reporting procedures. Any vehicle deficiencies affecting potentially hazardous foods should be evaluated as critical deficiencies.*

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Small amounts of dry, dark hardened dough was observed on the tray ledges in the rear compartment of a delivery van.	X
2. A hole, about one by two feet in size had rusted through the floor of a delivery van. Water, dirt or other contaminants may contact product when the van is in motion. No product on hand. Interior was clean.	X

16-D. Morgue area or bottle return area improperly maintained

Information Note

Morgue and bottle return areas are, by their nature, inherently unsanitary. Spillage or leakage from cracked, broken or opened food containers provides an ideal vermin harborage area and often may provide an avenue for product cross contamination.

<u>Deficiency Examples</u>	<u>Critical/General</u>
1. Moderate spillage of container contents noted inside morgue area product storage boxes.	X

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Critical/General

2. No specific morgue area defined in the establishment. Boxes and containers of product were noted stored, in small amounts, on various shelves in the stock room.	X
-

16-E. Shellfish tags or records improperly maintained

Information Note

See Sub-Section 1055, Memorandum of Understanding Between the New York State Department of Health, the New York State Department of Environmental Conservation and the New York State Department of Agriculture and Markets, and Sub-Section 2010," Shellfish From Unapproved Sources, Critical Deficiency No. 1-E," , for useful information.

No. 1-E clearly states most deficiencies relating to shellfish tags and records are viewed as critical deficiencies. However, if in the opinion of the Inspector, the establishment has made a good faith effort to comply with the regulations or if the improper record or tag maintenance appears to be inadvertent or isolated, the Inspector may choose to score the deficiency as a general item. A brief, concise explanation and documentation must be provided.

Deficiency Examples

Critical/General

1. Two bags of clams, of 10 being offered for sale, were lacking the required tag.	X
2. The shellfish purchase date/sales date log was not complete and some entries were illegible.	X

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SANITARY INSPECTIONS
SPECIALIZED INSPECTION GUIDELINES
SUB-SECTION 2020**

SPECIALIZED INSPECTION GUIDELINES

The “Specialized Inspection Guidelines” are found on the back of the FSI-898 and in the Deficiency Checklist screen of the electronic system. The critical (red) items in the guidelines relate to activities having the potential of being major threats to the public health and welfare if established procedures are not diligently followed.

Each guideline item specifically refers to a complex activity within a particular food operation. Because of this complexity and the need for effective regulatory oversight the inspector should review the rules and regulations, appropriate to each activity listed herein, before inspecting these operations.

Item 17 - Low Acid Foods - Circular 940, Part 277 of Title 1NYCRR and 21 CFR, Part 113

Item 18 - Acidified Foods - 21 CFR, Part 114

Item 19 - Water Activity Reduced Foods - 21 CFR, Part 113

Item 20 - Salvage Dealers - Article 17-B and Part 256, 1 NYCRR, Circular 855

Item 21 - Licensable Food Operations - Refer to Sub-Section 4065, Licenses and Permits, for information relating to Items 21-A and 21-B

Item 22 - Vacuum or Modified Atmosphere Packaging – Article 17, Part 271, Circular 962.

Item 23 - Cured and/or Smoked Fish Processors - Section 262 of 1NYCRR, Circular 1032

Item 24 – Specialized food processing requiring a HACCP plan – Article 17, Part 271, Circular 962.

The general items (blue), because of their integral relationship with the critical items, should always be carefully reviewed and documented.

See your Food Inspector II or Food Inspector III for additional information.

**SANITARY INSPECTIONS
SPECIALIZED INSPECTION GUIDELINES
SUB-SECTION 2020**

Approval Procedures for Reduced Oxygen Packaging at Retail

- Establishments that plan to conduct Reduced Oxygen Packaging at Retail are mailed an information letter and 20-C license application.
- The establishment must then submit a list of products they wish to Reduce Oxygen Package along with a completed Article 20-C application. (Meets 271- 2.24)
- An approval letter and list of approved products is then mailed to the firm. A copy is retained in the establishments file and a letter is e-mailed to the zone supervisor and the region chief. (Copies of these letters can also be found on the G Drive under Licensing Folder – Vac Pack Sub-Folder – firm’s establishment number.)

**SANITARY INSPECTIONS
SPECIALIZED INSPECTION GUIDELINES
SUB-SECTION 2020**

EXAMPLE #1

In replying refer to
Establishment #

July 11, 2006

Re: Application to Package Food Products in Reduced Oxygen Containers

The purpose of this letter is to advise you that your establishment is not authorized to conduct reduced oxygen packing of food products. The term reduced oxygen packaging refers to vacuum, modified atmosphere, controlled atmosphere, sous vide and cook-chill packaging.

Section 271-2.24 Reduced Oxygen Packaging from our Retail Food Store Regulations states as follows:

- (a) A food establishment that packages food using a reduced oxygen packaging method shall have a HACCP plan that contains the information specified under Section 271-9.6(d) and that:
 - (1) Identifies the food to be packaged;
 - (2) Limits the food packaged to a food that does not support the growth of *Clostridium botulinum* because it complies with one of the following:
 - (i) Has an a_w of 0.91 or less,
 - (ii) Has a pH of 4.6 or less,
 - (iii) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR section 318.7, "Approval of substances for use in the preparation of products," and 9 CFR section 381.7, "Restrictions on the use of substances in poultry products," and is received in an intact package, or

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EXAMPLE #1 (PAGE 2)

- (iv) Is a food with a high level of competing organisms such as raw meat or raw poultry;
 - (v) Is a frozen food which does not meet the criteria of (i), (ii) or (iii) and is conspicuously labeled, "Important – Keep Frozen Until Use;"
 - (vi) Is a food which contains some other barrier which precludes the growth of *Clostridium botulinum*.
- (3) Specifies methods for maintaining food at 41°F (5°C) or less;
- (4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
- (i) Maintain the food at 41°F (5°C) or less, and
 - (ii) Discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;
- (5) Limits the shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;
- (6) Includes operational procedures that:
- (i) Prohibit contacting food with bare hands,
 - (ii) Identify a designated area and the method by which:
 - (a) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, and
 - (b) Access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation, and
 - (iii) Delineate cleaning and sanitization procedures for food contact surfaces; and
- (7) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:
- (i) Concepts required for a safe operation,

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EXAMPLE #1 (PAGE 3)

- (ii) Equipment and facilities, and
 - (iii) Procedures specified under Subparagraph (a)(6) of this section and Section 271-9.6(d).
- (b) Except for fish that is frozen before, during and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.

We will consider license applications to permit reduced oxygen packaging of foods provided such operations meet applicable Agriculture and Markets Statutes and Regulations.

You must submit a revised Article 20-C Food Processing License Application that identifies the foods to be packaged in reduced oxygen containers that meet the above criteria.

If you, or your company, require additional information on this topic or our procedures, please write or call my office at (518) 457-7139.

Sincerely yours,

Supervisor
License Unit

Encs.

cc: Region Chief
Zone Supervisor

**SANITARY INSPECTIONS
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EXAMPLE #2

In replying refer to
Est. No. #

July 11, 2006

Re: Authorization for Reduced Oxygen Packaging at Retail

Gentlemen:

Your request to conduct reduced oxygen repackaging of specific food products (see attached list) as part of the food processing activities in your establishment licensed under Article 20-C is approved.

This approval is contingent upon your compliance with applicable New York State Department of Agriculture and Markets statutes and regulation governing food safety and labeling.

We also recommend that you adhere to the enclosed "Rules and Regulations for Reduced Oxygen Packaging at Retail". Products that do not meet two or more of the barriers listed in the informational letter, will be required to have a HACCP plan that contains all information under Section 271.9.6 (d).

This authorization to conduct reduced oxygen packaging is based on currently available scientific information and may be subject to revocation or revision if new information is received which suggests the process as presently approved represents an unacceptable threat to public health.

We presume that your firm recognizes the inherent risk involved in reduced oxygen packaging and will exercise extreme caution in its use.

Sincerely,

Supervisor License Unit

Enc.

cc: Region Chief
Zone Supervisor

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**List of Products Approved for Vacuum Packaging
(USDA Inspected)**

Bacon
Pepperoni
Ham
Hot Dogs
Canadian Bacon
Dried Sausage/Sopresetta
Smoked Pork Chops

Cheese

Aged Cheddar
Horseradish Cheddar
Roasted Garlic Cheddar
Smoked Cheddar
Horseradish & Bacon Cheddar
Pepperoni & Cheddar
Mozzarella
Peccorino Romano
Asiago
Parmisan
Gruyere
Bergmost
Gouda
Smoked Gouda
Swiss
Munster
Colby
Blue
Provolone
Aged Provolone

Frozen - Immediately

Various Cuts of Raw Meats
Lamb
Pork
Veal *
Poultry * * From Approved Sources
Rabbit *
Duck
Misc. Sausage made from Pork

Seafood

(Frozen –Before, During, After)
Shrimp
Lobster Tail
Scallops
Tuna

**ALL OF THE ABOVE MUST BE LABELED WITH A 14-DAY “USE BY DATE”
FROM THE DATE OF PACKAGING**

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SANITARY INSPECTIONS
VEHICLE INSPECTIONS
SUB-SECTION 2025

VEHICLE INSPECTIONS

Food vehicles are subject to many of the same deficiencies found in other food establishments. Inspecting vehicles carrying food or ingredients is an important part of your assigned duties. The following are descriptions of various vehicle types and inspection procedures:

1. **Delivery vehicles owned and operated by existing food establishments that have an establishment number:** These vehicles make deliveries of foods or ingredients to establishments under the jurisdiction of various federal, state and local agencies, as well as directly to the consumer.

When inspecting these vehicles the county code of the home plant or depot of the vehicle should be entered on the Sanitary Inspection Report (FSI-894). Leave the remaining four digit spaces blank. Do not enter the full establishment number of the home plant or depot.

2. **Common carriers *not* owned or operated by an establishment under our jurisdiction:** These vehicles will deliver, or pick up, a variety of foods, ingredients and non-food items to, or from, establishments under the jurisdiction of various federal, state and local agencies, as well as directly to the consumer.

Common Carriers in transit through New York State and not making pickups or deliveries of foods or ingredients within this state are not under the jurisdiction of this agency and should not be inspected.

When inspecting vehicles at establishments under our jurisdiction the county code of the main office or depot of the vehicle, if in New York State, should be entered on the Sanitary Inspection Report (FSI-894). If not in New York State, enter County Code No. 65.

When inspecting these vehicles while they are making a delivery (or pick-up) at other than their home plant or depot, please follow these procedures on the Sanitary Inspection Report (FSI-894):

- A. Enter "K" (vehicle) in TYPE space.
- B. Enter the IPH category as No. 6.
- C. Enter the owner, trade name, street, city and ZIP code as taken from the vehicle registration form.
- D. Enter the county code of the main plant or depot leaving the four digit spaces blank.

**SANITARY INSPECTIONS
VEHICLE INSPECTIONS
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On the Supplemental Sanitary Inspection Report (FSI-898):

- E. Enter "delivery vehicle" or "common carrier" as appropriate and enter the license plate information.
- F. List all deficiencies on the FSI-898 and circle the item number(s) on the FSI-894.
- G. Enter the owner's name, trade name, address and establishment number of the place where the vehicle was inspected.
- H. Complete the rest of the FSI-894 and 898 as required.
- I. List the general categories of food products and non-food products being carried in the vehicle.

If critical conditions are reported, a reinspection or limited (re)inspection will be necessary. Since the main plant and depot may be out of the Inspector's area, the Food Inspector II will arrange for appropriate follow-up activity.

Any Sanitary Inspection Report marked as a type K, identified as a delivery vehicle or common carrier and having critical deficiencies being reported will be routed by the Division Office mail desk to the Food Safety and Compliance Unit for special handling.

DO NOT submit OCR's for the Transient Vendor Vehicle types noted under No. 3, below.

- 3. **Transient vendor vehicles** such as seafood sales trucks, selling exposed filleted fish, scallops, etc., and/or doing cutting or filleting operations normally found in such places as gas station parking lots, roadside parking areas and shopping plazas **must** be inspected as retail food establishments subject to the provisions of Article 17 of the Agriculture and Markets Law and Parts 261 & 271 of the Official Compilation of Codes, Rules and Regulations.

When inspecting these transient vendor vehicles, follow these procedures:

On the Sanitary Inspection Report (FSI-894):

- A. Enter "K" (Vehicle) in the Type space.
- B. Enter the owner, trade name, street, city and ZIP code as taken from the vehicle registration form.
- C. Enter the IPH category as No. 3.

**SANITARY INSPECTIONS
VEHICLE INSPECTIONS
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- D. Enter the code of the county where you are inspecting the vehicle in the first two establishment number spaces. Leave the other four digit spaces blank.

On the first line of the Supplemental Sanitary Inspection Report (FSI-898):

- E. Enter "Transient Vendor Vehicle" and the license plate information.
- F. On the next several lines, enter the owner, trade name and address of the place where the transient vendor vehicle was inspected, include an establishment number if available, if not, enter the county code.
- G. List all deficiencies on the FSI-898 and circle the item number(s) on the FSI-894.
- H. Complete the rest of the FSI-894 and FSI-898 as required.

If critical deficiencies are reported, a reinspection will be necessary. Since transient vendor vehicles seldom stay in one location for extended periods, the Regional Supervisor will arrange for and monitor appropriate follow-up action.

4. **Semi-permanent vendor vehicles routinely found at regional markets, farmers markets, craft fairs, etc.** The operators of these vehicles normally rent or lease the same space or location year after year.

Frequently, the site or location will have basic or rudimentary sanitary facilities available for the use of the operators. Because of the more-than-transient nature of the vehicle owner's operations at these locations, these semi-permanent vendor vehicles will be registered as retail food stores and will be subject to all applicable provisions of Article 17, and Article 20-C of the Agriculture and Markets Law and Parts 261 and 271 of the Official Compilations of Codes, Rules and Regulations.

When inspecting these semi-permanent vendor vehicles follow these procedures:

On the Sanitary Inspection Report (FSI-894):

- A. Enter "JAK" or "JACK" (as appropriate) in the Type space.
- B. Enter the owner, trade name, street, city and ZIP code to reflect the actual location of the inspection.
- C. Enter the IPH category appropriate for the type of operation.
- D. Since most of these operators often have primary businesses at other locations, the OCR will specify a "special mailing address" (if appropriate). See Sub-Section 2045, OCR procedure number 7-D.
- E. Enter the establishment number if assigned and known. If not, enter the county code. Leave the other four digit spaces blank.

**SANITARY INSPECTIONS
VEHICLE INSPECTIONS
SUB-SECTION 2015**

On the first line of the Supplemental Sanitary Inspection Report (FSI-898):

- F. Enter "Semi-Permanent Vendor Vehicle" and the license plate information if available.
- G. List all deficiencies on the FSI-898 and circle the item number(s) on the FSI-894.
- H. Complete the rest of the FSI-894 and FSI-898 as required.

If critical conditions are reported during an inspection, a reinspection will be necessary. Since the operation can be expected to be found in the same place at regular times and an establishment number will be assigned, the reinspection will be handled in a routine manner.

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Field Operations Manual**

**SANITARY INSPECTIONS
HOME PROCESSORS (FSI-898-A)
SUB-SECTION 2030**

Section 276.3 of the New York State Agriculture and Markets regulations states in part that "**Home processed food ... shall mean any food processed in a private home or residence using only the ordinary kitchen facilities of that home . . . but shall exclude potentially hazardous foods ...**"

NOTE: Commercial equipment is not considered ordinary kitchen facilities.

Processors of home processed foods who sell or offer for sale such foods may be exempted from the licensing requirements of Article 20-C, provided that the following conditions are met:

1. All finished product containers are clean, sanitary and properly labeled.
2. All home processed foods produced under this exemption are neither adulterated nor mis-branded.
3. Glass containers for jams, jellies, marmalades and similar products are provided with suitable rigid metal covers.

In order to protect public health and to minimize the potential of food product adulteration, this exemption is restricted to the following non-potentially hazardous home processed foods.

1. Bakery products, i.e., bread, rolls, cookies, cakes, brownies, fudge, and double-crust fruit pies for wholesale marketing or retail agricultural venues such as farms, farm stands, farmers markets, green markets, craft fairs and flea markets.
2. Traditional fruit jams, jellies, and marmalades
3. Candy (*excluding chocolate*)
4. Spices or herbs
5. Snack items such as popcorn, caramel corn and peanut brittle

Internet sales are not included in this exemption. Home processors whose residences contain separate segregated facilities for food processing, while not qualifying for a home processor exemption, may apply for licensing under Article 20-C.

NOTE: In any event, all operators must consult with local zoning officials for approval before commencing any food processing operations.

The exemption relates only to Article 20-C licensing. The exempt firm will be subject to inspection by the Department of Agriculture and Markets.

SANITARY INSPECTIONS
HOME PROCESSORS (FSI-898-A)
SUB-SECTION 2030

License-exempt home processors will not be routinely inspected. An initial inspection is to be performed. Thereafter, inspect only in response to a complaint or evidence of a problem. The Sanitary Inspection Report used for these firms will consist of the Sanitary Inspection Report cover sheet (FSI-894) and the Home Processor Supplemental Sanitary Inspection Report form (FSI-898-A) for home processors (see example 1). The IPH for these firms will continue to be "6". In all cases, the type of establishment will be the letter "H."

No establishment number should be given to any Article 20-C license exempt home processor. Use the county code and 4 A's as the establishment number.

Residences which contain separate, segregated facilities for food processing, however, must apply for licensing under Article 20-C, and shall be listed as a type "C" (if appropriate). In any case, operators must be sure they are not violating any local zoning ordinances.

SANITARY INSPECTIONS
HOME PROCESSORS (FSI-898-A)
SUB-SECTION 2030

FSI-898-A (Rev. 9/05) pm5

NYS Department of Agriculture and Markets
Division of Food Safety and Inspection

HOME PROCESSOR SUPPLEMENTAL SANITARY INSPECTION REPORT

Date							
Est. No.							

Est. Name

EXAMPLE #1

THIS ESTABLISHMENT IS A 20-C EXEMPT HOME PROCESSOR APPROVED TO PROCESS THE FOLLOWING NON-POTENTIALLY HAZARDOUS FOOD PRODUCTS

1. _____	2. _____
3. _____	4. _____

This establishment has a (municipal) (private) water supply (private water supplies must be analyzed annually).

Establishment telephone number

Last water analysis date _____

Product labeling reviewed

Yes ☐ No ☐

Firm will submit labels for review

Yes ☐ No ☐

Item No's:
Gen. &
Spec. Lists

DEFICIENCIES NOTED

Inspector(s)
Signatures

Signature of
Establishment
Representative

Title

Date

I have received a copy of this report consisting of _____ pages. The deficiencies noted in this Sanitary Inspection Report including those on all preceding sheets, if attached, are violations of the Agriculture and Markets Law. Corrections must be made immediately. The Department may institute action without further inspection in cases of substantial violation or deficiency.

**SANITARY INSPECTIONS
HOME PROCESSORS (FSI-898-A)
SUB-SECTION 2030**

HOME PROCESSORS

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NOTE: Commercial equipment is not considered ordinary kitchen facilities.

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3. Candy (*excluding chocolate*)
4. Spices or herbs
5. Snack items such as popcorn, caramel corn and peanut brittle

Internet sales are not included in this exemption. Home processors whose residences contain separate segregated facilities for food processing, while not qualifying for a home processor exemption, may apply for licensing under Article 20-C.

NOTE: In any event, all operators must consult with local zoning officials for approval before commencing any food processing operations.

The exemption relates only to Article 20-C licensing. The exempt firm will be subject to inspection by the Department of Agriculture and Markets. For more detailed information, please contact the nearest regional office.

REGIONAL OFFICES

<u>ALBANY</u>	<u>SYRACUSE</u>	<u>ROCHESTER</u>	<u>BUFFALO</u>	<u>NEW YORK CITY</u>
(518) 457-5459	(315) 487-0852	(585) 427-2273	(716) 847-3185	(718) 722-2876

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035**

Overview

The Division of Food Safety and Inspection and US Food and Drug Administration (FDA) have adopted a food safety program developed nearly 30 years ago for astronauts and is applying it to seafood and juice. FDA intends to eventually use it for much of the U.S. food supply. The program for the astronauts focused on preventing hazards that could cause food-borne illnesses by applying science-based controls, from raw material to finished products. Application of this same system in the food industry will do the same.

Traditionally, industry and regulators have depended on spot-checks of manufacturing conditions and random sampling of final products to ensure safe food. This approach, however, tends to be reactive, rather than preventive, and can be less efficient than the new system.

The system is known as Hazard Analysis and Critical Control Point (HACCP). Many of its principles already are in place in the low-acid canned food and acidified food industry. FDA established HACCP for the seafood industry in a final rule December 18, 1995 and for the juice industry in a final rule released January 19, 2001. New York Agriculture and Markets have adopted both of these federal rules and they are now state law as well.

In 1998, the U.S. Department of Agriculture (USDA) established HACCP for meat and poultry processing plants, as well. Most of these establishments were required to start using HACCP by January 1999. Very small plants had until Jan. 25, 2000. (USDA regulates meat and poultry; FDA all other foods.)

HACCP has been endorsed by the National Academy of Sciences, the Codex Alimentarius Commission (an international food standard-setting organization), and the National Advisory Committee on Microbiological Criteria for Foods.

What is HACCP?

HACCP involves seven principles:

- **Analyze hazards.** Potential hazards associated with a food and measures to control those hazards are identified. The hazard could be biological, such as a microbe; chemical, such as a toxin; or physical, such as ground glass or metal fragments.
- **Identify critical control points.** These are points in a food's production--from its raw state through processing and shipping to consumption by the consumer--at which the potential hazard can be controlled or eliminated. Examples are cooking, cooling, packaging, and metal detection.

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

- **Establish preventive measures with critical limits for each control point.** For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of any harmful microbes.
- **Establish procedures to monitor the critical control points.** Such procedures might include determining how and by whom cooking time and temperature should be monitored.
- **Establish corrective actions to be taken when monitoring shows that a critical limit has not been met**--for example, reprocessing or disposing of food if the minimum cooking temperature is not met.
- **Establish procedures to verify that the system is working properly**--for example, testing time-and-temperature recording devices to verify that a cooking unit is working properly.
- **Establish effective recordkeeping to document the HACCP system.** This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems. Each of these principles must be backed by sound scientific knowledge: for example, published microbiological studies on time and temperature factors for controlling foodborne pathogens.

Advantages

HACCP offers a number of advantages over the current system. Most importantly, HACCP:

- focuses on identifying and preventing hazards from contaminating food
- is based on sound science
- permits more efficient and effective government oversight, primarily because the recordkeeping allows investigators to see how well a firm is complying with food safety laws over a period rather than how well it is doing on any given day
- places responsibility for ensuring food safety appropriately on the food manufacturer or distributor
- helps food companies compete more effectively in the world market
- reduces barriers to international trade.

The HACCP Concept

HACCP is essentially the design, management and monitoring of an organized system of controls over those critical points in a process that affect, either beneficially or adversely, the compliance of the finished product with certain desirable characteristics. It can be explained very simply as the analysis of the process hazards and the control of the critical points.

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

The primary responsibility for implementing HACCP as a control system for the production, holding, distribution and sale of food products rests with the food industry. The HACCP inspection approach currently used by the New York State Department of Agriculture and Markets (NYSA&M) is designed to be used as a tool to evaluate the manufacturing, storage and distribution system for a food product whether or not the firm itself uses a HACCP system.

From a regulatory position, HACCP inspections assist in identifying hazards or conditions which may contribute to the adulteration of food products. These inspections include:

1. An interview with the most responsible person in the establishment to determine:
 - A. Product formulation
 - B. Processing procedures
 - C. Storage procedures (location/time/temperature) prior to distribution or consumption
 - D. Identify and examine the ingredients to be used in the manufacture of the product for the potential to support microbe growth
2. Visual observation of the product process (from blending of ingredients to final storage prior to distribution or sale) including time and temperature checks
3. Identification of critical control points throughout the process
4. Clear description and diagram of the product process reviewed
5. Documentation of all violative conditions and/or unacceptable practices
6. Review of deficient conditions with establishment representative and a commitment for correction of the deficiencies

In New York State, HACCP inspections are conducted at food processing establishments when:

1. New businesses present a unique, complex or hazardous processing concern
2. Food sample analysis indicate bacterial or chemical concerns
3. A food product is involved in numerous consumer complaints
4. Establishments are involved in foodborne illness complaints
5. When inspection personnel have a concern about a particular food process
6. As required for seafood and fruit juice products

HAZARDS – BIOLOGICAL, CHEMICAL AND PHYSICAL

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
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To perform a hazard analysis for the development of a HACCP plan, food establishments must first gain a working knowledge of potential hazards. The HACCP plan is designed to control all reasonably likely food safety hazards. Such hazards are categorized into three classes: biological, chemical and physical.

Biological hazards include harmful bacteria, viruses or parasites (e.g. salmonella, hepatitis A and trichinella). Chemical hazards include compounds that can cause illness or injury due to immediate or long-term exposure. Physical hazards include foreign objects in food that can cause harm when eaten, such as glass or metal fragments.

It is important to understand that for the purposes of HACCP, hazards only refer to the conditions or contaminants in food that can cause illness or injury to people. Many conditions are highly undesirable in food, such as the presence of insects, hair, filth or spoilage. Economic fraud and violations of regulatory food standards are equally undesirable. All of these defects must be controlled in food processing. However, they often are not directly related to the safety of the product. Unless these conditions directly affect food safety, they are not included in a HACCP plan.

- **Biological Hazards**

Foods can contain biological hazards. These hazards can be introduced from raw materials or from food processing steps used to make the final product.

- **Microorganisms**

Organisms too small to be seen with the naked eye are called *microorganisms*. Microorganisms live everywhere: air, dirt, fresh and salt water, skin, hair, animal fur and plants.

Microorganisms are classified into various groups. A few groups important in foods include yeasts, molds, bacteria, viruses and protozoa. Since microorganisms are so widespread, it is important to understand when to be concerned about them and how to deal with them.

Although thousands of kinds of microorganisms exist, only a few pose hazards to humans. These hazardous microorganisms, or *pathogens*, will be discussed in more detail later.

Many microorganisms are beneficial. Certain kinds of yeast, molds and bacteria help make cheese, sour cream, yogurt and other fermented dairy products. Particular kinds of yeast are used in making beer, wine and other fermented beverages. We add these microorganisms to our foods intentionally, and they cause no harm. In fact, studies show that some of these microorganisms contribute to good health.

People may come into contact with thousands of kinds of yeasts, molds, bacteria, viruses and protozoa daily without ill effect. Therefore, when foods are processed and preserved, food processors and regulators need only be concerned with some microorganisms, particularly pathogens.

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
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Although microorganisms are too small to be seen without a microscope, they are alive and have certain needs to live and grow. Without adequate food, water and temperature, microorganisms stop growing and multiplying. Some die; others stop functioning until they get the elements they need. Some preservation methods, such as drying or smoking, control the water or nutrients in food, making these essential elements unavailable to microorganisms. Temperature abuse, such as improper hot or cold holding temperatures can significantly increase the number of microorganisms.

Different microorganisms respond differently to air. Like most plants and animals, many microorganisms need air to live and will die or stop growing if deprived. However, many microorganisms can function without air. Some are poisoned by it. Unfortunately, pathogens exist in each of these categories. Although some microorganisms can be controlled by the amount of air they receive, it is not an effective way of controlling all pathogens.

Microorganisms multiply in different ways. The most common method, especially for yeasts, bacteria and protozoa, is to grow large and divide. One microorganisms splits into two, two into four, four into eight, eight into sixteen and so on. By doubling, microorganisms multiply quickly. Under ideal conditions, some bacteria double every 20 minutes. Potentially, one microorganism can multiply to more than 30,000 in five hours and to more than 16 million in eight hours. Fortunately, most microorganisms grow more slowly than this and we can slow them even more by controlling the food, water and temperature that they need to grow and multiply.

Most spoiled foods do not present a health risk and not all food that appears normal is safe to consume.

When microorganisms grow, they often produce by-products. The more they grow, the more by-products they produce. Some of the by-products are desirable in the right foods. For example, when yeasts grow in dough, they produce carbon dioxide, acids and flavors. The dough rises and we make bread. However, when the same yeasts grow and produce the same by-products in another food, such as fruit juice, it may not be desirable. Then we call it spoilage. Such spoilage is undesirable and processors strive to avoid it in food. In addition, some by-products produced by pathogens are toxic and can cause disease.

Spoiled food may not look, smell or taste good, but only food spoiled by pathogens or contaminated by toxic microbial by-products can make a person sick. Food spoilage or decomposition that can result in food safety problems should be prevented or controlled by a HACCP program.

During the processing of foods, the amounts and types of microorganisms can be increased, held constant, reduced or destroyed. Even though processing can be used to destroy harmful microorganisms, many safe microorganisms can survive the treatment and continue to live.

Among the five groups of microorganisms described earlier, only bacteria, viruses and protozoa include the kinds of microorganisms that can make food unsafe. Generally, yeast and molds do not pose a biological hazard in food. Some molds produce hazardous toxins, but these toxins are considered chemical hazards.

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
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- **Bacterial Hazards**

Bacterial hazards are defined as those bacteria that, if they occur in food, may cause illness in humans, either by infection or intoxication. Foodborne infections are caused by the ingestion of pathogens that grow within the body, usually in the intestinal tract. They differ from foodborne intoxication, which is a condition caused by the ingestion of toxins produced by microorganisms in the food.

Bacterial hazards can also be grouped into sporeformers and non-sporeformers. Certain types of bacteria (e.g. *Clostridium* and *Bacillus* spp.) pass through a dormant stage in their life cycle called a spore. Although the microorganism exists as a spore, it is very resistant to chemicals, heat and other treatments that would normally be lethal to non-sporeforming bacteria. Because they are dormant, spores are not hazardous as long as they stay spores. Unfortunately, if they survive a processing step designed to kill non-sporeforming bacteria, they may become a hazard in the food if they are allowed to grow. When sporeformers are a concern, the process steps used to control them are often much more severe than if only non-sporeformers need to be controlled.

- **Viral Hazards**

Like other microorganisms, viruses exist everywhere. They are very small particles that cannot be seen with a light microscope and cannot reproduce by themselves. Although they are alive, viruses differ from other microorganisms in what they need to live and how they multiply. Viruses exist in foods without growing, so they need no food, water or air to survive. They do not cause spoilage. Viruses cause illness by infection. They can infect living cells and reproduce inside the host cell using material from it. Viruses only grow once they enter a suitable host. Only some viruses consider humans a suitable host. Viruses can survive in human intestines, contaminated water and frozen foods for months.

Viruses can be found in people who were previously infected but are no longer ill. Viruses can also be present in people who show no outward signs of illness (carriers). Transmission of viruses to foods is usually related to poor hygienic practices. People who have viruses shed the particles when they defecate. Food handlers with viruses can transmit them to food if they forget to wash and sanitize their hands properly. This route can also result in contamination of food with bacterial hazards.

- **Parasitic Hazards (Worms and Protozoa)**

Parasites are organisms that need a host to survive, living on or within it. Thousands of kinds of parasites exist worldwide. Only about 20 percent can be found in food or water and less than 100 are known to infect people through consumption. There are two types of parasites that can infect people through food or water: parasitic worms and protozoa. Parasitic worms include roundworms (nematodes), tapeworms (cestodes) and flukes (trematodes). These worms vary in size from barely visible to several feet in length. Protozoa are single-cell animals and most cannot be seen without a microscope.

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For most foodborne parasites, the food is part of their natural life cycle (e.g. nematode worms in fish and meat). They have the opportunity to infect humans when people eat them along with the food. The two factors most important to parasitic survival are a proper host (i.e. not all organisms can be infected by parasites) and a suitable environment (i.e. temperature, water, salinity, etc.).

Some parasites may be transmitted through food or water that is contaminated by fecal material shed by infected hosts. Methods of preventing transmission of parasites to foods by fecal contamination include:

- good personal hygiene practices by food handlers
- proper disposal of human feces
- elimination of insufficiently treated sewage to fertilizer crops and
- proper sewage treatment.

Consumer exposure to parasites depends on food selection, cultural habits and preparation methods. Most parasites do not harm humans but may be aesthetically unpleasant. Parasitic infections are normally associated with raw or undercooked foods because thorough cooking of foods eliminates all foodborne parasites. In specific instances, freezing can be used to destroy parasites in food. However, consuming raw foods containing infective parasites can pose a hazard.

- **Chemical Hazards**

Chemical contaminants may be naturally occurring or may be introduced at any stage in food production and processing. Chemicals can be helpful and are purposefully used with some foods, such as pesticides on fruits and vegetables. Chemicals are not hazardous if properly used or controlled. Potential risks to consumers increase when chemicals are not controlled or the recommended treatment rates are exceeded. The presence of a chemical may not always represent a hazard. The amount of the chemical may determine whether it is a hazard or not. Some may require exposure over prolonged periods to have a toxic effect. Regulatory limits are set for some of those contaminants.

Chemical hazards can be separated into three categories:

1. Naturally occurring chemicals
2. Intentionally added chemicals
3. Unintentionally or incidentally added chemicals

1. *Naturally Occurring Chemicals (including allergens)*

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These chemicals are derived from a variety of plants, animals or microorganisms. In most cases, these naturally occurring chemicals are found prior to, or during, harvest. Although many naturally occurring toxins are biological in origin, they are traditionally categorized as chemical hazards.

Example:

The following are examples of foods containing naturally occurring chemical hazards:

Source	Why a hazard?
<i>Certain fish species</i> (e.g. tuna, mahi-mahi)	Spoilage of certain species of fish can result in production of toxic levels of histamine and related compounds.
<i>Nuts, Seafood</i>	Certain varieties or species produce an allergic reaction in sensitive people.
<i>Corn</i>	Certain molds that grow on corn can create toxins (e.g. aflatoxin).
<i>Molluscan shellfish</i>	Some of the microscopic organisms and plants upon which they feed produce a toxin, such as domoic acid, that affect people but not shellfish.

2. Intentionally Added Chemicals

These chemicals are intentionally added to food at some point during the food's growth and distribution. Intentionally added chemicals are safe when used at established safe levels but can be dangerous when those levels are exceeded.

Example:

The following are examples of food additives that may be chemical hazards if used improperly:

Source	Why a hazard?
<i>FD&C Yellow No. 5</i>	Can produce an allergic-type reaction in (food coloring) sensitive people.
Source	Why a hazard?
<i>Sodium nitrite</i> (preservative)	Can be toxic in high concentrations.

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Vitamin A
(nutrient supplement)

Can be toxic in high concentrations.

Sulfiting agents
(preservative)

Can cause allergic-type reaction in sensitive people.

3. Unintentionally or Incidentally Added Chemicals

Chemicals can become part of a food without being intentionally added. These incidental chemicals might already be in a food ingredient when it is received. For example, certain seafood may contain small, but legal, residues of approved antibiotics. Packaging materials that are in direct contact with ingredients or the product can be a source of incidental chemicals, such as sanitizers or inks. Most incidental chemicals have no effect on food safety and others are only a concern if they are present in too high an amount. Incidental chemicals also include accidental additions of prohibited substances such as poisons or insecticides that may not be allowed at any level.

Example:

The following are examples of incidental contaminants that may be chemical hazards:

Source	Why a hazard?
<i>Agricultural chemicals</i> (e.g. pesticides, herbicides)	Can be acutely toxic if present in the food at high levels and may cause health risks with long-term exposure.
<i>Cleaning chemicals</i> (e.g. acids, caustics)	Can cause chemical burns if present in the food at high levels.
<i>Maintenance chemicals</i> (e.g. lubricants, paint)	Chemicals that are not approved for food use and may be toxic.

• Physical Hazards

Physical hazards include any potentially harmful extraneous matter not normally found in food. When a consumer mistakenly eats the foreign material or object, it is likely to cause choking, injury or other adverse health effects. Physical hazards are the most commonly reported consumer complaints because the injury occurs immediately or soon after eating and the source of the hazard is often easy to identify. Physical hazards can result from product contamination or poor food handling procedures from the farm to the consumer, including those within the food establishment.

Physical Hazards can be controlled by:

- Preventing foreign objects from getting into food.

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- Using metal detectors or other techniques to detect hazards in food.

Types of materials that can be physical hazards in foods:

- *Metal or metal fragments* can get into food from food processing or handling equipment like saws or mixers that have metal blades, wire mesh conveyor belts, screens, can openers and portion control equipment. Other sources of metal fragments can come from buckshot, wire, staples, building materials and employees. Metal fragments can cause a variety of injuries to consumers such as cuts, punctures or broken teeth. This hazard is controlled by preventing or minimizing equipment malfunctions and using monitoring tools such as metal detectors when necessary.
- *Glass and other foreign material* can get into food from containers like glass jars, light bulbs that explode or other objects from the plant or plant workers. Glass and other materials can physically harm consumers by causing cuts, bleeding or choking. Preventing contamination is the most effective way to control these hazards and appropriate procedures are generally included in the plant's sanitation standard operating procedures.

The following are examples of materials that may be physical hazards:

Material	Why a hazard?
Glass	Cuts, bleeding; may require surgery to find or remove.
Metal	Cuts, broken teeth; may require surgery to remove.
Wood	Cuts, infection, choking; may require surgery to remove.
Bone	Choking, trauma
Plastic	Choking, cuts, infection; may require surgery to remove.

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Example List of Processing Hazards and Controls

The table below contains a list of processing hazards and controls commonly used in making meat and poultry products. They are listed in alphabetical order. (B=Biological hazard, C=Chemical hazard, and P=Physical hazard)

PROCESSING: EXAMPLES OF PROCESSING STEPS	B	C	P	DESCRIPTION OF BIOLOGICAL, CHEMICAL OR PHYSICAL HAZARDS FOR THE PROCESS STEPS	CONTROLS OR PREVENTIVE MEASURES
Acidifying or Brining	X			-Multiplication of pathogens due to final pH >4.6	-Shelf-stable, non-heat treated acidified product must obtain a pH of 4.6 or lower
Cooling	X			-Growth of pathogens due to improper temperatures -Germination of spore-forming pathogens due to slow chilling (e.g. <i>C. perfringens</i>)	-Cooked product will be cooled according to established procedures by a processing authority, scientific studies and/or regulatory requirements.
Cooking	X			-Survival of pathogens due to improper procedures	-Time/Temperature combinations are adequate to destroy the pathogens of concern
Drying (Meat)	X			-Bacterial growth due to inadequate control over time, temperature and humidity	-A water activity will be specified that in conjunction with other barriers will inhibit growth of pathogenic microorganisms e.g. for shelf-stable sausage A_w of 0.91 and a pH of 4.6

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PROCESSING: EXAMPLES OF PROCESSING STEPS	B	C	P	DESCRIPTION OF BIOLOGICAL, CHEMICAL OR PHYSICAL HAZARDS FOR THE PROCESS STEPS	CONTROLS OR PREVENTIVE MEASURES
Formulation	X			-Contamination by employee handling - Incorrect formulation -Contamination through damaged packages	-Careful employee practices used at all times to make sure that there is no contamination of product. This may be included as part of a plant's SSOPs or GMPs -Ingredient packages will be clean and intact -Ingredients will be added to product according to requirements.
		X		-Excessive addition of restricted ingredients/additives could be toxic to the consumer	-Restricted ingredients will be added to product according to requirements.
Freezing (Meats)	X			-Survival of parasites due to improper time/temperature application -growth of pathogens due to temperatures abuse	-Rapid cooling and freezing
Grinding	X			-Contamination by employee handling -Recontamination by pathogens in product accumulations	-Careful employee practices to make sure that there is no contamination of product. This may be included as part of a plant's SSOP's or GMPs. -Product will not be allowed to accumulate at the end of the grinder. -The temperature of the grinding room will be maintained at 50 degrees Fahrenheit.
		X		-Contamination from lubricants	-Food grade lubricants will be used on areas of the machinery where a potential for product contamination exists. This may be included as part of a plant's GMPs.
			X	-Contamination from extraneous material	-All boneless product will be reinspected before being loaded into the grinder.

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PROCESSING: EXAMPLES OF PROCESSING STEPS	B	C	P	DESCRIPTION OF BIOLOGICAL, CHEMICAL OR PHYSICAL HAZARDS FOR THE PROCESS STEPS	CONTROLS OR PREVENTIVE MEASURES
Handling and Inspecting of Empty Containers and Packaging Materials	X	X	X	-Recontamination through damaged or soiled containers/packaging material	-Packaging materials and empty containers will be protected from contamination during their storage and handling. -No materials or containers that appear to be contaminated with foreign material will be used.
Packaging (Modified Atmospheric Packaging, Vacuum Packaging, Sealing)	X	X		-Contamination from packaging material	-Ensure adequate barrier formation.
			X	-Contamination from metal clips or other foreign material resulting from the packaging process or equipment operation	-No detectable foreign material will be allowed in or on the product or immediate product containers.
Peeling	X			-Contamination by pathogens in product accumulations -Contamination from employee handling	-Careful employee practices to make sure that there is no contamination of product.* -Product will not be allowed to accumulate in/on peeling equipment.
			X	-Contamination from extraneous material	-Peeling equipment will be maintained in a proper operating condition.* -No foreign material in the finished product.
Receiving	X			-Contamination through damaged containers -Growth of pathogens due to inappropriate storage conditions (temperature, humidity) -Growth of pathogens due to temperature abuse -Contamination from receiving equipment (pumps, hoses)	-Product must be received in sound containers and at temperatures appropriate for the type of product.

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PROCESSING: EXAMPLES OF PROCESSING STEPS	B	C	P	DESCRIPTION OF BIOLOGICAL, CHEMICAL OR PHYSICAL HAZARDS FOR THE PROCESS STEPS	CONTROLS OR PREVENTIVE MEASURES
Receiving (cont'd)		X		-Cross-contamination from non-food chemicals	-Product must be received in sound containers and be accompanied by a letter of guarantee from the supplier if such letter is not on file. This may be included in the plant's GMPs.
			X	-Contamination from extraneous material (wood, nails from pallets, plastic pieces)	-Product must be received in sound containers. This may be included in the plant's GMPs.
Reworking	X			-Contamination by employee handling -Contamination from pathogen accumulations in product improperly stored, rework product or emulsion	-Careful employee practices to make sure that there is no contamination of product.* -Temperature of storage coolers will preclude microbial growth in and/or on product.
			X	-Contamination from foreign material	-Careful employee practices to make sure that there is no contamination of prdouct.*
Sale at Retail	X			-Growth due to temperatures inadequate to prevent excess microbial growth	-Product will not be sold unless it is at a temperature that precludes microbial growth.
			X	-Contamination from extraneous material introduced through damaged packages	-All product packages will be intact.
Thawing	X			-Growth of pathogens due to improper temperatures	-Thawing conducted according to requirements to prevent growth of pathogens.

*This may be included in a plant's SSOPs.

Prerequisite Programs

HACCP is *not* a stand-alone program but is one part of a larger system of control procedures. For HACCP to function effectively, it should be accompanied by prerequisite programs.

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HACCP systems are designed to prevent and control food safety hazards associated with food from the time a company receives raw material through production to distribution to the consumer. HACCP systems must be built upon a firm foundation of compliance with current Good Manufacturing Practices (GMPs) and acceptable sanitation standard operating procedures (SSOPs). GMPs and sanitation procedures affect the processing environment and should be considered prerequisite programs to HACCP.

The Good Manufacturing Practices define measures of general hygiene as well as measures that prevent food from becoming adulterated due to unsanitary conditions. The GMPs are broadly focused and encompass many aspects of plant and personnel operations. SSOPs are procedures used by food processing firms to help accomplish the overall goal of maintaining GMPs in the production of food. Typically, SSOPs describe a particular set of objectives associated with sanitary handling of food and the cleanliness of the plant environment and the activities conducted to meet them.

When SSOPs are well designed and fully and effectively implemented, they are valuable in controlling hazards. Identification of critical control points may be influenced by the effectiveness of a GMP program, including industry SSOPs. For example, SSOPs can help control bacterial hazards by specifying procedures to: 1) avoid product cross-contamination by proper product flow and limiting employee tasks and movement; 2) locate hand washing and sanitizing stations near the processing area to facilitate proper hand washing; 3) ensure appropriate equipment maintenance and cleaning and sanitizing procedures. SSOPs can likewise be used to help control chemical contamination from sanitizer and other chemicals found in food processing operations.

In some situations, SSOPs may reduce the number of critical control points in HACCP plans. Relegating control of a hazard to SSOPs rather than the HACCP plan does not minimize its importance or indicate lower priority. In fact, hazards are typically controlled effectively by a combination of SSOPs and HACCP critical control points. For instance, plant sanitation, employee hygiene and strict handling procedures are often as important for controlling *Listeria monocytogenes* in cooked food operations as the actual cooking and refrigeration steps that might be identified as critical control points in HACCP plans.

When SSOPs are in place, HACCP can be more effective because it can concentrate on the hazards associated with the food or processing and not on the processing plant environment. If sanitation controls are included as part of a HACCP plan, they must lend themselves to all aspects of a critical control point (CCP) such as establishing critical limits, monitoring, corrective actions, verification and recordkeeping procedures.

A Clean-in-Place (CIP) system for equipment is a good example of sanitation controls that could be handled as a CCP within a HACCP plan. A CIP system's effectiveness can be monitored, critical control points can be established, monitoring records can be maintained and appropriate corrective actions can be established when the critical limits are not met. On the other hand, a processor's pest control program should be included in its SSOP rather than its HACCP plan.

Even without HACCP, the level of plant sanitation and GMPs must comply with the law. Contrary to popular perception, sanitation control is not limited to cleaning equipment. Although clean

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equipment and a clean working area are essential for producing safe foods, so are personnel practices, plant facilities, pest control, warehouse practices and equipment and operation design. Each should be addressed in a complete written sanitation program designed to comply with existing regulations. An important component in any sanitation program is monitoring. Methods of monitoring sanitation practices will vary according to the type and size of a food processing operation. Typically, a checklist can be used to record conditions and sanitation procedures. The frequency of checks will vary to assure the SSOPs remain in control. For example, in certain processing plants, the safety of the processing water may be checked annually. However, the location of other plants may require more frequent inspection. Grounds around a plant may require monthly checks to discourage attraction of pests, but cooler storage areas and floor drains may need daily inspection. Multiple daily checks would be important for work surfaces, hand wash stations and employee attire.

Eight key sanitation conditions and practices:

- Safety of water
- Condition and cleanliness of food contact surfaces
- Prevention of cross-contamination
- Maintenance of hand washing, hand sanitizing and toilet facilities
- Protection from adulterants
- Labeling, storage and use of toxic compounds
- Employee health conditions
- Exclusion of pests

Most importantly, any correction necessary to maintain control of the SSOPs should also be documented so that it can accompany or be referenced to any noted problem. This corrective action is part of the SSOP records.

Examples of Common Prerequisite Programs

- **Facilities.** The establishment should be located, constructed and maintained according to sanitary design principles. There should be one direction product flow and traffic control to minimize cross-contamination from raw to cooked materials.
- **Supplier Control.** Each facility should ensure that its suppliers have in place effective GMP and food safety programs.

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- **Specifications.** There should be written specifications for all ingredients, products and packaging materials.
- **Production Equipment.** All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.
- **Cleaning and Sanitation.** All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place.
- **Personal Hygiene.** All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene.
- **Training.** All employees should receive training in personal hygiene, GMPs, cleaning and sanitation procedures, personal safety and their role in the HACCP program. Companies may wish to maintain records of employee training activities.
- **Chemical Control.** Documented procedures must be in place to assure the segregation and proper use of nonfood chemicals in the plant. These include cleaning chemicals, fumigants and pesticides or baits used in or around the plant.
- **Receiving, Storage and Shipping.** All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to ensure their safety and wholesomeness.
- **Traceability and Recall.** All raw materials and products should be lot coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.
- **Pest Control.** Effective pest control programs should be in place.

Other examples of prerequisite programs might include quality assurance procedures; standard operating procedures for sanitation, processes, product formulations and recipes; glass control; procedures for receiving, storage and shipping; labeling and employee food and ingredient handling practices.

Preliminary Steps in Developing a HACCP Plan

HACCP is often thought of in terms of its seven basic principles. However, it also includes preliminary steps. Failure to properly address the preliminary steps may lead to ineffective design, implementation and management of the HACCP plan.

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In preparation for developing a HACCP plan, a firm must have a solid foundation.

- ***HACCP Team Assembly***

Assembling a HACCP team is an important step in building a HACCP program. The team should consist of individuals with different specialties. The team may include personnel from maintenance, production, sanitation, quality control and laboratory. The HACCP team should include members who are directly involved with the plant's daily operations.

The team develops the HACCP plan, writes SSOPs and verifies and implements the HACCP system. The team should be knowledgeable about food safety hazards and HACCP principles. When issues arise that cannot be resolved internally, it may be necessary to enlist outside expertise.

Although one person may be able to analyze hazards and develop a HACCP plan successfully, many industries find it helpful to build a HACCP team. When only one person develops the HACCP plan, some key points can be missed or misunderstood in the process. The team approach minimizes risk that key points will be missed or that aspects of the operation will be misunderstood. It also encourages ownership of the plan, builds company involvement and brings in different areas of expertise.

In small companies, the responsibility for writing the HACCP plan may fall to one person. If it is possible to build a HACCP team in a small company, employees knowledgeable of various divisions, including owners, should be members. Universities, cooperative extension, consulting groups, model plans and published guidance can provide additional assistance.

- ***Description and Intended Use of Product***

Once a HACCP team is established, the members first describe the product, the method of distribution, the intended customer (e.g. general public, infants, elderly) and consumer use of the product (e.g. consumed without further cooking, heat-and-serve, cooked).

To adequately describe your products you need to think about and make a list of the various products that you handle or process as well as the various product forms for each of these species. You will use this list to properly identify all of the potential food safety hazards that could be associated with your products when you conduct your Hazard Analysis. Establishments such as full service wholesalers may handle 50 to 100 different products over the course of a year.

- ***Identify the Intended Consumers of Your Products***

The purpose of this step is to identify which products might be sold to consumers at higher risk from food borne illness.

Most firms who sell their products to retail stores or restaurants would identify the intended consumers of their products as the general public. For most healthy people in the general population, the risks associated with food borne illness are not likely to be life threatening.

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However, some groups of people are much more likely to experience complications from a food borne illness that could be life threatening.

Processors who sell their products to firms that serve special higher risk populations may need to add additional controls for some food safety hazards.

Examples of firms or organizations that serve higher risk groups include hospitals, clinics, nursing homes, elderly feeding centers, day-care centers, schools, etc. that serve the elderly, young children or people with acute or chronic illnesses that make them more susceptible to complications of food borne illness.

- ***Development and Verification of the Product's Flow Diagram***

A flow diagram shows in simple block or symbol form the steps required to manufacture and distribute a food product. This step provides an important visual tool that the HACCP team can use to complete the remaining steps of the HACCP plan development. Only a clear, simple, but complete description of the process is needed.

It is important to include all the steps within the facility's control, including receiving and storage steps for all raw materials. The flow diagram should be clear and complete enough so that people unfamiliar with the process can quickly comprehend your processing stages.

Since the accuracy of the flow diagram is critical to conduct a hazard analysis, the steps outlined in the diagram must be verified at the plant. If a step is missed, a significant safety issue may not be addressed.

The HACCP team should walk through the facility and make any changes required in the flow chart. The walk-through allows each team member to gain an overall picture of how the product is made. It may be helpful to invite additional plant personnel to review the diagram during the walk-through.

HAZARD ANALYSIS

The hazard analysis step is fundamental to the HACCP system. To establish a plan that effectively prevents food safety hazards, it is crucial that all significant safety hazards and the measures to control them be identified.

As previously stated, a hazard is a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. The term hazard, when used in the context of HACCP, is limited to safety.

- ***Considerations for the HACCP Team***

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During the hazard analysis, the potential significance of each hazard should be assessed by considering the likelihood of occurrence and severity. This is usually based upon a combination of experience, epidemiological data and information in the technical literature. Severity is the seriousness of a hazard.

During the hazard analysis, factors that may be beyond the immediate control of the processor must be considered. For example, product distribution may be beyond the direct control of your firm, but information on how the food will be distributed could influence how the food will be processed and/or packaged.

For some processors, the expertise necessary to properly assess the likelihood of occurrence and severity of the various hazards is available within the company. However, others may need to seek outside assistance to address this issue correctly.

The HACCP team has the initial responsibility to decide which hazards are significant and must be addressed by the HACCP plan. Keep in mind that there may be differences of opinion, even among experts, as to the significance of a hazard. The HACCP team may rely on available guidance materials and the opinions of experts who assist in the development of HACCP plans. During the hazard analysis, safety concerns must be differentiated from quality concerns.

Hazard Analysis

One approach to hazard analysis divides it into two activities – hazard identification and hazard evaluation. Hazard identification should result in a list of potential hazards at each operational step in the process from the receipt of raw materials to the release of the finished product. During hazard identification, the team need not be confined by the hazard's likelihood of occurrence or its potential for causing disease.

All potentially significant hazards must be considered.

After hazard identification, the team conducts a hazard evaluation: a three-step process in which the list of potential hazards developed during the hazard identification is narrowed to those hazards that are significant to the product and process in question.

The steps in hazard evaluation are:

1. Assess severity of health consequences if potential hazard is not properly controlled
2. Determine the likelihood of occurrence of potential hazard if not properly controlled and
3. Determine, using information from steps 1 and 2, if the potential hazard is to be addressed in the HACCP plan.

HACCP focuses solely on hazards that are **reasonably likely to occur and likely to result in an unacceptable health risk to consumers if not controlled**. Without this focus, it would be tempting to try to control too much and thus lose sight of the truly relevant hazards.

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- ***Hazard Analysis Worksheet***

A hazard analysis worksheet has been developed and can be used to organize and document the steps taken during the hazard analysis - it is shown below. The worksheet is currently being used by most of the seafood industry and the regulatory agencies, although it is not required by FDA. However, it does help to assure that you complete all steps in your hazard analysis and that the results are written down. This written document may come in hand if you are asked to discuss your decisions concerning a particular hazard. As you can see, there is a space at the top of the Worksheet to write down your firm's name and address, as well as the information gathered in the Preliminary Steps regarding the products, method of storage and distribution and intended use and consumers of your products.

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Hazard Analysis Worksheet

Firm Name: _____ **Product Description:** _____

Firm Address: _____ **Method of Storage and Distribution:** _____

_____ **Intended Use and Consumer:** _____

(1) Ingredient/ Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards significant? (Yes/No)	(4) Justify your decision for column 3	(5) What control measure(s) can be applied to prevent significant hazards?	(6) Is this step a critical control point? (Yes/No)
	Biological				
	Chemical				
	Physical				
	Biological				
	Chemical				
	Physical				

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Control Measures

Control measures are actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. In practice, control measures encompass a wide array of activities.

Examples of Control Measures

The following are examples of control measures that could be used to control the three types of hazards.

A. Biological Hazards

Bacteria

1. Time/temperature control (e.g. proper control of refrigeration and storage time minimizes the growth of pathogens)
2. Heating and cooking processes (e.g. thermal processing)
3. Cooling and freezing (e.g. cooling and freezing retard the growth of pathogenic bacteria)
4. Fermentation and/or pH control (e.g. lactic acid producing bacteria in yogurt inhibit the growth of some pathogenic bacteria that do not grow well in acidic conditions)
5. Addition of salt or other preservatives (e.g. salt and other preservatives inhibit growth of some pathogenic bacteria).
6. Drying (e.g. the drying process may use enough heat to kill pathogenic bacteria, but even when drying is conducted at lower temperatures, it may remove enough water from the food to prevent some pathogens from growing).
7. Source control (e.g. the presence or amount of pathogens in raw materials may be controlled by obtaining them from non-contaminated sources).

Viruses

1. Cooking methods (e.g. adequate cooking will destroy viruses).

Parasites

1. Dietary control (e.g. preventing the parasite from having access to the food. For example, infection from *Trichinella spiralis* in pork has decreased due to better control of pigs' diets and environments. However, this control method is not always practical for all species of animals used for food. The diet and environment of wild fish cannot be controlled, for instance).

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2. Inactivation/removal (e.g. some parasites are resistant to chemical disinfection but can be inactivated by heating, drying or freezing. In some foods, visual examination may detect parasites. A procedure called “candling” enables processors to examine fish on a brightly lit table. Over the light, worms, if present, are easy to see and remove. This procedure cannot ensure 100 percent detection. Therefore, it should be combined with other means of control, such as freezing for a specified amount of time.)

B. Chemical Hazards

1. Source control (e.g. vendor certification and raw material testing)
2. Production control (e.g. proper use and application of food additives)
3. Labeling control (e.g. finished product properly labeled with ingredients and known allergens)

C. Physical Hazards

1. Source control (e.g. vendor certification and raw material testing)
2. Production control (e.g. use of magnets, metal detectors, sifter screens, destoners, clarifiers, air tumblers and x-ray equipment)

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DETERMINE THE CRITICAL CONTROL POINTS

For every significant hazard identified during the hazard analysis there must be one or more CCPs where the hazard is controlled. The CCPs are the points in the process where the HACCP control activities will occur.

A CCP should be a specific point in the process flow where application of a control measure effectively prevents, eliminates or reduces the hazard to an acceptable level.

It may not be possible to fully eliminate or prevent a hazard. In some processes and with some hazards, minimization may be the only reasonable goal of the HACCP plan. For example, when producing a product that will be consumed raw or partially cooked, no lethal treatment may exist to eliminate a pathogen hazard or no technology may exist to detect and prevent a chemical or physical hazard. In these cases, it may be necessary to select CCPs that allow significant hazards to be reduced to acceptable levels.

Although hazard minimization is acceptable in some instances, it is important that all food safety hazards be addressed and that any limitations of the HACCP plan to control those hazards be understood.

- ***CCPs vs. Control Points***

Many points in the flow diagram not identified as CCPs may be considered control points. These may address control of quality factors such as color or flavor or non-HACCP regulatory requirements such as standards of fill. A HACCP plan can lose focus if points are unnecessarily identified as CCPs.

Only points at which food safety hazards can be controlled are considered to be CCPs. A tendency exists to control too much and to designate too many CCPs. A CCP should be limited to that point or those points at which control of the hazards can best be achieved. For example, a metal hazard can be controlled by ingredient sourcing, magnets, screens and a metal detector, all in one line. However, sourcing, magnets and screens would not be considered CCPs if the metal hazard is best controlled by use of metal detection and product rejection.

- ***Multiple CCPs and Hazards***

A CCP can be used to control more than one hazard. For example, refrigerated storage might be a CCP to control pathogen growth and histamine formation. Likewise, more than one CCP may be needed to control a hazard. In controlling pathogens in cooked hamburger patties, the cook and the patty-forming steps could both be identified as CCPs if cooking time is based on a maximum patty thickness.

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- ***CCPs are Product and Process Specific***

CCPs identified for a product on one processing line may be different for the same product on another line. This is because the hazards and the best points for controlling them may change with differences in:

- plant layout,
- formulation,
- process flow,
- equipment,
- ingredient selection and
- sanitation and support programs.

Although HACCP models and generic HACCP plans can be useful in considering CCPs, the HACCP requirements of each formulation and processing line must be considered separately.

- ***CCP Decision Tree***

The CCP decision tree is but one example of numerous other decision trees that have been developed to assist in the appropriate determination of CCPs.

Question 1. *Does a control measure(s) exist at this step or subsequent steps in the process flow for the identified hazard?*

If your answer is Yes, ask Question 2.

If you cannot identify a control measure in the process for the hazard, answer No. If the answer is No, then ask: Is control at this step necessary for safety? If this answer is No to, the step is not a CCP for that hazard. Move to the next hazard at that step or to the next step with a food safety hazard. If the answer is Yes, then you have identified a significant hazard that is not being controlled. In this case, the step, process or product must be redesigned to include a control measure. Sometimes there is no reasonable control measure available. In such cases, HACCP does not provide assurance that food products are safe.

Question 2. *Does this step eliminate or reduce the likely occurrence of a significant hazard to an acceptable level?*

To answer this question, consider if this is the **best** step at which to control the hazard? If the answer is Yes, then the step is a CCP; move to the next food safety hazard. If the answer is No, ask Question 3.

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Question 3. *Could contamination with an identified hazard or hazards occur in excess of acceptable levels, or could these increase to unacceptable levels?*

The question refers to contamination that exists, occurs or increases at this step. If the answer is No, then the step is not a CCP for that hazard. Move to the next hazard at that step or the next step with a food safety hazard.

If the answer is Yes, then ask the fourth question.

Question 4. *Will a subsequent step eliminate the identified hazard or hazards or reduce the likely occurrence to an acceptable level?*

If you answer No, then this step is a CCP. If you answer Yes, then this step is not a CCP for this hazard. In this case, be sure the hazard is controlled by a sequent processing step

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CCP Decision Tree Table

1. DO CONTROL MEASURES EXIST AT THIS STEP OR SUBSEQUENT STEPS FOR THE IDENTIFIED HAZARD?

YES

2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD TO AN ACCEPTABLE LEVEL?

YES

NO

3. COULD CONTAMINATION WITH IDENTIFIED HAZARDS OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS?

YES

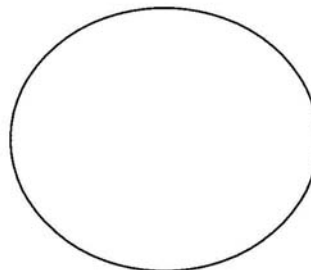
NO

NO

4. WILL A SUBSEQUENT STEP ELIMINATE IDENTIFIED HAZARDS OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL?

YES

**CRITICAL
CONTROL
POINT**



MODIFY STEP, PROCESS OR PRODUCT

NO

YES

IS CONTROL AT THIS STEP NECESSARY FOR SAFETY?

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HAZARD ANALYSIS WORKSHEET

(1) Ingredient/processing step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any potential food safety hazards significant? (Yes/No)	(4) Justify your decision for Column 3	(5) What control measure(s) can be applied to prevent significant hazards?	(6) Is this step a critical control point? (Yes/No)
	BIOLOGICAL:				
	CHEMICAL				
	PHYSICAL				

Firm Name: _____

Product Description: _____

Firm Address: _____

Method of Storage and Distribution: _____

Signature: _____

Intended Use and Consumer: _____

Date: _____

ESTABLISH CRITICAL LIMITS

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Critical limits must be established for each CCP identified in the hazard analysis.

A critical limit represents the boundaries that are used to ensure that an operation produces safe products. Each CCP must have one or more critical limits for each food safety hazard. When the process deviates from the critical limit, a corrective action must be taken to ensure food safety.

Establishing Critical Limits

In many cases, the appropriate critical limit may not be readily apparent or available. Tests may need to be conducted or information gathered from sources such as scientific publications, regulatory guidelines, experts or experimental studies.

Resources of Available Information

Scientific Publications

Critical limits can be established by reviewing scientific studies. Information on specific hazards, products and processes is available in scientific journals, food science textbooks, microbiology textbooks or other references. If you decide to use this type of information to establish your critical limits, you should keep the documents on hand at your processing facility.

Regulatory Guidelines

Federal tolerances, action levels and guidance levels are established for some of the most toxic and persistent contaminants that are found in food. Regulatory rules and guidelines established by state or local food inspection authorities should also be considered (i.e. NYS smoked fish regulations require 3.5% wps in vacuum packaged smoked fish).

Experts

Experts in a particular field can be used to help establish critical limits. For example, thermal process authorities, food scientists, microbiologists, trade associations, universities, Sea Grant or extension programs, consultants and equipment manufacturers are considered "experts" in their field.

Experimental Studies

Experimental studies can be conducted to determine critical limits for the unique equipment, processes and/or products that you process. These can involve in-house studies or may be studies done at a contract laboratory.

If the information needed to define the critical limit is not available, a conservative value should be selected. The rationale and reference material used to establish a critical limit should become part of the support documentation for the HACCP plan.

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Often a variety of options exist for controlling a particular hazard. The control options usually necessitate the establishment of different critical limits. The selection of the best control option and the best critical limit is often driven by practicality and experience.

Establishing Operating Limits

If monitoring shows a trend toward lack of control at a CCP, operators should take action to bring the CCP under control before the critical limit is exceeded. The point where operators take such an action is called the operating limit. Operating limits should not be confused with critical limits. Operating limits are established at a level that would be reached before the critical limit is violated.

The process should be adjusted when the operating limit is reached to avoid violating critical limits. These actions are called process adjustments. A processor may use these adjustments to avoid loss of control and the need to take corrective action. Spotting a trend toward loss of control early and acting on it can save product rework, or worse yet, product destruction. Corrective action is only required when the critical limit is exceeded.

Operating limits may be selected for various reasons:

- For quality reasons (e.g. higher cooking temperatures for flavor development or to control organisms that can cause spoilage).
- To avoid exceeding a critical limit (e.g. a cooking temperature higher than the critical limit could be used as an alarm point to warn the operator that the temperature is approaching the critical limit and needs adjusting).
- To account for normal variability (e.g. a fryer with a 5 F variability should be set at least 5 F above the critical limit to avoid violating it).

When a corrective action is necessary, processors must be able to identify and segregate the affected lots. If lot sizes are big, large quantities of product may require segregation and corrective action despite the fact that only a small amount of product was produced when critical limits were exceeded. Coding production into smaller lots means far less product may be involved when violation of a critical limit occurs. Therefore, wise processors should change codes often during the production day and match monitoring frequency with code changes.

Process Adjustments and Production Codes

A **Process Adjustment** is "an action taken by the firm to bring the process back within operating limits."

The process should be adjusted when the operating limit is reached to avoid violating the critical limit. These actions are called process adjustments. A processor may use these adjustments to avoid loss of control and the need to take corrective action. Spotting a trend toward loss of control early

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CRITICAL CONTROL POINT MONITORING

Introduction

In this Module we will learn about the 4th Principle of HACCP - **Monitoring**. In the last module we learned how to set critical limits for significant hazards at each of the CCPs. Now we need to figure out what monitoring procedures we will use to determine that our critical limits are consistently met.

What Is Monitoring?

The definition of monitoring is to conduct **a planned sequence of observations or measurements used to assess whether a CCP is under control. It is also used to produce an accurate record for future use in verification.**

Monitoring is the process that the operator relies upon to show control at a CCP. Accurate monitoring indicates when there is a loss of control and a deviation from a critical limit. When a critical limit is compromised, a corrective action is needed. Corrective actions will be discussed in the next Module.

A key concept in the monitoring definition is that monitoring procedures should be planned or determined prior to processing and should be chosen to demonstrate that the critical limit has been met. Monitoring can include observations and/or measurements of some value associated with the critical limit.

Let's look at an example where a CCP is established at cooler storage. Critical limits are set for both maximum cooler temperature and maximum time. The monitoring must then measure both the time and temperature of the cooler at a frequency adequate to show that the critical limit has not been exceeded.

Purpose of Monitoring?

The purpose of monitoring procedures is:

- To determine that the critical limit has been met.
- To identify when there is loss of control (a deviation occurs at a CCP).
- To track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments.
- To provide written documentation of the process control system.

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Design of a Monitoring System

To be effective, a monitoring system must be explicit. At this stage we have already identified **where** monitoring will take place - at the CCP.

We now need to identify:

- **What** will be monitored.
- **How** the critical limits and control measures will be monitored.
- **When** (how frequently) monitoring will be performed.
- **Who** will perform the monitoring.

What will be Monitored?

What is monitored must be directly related to the established critical limit. It may be a characteristic of the product or of the process that will demonstrate that the critical limit has been met. **What** is usually a **measurement** or **observation** to assess if the CCP is operating within the critical limit.

Examples of monitoring procedures that require a measure

- Measurement of cold storage temperatures when critical for temperature sensitive products. Hazards such as pathogen growth and histamine formation may have critical limits set for cooler temperature.
- Measurement of the pH of an acidifying ingredient when critical for the production of an acidified food.
- Measurement of conveyor belt or line speed when critical to adequate cooking or chilling processes.

Examples of monitoring procedures that require an observation

- Checking for adequate ice when critical to control pathogen growth or histamine formation.
- Checking the harvest area listed on a tag attached to a container of raw molluscan shellfish to ensure that they were harvested from approved waters.

How Critical Limits will be Monitored

When determining how to monitor you should select methods that provide real time and accurate results that will tell you if the critical limit has been met. There is no time for lengthy analytical testing because critical limit failures must be detected quickly and an appropriate corrective action instituted before the product is distributed.

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Physical and chemical measurements are preferred monitoring methods because testing can be done rapidly. Physical and chemical measurements could include product or process conditions such as pH, time, temperature, salinity, product size or thickness, etc.

Microbiological testing is seldom effective for monitoring CCPs. Very often the analytical methods are expensive and it may take several days or more to get test results. Additionally, large sample sizes are usually needed to do a statistically adequate job of finding pathogenic organisms at levels that may cause illness.

Monitoring Devices or Equipment

The selection of monitoring devices or equipment is a major consideration during development of a HACCP plan. Equipment used for monitoring CCPs varies with the attribute being monitored. Examples of monitoring equipment can include:

- Thermometers, thermocouples and continuous temperature recording devices
- Clocks, stop watches
- Scales
- pH meters
- Salimeter
- Water activity meters
- Rapid chemical tests

The equipment chosen for monitoring at the CCP must be accurate to ensure control of the hazard. The variability of the monitoring equipment should be considered when setting the critical limit. For example, if a minimum internal temperature of 145°F is necessary to kill pathogens in a product and the thermometer has an accuracy of $\pm 2^\circ\text{F}$, then the critical limit should be set no lower than 147°F. Periodic calibration or standardization is necessary to ensure accuracy.

When - Monitoring Frequency

A complete monitoring procedure includes the frequency of monitoring. The frequency can be continuous or non-continuous (intermittent).

Continuous Monitoring

Where possible, continuous monitoring should be used. Continuous monitoring is possible for many types of physical and chemical parameters. Let's look at some examples of continuous monitoring:

- The time and temperature of a batch pasteurization process for crabmeat may be continuously monitored and recorded on a temperature-recording chart.
- Each package of frozen cooked shrimp may be passed under a metal detector.
- Cooler or freezer temperature can be continuously monitored and recorded using a temperature-recording chart.

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A monitoring instrument that produces a continuous record of the measured value will not control the hazard on its own. The continuous record needs to be observed periodically and action taken when needed. This too is a component of monitoring. The length of time between checks will directly affect the amount of rework or product loss when a critical-limit deviation is found. In all cases, the checks must be performed in time to ensure that product is isolated before shipment when a critical limit deviation occurs.

Non-Continuous (Intermittent or Periodic) Monitoring

When it is not possible to monitor a CCP on a continuous basis, it is necessary for the monitoring interval to be short to detect possible deviations from critical limits or operating limits. The frequency of intermittent or periodic monitoring should be partially determined from historical knowledge of the product and process.

Questions that will help determine the correct monitoring frequency include:

- How much does the process normally vary (i.e. how consistent is the data)? If the data varies considerably, the time between monitoring checks should be short.
- How close are the normal values to the critical limit? If the normal values are close to the critical limit, the time between monitoring checks should be short.
- How much product is the processor prepared to risk if the critical limit is exceeded?

Some examples of potential periodic monitoring frequencies include:

- Measuring temperature of batter on a breading line at specified time intervals (e.g. every 2 hours).
- Measuring core temperature of a pasteurized product at specified time intervals (e.g. every 15 minutes).
- Checks of cooler storage temperatures at specified time intervals (e.g. every 2 hours during processing operations).

Who will Monitor?

To complete the monitoring procedure, you need to specify **who** will be responsible for monitoring. The person who conducts monitoring should be trained to perform that specific monitoring activity.

Assignment of the responsibility for monitoring is an important consideration when developing a HACCP plan. In most cases you will not want to identify an individual by name in the HACCP plan, but we will identify the individual's position such as a retort operator, quality control

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supervisor, etc. A number of different individuals may then be trained to conduct that monitoring activity on any given day.

Examples of the types of individuals who could be assigned to conduct CCP monitoring might include any one of the following:

- Line personnel
- Equipment operators
- Supervisors
- Maintenance personnel
- Quality assurance personnel

Factors to Consider in Determining "Who will Monitor"

Monitoring by line personnel and equipment operators can be advantageous since they are continuously viewing the product and/or equipment and can readily observe changes from the norm. Also, including line personnel in HACCP activities has the advantage of building a broad base of understanding and commitment to the HACCP program.

Those responsible for monitoring a CCP should:

- Be trained in the specific CCP monitoring techniques that will be used.
- Fully understand the importance of CCP monitoring.
- Have ready access to the monitoring activity.
- Accurately report each monitoring activity.
- Immediately report critical-limit deviations so that immediate corrective actions can be taken.

The monitor's duties should require that all unusual occurrences and deviations from critical limits be reported immediately to make sure adjustments and corrective actions are made in a timely manner. All records and documents associated with CCP monitoring must be signed or initialed by the person doing the monitoring.

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CORRECTIVE ACTIONS

What is a Corrective Action?

Corrective Actions are the "**procedures followed when a deviation occurs.**" In this case, a **deviation** is a "failure to meet a critical limit." So a corrective action describes the procedures that will be used when your monitoring shows that you have failed to meet a critical limit.

When monitoring shows that a critical limit deviation has occurred, a Corrective Action **must** be taken. In other words, the status and safe disposition of the product affected by the deviation must be determined and control of the process must be restored. It may be possible, and is always desirable, to correct the problem as soon as possible.

When critical limits are violated at a CCP, the predetermined, documented corrective actions should be instituted. These corrective actions should state procedures to restore process control and determine the safe disposition of the affected product. It may be possible, and is always desirable, to correct the problem on the spot.

Corrective action options include:

- Isolating and holding product for safety evaluation
- Diverting the affected product or ingredients to another line where deviation would not be considered critical
- Reprocessing
- Destroying product

The primary objective is to establish a HACCP program that permits rapid identification of deviations from a critical limit. The sooner the deviation is identified, the more easily corrective actions can be taken and the greater the potential for minimizing the amount of non-compliant product. An individual who has a thorough understanding of the process, product and HACCP plan and who has the authority to make decisions needs to be assigned the responsibility of making corrective actions.

Effective corrective action plans must:

- Correct and eliminate the cause of the noncompliance to assure that the CCP is brought back under control.
- Segregate, assess and determine the disposition of the non-compliant product.

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All corrective actions taken must be documented. Documentation will assist the firm in identifying recurring problems so that the HACCP plan can be modified. Additionally, corrective action records provide proof of product disposition.

Components of Corrective Actions

There are two components of corrective actions: 1) to correct and eliminate the cause of the deviation and restore process control and 2) to identify the product that was produced during the process deviation and determine its disposition.

- ***Correct and Eliminate the Cause of the Deviation and Restore Process Control***

Corrective actions must bring the CCP back under control. A corrective action should take care of the immediate (short-term) problem as well as provide long-term solutions. The objective is to implement a short-term fix so that control can be re-established and the process started again as soon as possible without further process deviation.

It may be necessary to determine the cause of the deviation to prevent future recurrence. A critical limit failure that was not anticipated or reoccurs should result in an adjustment to the product or process or a re-evaluation of the HACCP plan.

One outcome of the re-evaluation may be a decision to modify the HACCP plan. A permanent solution to eliminating or minimizing the initial cause or causes for the process deviation should be implemented if necessary. Specific instructions for corrective actions must be available to plant workers and should be part of the documented HACCP plan.

- ***Identify the Product that was Produced During the Process Deviation and Determine the Disposition***

When a deviation occurs, identify nonconforming product. There are four steps that may be used for determining product disposition and developing a corrective action plan.

Corrective Action Format Examples

Corrective actions are usually written in an “if/then” format. The “if” part of the corrective action describes the condition and the “then” part describes the action taken.

Corrective Action Records

Predetermined corrective actions are written into the HACCP plan. When critical limits are exceeded and a corrective action occurs, it is recorded. A corrective action report form is helpful.

The corrective action report should contain the following:

- Product identification (e.g. product description, amount of product on hold)

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- Description of the deviation
- Corrective action taken including final disposition of the affected product
- Name of the individual responsible for taking the corrective action
- Results of the evaluation when necessary

HACCP plan records should contain a separate file in which all deviations and corresponding corrective actions are maintained in an organized fashion. Corrective actions are recorded in column 8 of the HACCP plan form.

Determine Product Safety and Disposition

In summary, a corrective action plan should address both the process and the product by:

- **Correcting the problem** that caused the deviation using short-term and long-term solutions.
- **Identifying the product** produced during the critical limit deviation.
- **Determining if a food safety hazard exists.** If an expert's evaluation or testing shows that no hazard exists, the product may be released. Even if the product is released, both the critical limit deviation and the corrective action must be documented.
- If after an expert's evaluation or testing it is determined that a hazard exists or may exist, then you must **determine if the product can be reworked or diverted to another safe use.** Again, the corrective action must be documented.
- If the product cannot be reworked, reprocessed or diverted to another safe use, then the **product must be destroyed.** This is usually the most expensive option and is regarded as a **last resort.**
- If the critical limit deviation occurs at a receiving CCP, then the **product can simply be rejected.**

Corrective Action Format

Corrective Actions are usually written in an **"If/Then" format.** The **"If"** part of the corrective action describes the condition that caused the critical limit deviation. The **"Then"** part describes the action that must be taken. This action should describe how control of the process will be re-established and how the safety and disposition of the products affected by the deviation will be determined.

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Corrective Action Records

In a HACCP system, all Corrective Actions must be documented. The documentation will help the firm identify recurring problems so that HACCP Plan can be modified if necessary. It will also provide positive proof that corrective actions were taken when a Critical Limit deviation occurred.

A well-designed corrective action form can be used to provide the necessary documentation for critical limit deviations. The Corrective Action Report should contain the following information:

1. Date and time of the correction.
2. Product identification (e.g. product description, amount of product on hold)
3. Description of the Critical Limit deviation.
4. Corrective Action taken and final disposition of the affected product.
5. Name of the individual responsible for taking the corrective action.
6. Results of the safety evaluation (biological, physical or chemical test results and/or results of expert evaluation) when necessary.

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VERIFICATION PROCEDURES

Verification

One of the more complex HACCP principles is verification. Although it is complex, the proper development and implementation of the verification principle is fundamental to the successful execution of the HACCP plan. HACCP has spawned the use of a new adage – “trust what you verify,” which speaks to the heart of the verification principle. The purpose of the HACCP plan is to prevent food safety hazards and the purpose of verification is to provide a level of confidence that the plan is based on solid scientific principles, is adequate to control the hazards associated with the product and process and is being followed.

Perhaps one of the reasons verification has been difficult to understand is because there are several elements associated with this principle, including validation and reviews. Confusion also arises because the HACCP plan must include verification procedures for individual CCPs and for the overall plan. To facilitate understanding, each of these elements will be discussed.

- ***Validation***

Validation is an essential component of verification and requires substantiation that the HACCP plan, if implemented effectively, is sufficient to control the food safety hazards that are likely to occur. Validation of the plan occurs before the plan is actually implemented. The purpose of validation is to provide objective evidence that all essential elements of the plan have a scientific basis and represent a “valid” approach to controlling the food safety hazards associated with the specific product and process. There are several approaches to validating the HACCP plan, among them are: incorporation of fundamental scientific principles, use of scientific data, reliance on expert opinion or conducting in-plant observations or tests.

Validation can be performed by the HACCP team or by an individual qualified by training or experience. Validation activities may be similar in scope and time commitment to the original HACCP plan development. An in-plant validation should be performed initially before actual reliance on the HACCP plan and when factors warrant. These factors could include: changes to the raw materials, product or process; adverse review findings; recurring deviations; new scientific information about potential hazards or control measures; on-line observations; or new distribution or consumer-handling practices. Validation involves a scientific and technical review of the rationale behind each part of the HACCP plan from hazard analysis through each CCP verification strategy.

- ***Verification of CCPs***

Verification activities developed for CCPs are essential to ensure that the control procedures used are properly functioning and that they are operating and calibrated within appropriate ranges for food safety control. Additionally, CCP verification includes supervisory review of CCP calibration, monitoring and corrective action records to confirm compliance with the HACCP plan. CCP verification may also include targeted sampling and testing.

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- ***Calibration***

Verification activities at CCPs include calibration of monitoring devices to assure the accuracy of the measurements taken. Calibration is conducted to verify that monitoring results are accurate.

Calibration of CCP monitoring equipment is fundamental to the successful implementation and operation of the HACCP plan. If the equipment is out of calibration, then monitoring results will be unreliable. If this happens, the CCP should be considered out of control since the last documented acceptable calibration. This situation should be given ample consideration when establishing the frequency of calibration. Frequency of calibration should also be influenced by equipment sensitivity.

- ***Calibration Record Review***

Reviewing the equipment calibration records involves checking the dates and methods of calibration and the test results (e.g. equipment passing or failing). Calibration records are kept and reviewed. This review may be conducted as part of an audit.

- ***Targeted Sampling and Testing***

Verification may also include targeted sampling, testing and other periodic activities. Vendor compliance may be checked by targeted sampling when receipt of material is a CCP and purchase specifications are relied on as critical limits. Typically, when a monitoring procedure is not as stringent as desired, it should be coupled with a strong verification strategy.

When critical limits are set for equipment operation, product samples may be taken to ensure that the equipment settings are appropriate for product safety.

- ***CCP Record Review***

At least two types of records are generated at each CCP: monitoring and corrective action. These records are valuable management tools, providing documentation that CCPs are operating within established safety parameters and that deviations are handled in a safe and appropriate manner. However, records alone are meaningless unless someone in a supervisory capacity reviews them on a periodic basis to “verify” that the HACCP plan is being followed.

HACCP System Verification

In addition to the verification activities for CCPs, strategies should be developed for scheduled verification of the complete HACCP system. The frequency of the system-wide verification should be yearly (at a minimum) or whenever there is a system failure or a significant change in the product or process. The HACCP team is responsible for ensuring that this verification function is performed. Often, the HACCP team will contract an independent third party to conduct the system-wide verification activities.

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- ***System Verification Activities***

Systematic verification activities include on-site observations and record reviews. Reviews are usually performed by an unbiased person who is not responsible for performing the monitoring activities.

System verification should occur at a frequency that ensures the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

- **Determining When HACCP System Verification is Needed**

FDA's seafood HACCP regulation requires that a HACCP system verification be conducted at least once per year. This system verification may need to be conducted more frequently in the initial stages of HACCP plan implementation or if conditions in the operation change frequently. The frequency of this verification activity will likely change over time. A history of review findings that indicate that all CCPs are consistently in control may justify safely reducing the frequency. On the other hand, when adverse findings such as inconsistent monitoring activities, inconsistent recordkeeping and improper corrective actions are found, these problems should be corrected immediately and more frequent verification reviews should be scheduled to ensure that they do not reoccur. Adverse findings may indicate a need for subsequent validation of the HACCP plan. This process involves a technical review of the hazard analysis and each element of the HACCP plan to ensure that all relevant hazards have been accurately identified and controlled.

- ***End Product Microbiological Testing in HACCP Verification***

Microbiological testing is ineffective for routine monitoring but can be used as a verification tool. Microbiological testing can be used to determine (i.e. during verification audits) that the overall operation is under control.

The Role of Regulatory Agencies in HACCP Plan Verification

The major role of regulatory agencies in a HACCP system is to verify that HACCP plans are effective and are being followed. Verification normally will occur at the inspected facility; however, some aspects of verification may be conducted at other appropriate locations.

HACCP plans are unique documents prepared by a processor to ensure the control of a specific process or procedure. The plans may contain proprietary information and must be appropriately protected by the regulatory agency. Agency personnel must have access to records that pertain to CCPs, deviations, corrective actions and other information pertinent to the HACCP plan that maybe required for verification.

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

RECORDKEEPING PROCEDURES

Accurate recordkeeping is an essential part of a successful HACCP program. Records provide documentation that the critical limits have been met or that appropriate corrective actions were taken when the limits were exceeded. Likewise, they provide a means of monitoring so that process adjustments can be made to prevent a loss of control. They also document that the critical limits have been met and that appropriate corrective actions were taken when the critical limits were exceeded, as well as other components of the HACCP system. Likewise, they provide a means of monitoring trends so that adjustments or modifications to the process can be made as necessary to prevent loss of control.

Types of Records

1. HACCP Plan Support Documents

HACCP support documents include the information and data used to develop the HACCP plan. This includes the written hazard analysis worksheet and records of any information used in performing the hazard analysis and establishing the critical limits.

Support documents may include: sufficient data used to establish the adequacy of any barriers to bacterial pathogen growth, to establish the safe shelf life of the product (if age of the product can affect safety) and to establish the adequacy of a heating process in destroying bacterial pathogens. In addition to data, support documents may also include correspondence with consultants or other experts.

Support documents should also include:

- A list of the HACCP team and their responsibilities.
- A summary of the preliminary steps taken in the development of the HACCP plan.
- Prerequisite programs

2. Monitoring Records

HACCP monitoring records are primarily kept to demonstrate control at CCPs. HACCP records provide a useful way to determine if critical limits have been violated. Timely record review by a management representative ensures that the CCPs are being controlled in accordance with the HACCP plan. Monitoring records also provides a means by which regulators can determine whether a firm is in compliance with its HACCP plan.

By tracking the values recorded on monitoring records, an operator or manager can determine if a process is approaching its critical limit. Trends can be identified through record review to make necessary process adjustments. If timely adjustments are made before the critical limit is violated, processors can reduce or eliminate the labor and material costs associated with corrective actions.

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

Examples of CCP monitoring records may include:

- Storage temperature records for temperature-sensitive ingredients, in-process materials and finished products where temperature control is necessary to ensure product safety.
- Container seal examination records where the hermetic seal affects product safety.
- Salometer measurement records where salt brine is used to establish a barrier to bacterial pathogen growth in the finished product.

3. Corrective Action Records

Corrective action records as required for all CCP deviations.

4. Verification Records

Verification records should include:

- Modifications to the HACCP plan (e.g. changes in ingredients, formulations, processing, packaging and distribution)
- Processor audit records verifying supplier compliance with guarantees or certifications
- Verification of the accuracy and calibration of all monitoring equipment
- Results of microbiological challenge tests, environmental microbiological tests and periodic in-line and finished product microbiological, chemical and physical tests if applicable
- Results of in-house, on-site inspections and
- Results of equipment evaluation tests

Examples of verification records include:

- Temperature distribution studies for thermal processes
- Metal detector challenges
- Dud detector (used in canning industry) challenges

Record Monitoring Information

Monitoring information should be recorded at the time the observation is made. False or inaccurate records filled out before the operation takes place or ones that are completed later are inappropriate for a HACCP system.

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

Computerized Records

Computerized records are an option to recordkeeping. When using computerized records, include controls to ensure that records are authentic, accurate and protected from unauthorized changes.

Record Review

Monitoring records for CCPs and critical limit deviations must be reviewed in a timely manner by a representative of plant management. All records should be signed or initialed and dated by the reviewer.

The HACCP Plan Form

A Hazard Analysis Worksheet is used to record the results of the hazard analysis and identify the CCPs. Another worksheet called the **HACCP Plan Form** is used to develop the actual HACCP plan. An example of this form is shown on the following page.

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
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HACCP Plan Form									
Firm Name: _____				Product Description: _____					
Firm Address: _____				Method of Storage and Distribution: _____					
Intended Use and Consumer: _____									
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Records	Verification
			What	How	Frequency	Who			

Signature of Company Official: _____ Date: _____

The HACCP Plan form is divided into ten (10) columns. The information that you record in each column is:

- **Column 1:** List the CCPs that were identified in the hazard analysis. Each CCP is listed separately.
- **Column 2:** List each significant hazard that was identified in the hazard analysis at that CCP.
- **Column 3:** List the critical limit for each significant hazard.
- **Columns 4, 5, 6 and 7:** Describe the monitoring procedures (what, how, how often and who) for each critical limit.
- **Column 8:** Describe the corrective action procedure(s).
- **Column 9:** Describe what HACCP monitoring records will be kept.
- **Column 10:** Describe the verification procedure(s).

❖ **Model HACCP Plans**

Cooked Roast Beef
 Vacuum Packaged Hot Smoked Salmon
 Apple Cider

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

HACCP PLAN
(Cooked Roast Beef)

CCP	Hazard	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cooking	Pathogens	Temperature/Time 145°F internal temperature for 3 minutes.	Product Temperature	Measure Temperature at Geometric Center	Largest roast at end of every cook cycle	Deli manager	1. Identify & eliminate cause of deviation. 2. Bring the CCP under control after corrective action is taken. 3. Measures to prevent recurrence are established. 4. No product that is injurious to health or adulterated is sold.	Visual observation of employee conducting monitoring activities. Weekly calibration of temperature recording device.	Time/ Temperature Log Deviation/ Corrective Action Log Temperature Recording Device Calibration Log
			Time at specified temperature	Observe temperature for specified time.	Largest roast at end of every cook cycle.	Deli manager			
Cooling	Pathogens	During cooling, the product's maximum internal temperature shall not remain between 140°F and 70°F for more than 2 hours nor between 70°F and 41°F for more than 4 hours.	Product temperature	Recording thermometer	Largest roast of each lot.	Deli manager	1. Identify & eliminate cause of deviation. 2. Bring the CCP under control after corrective action is taken. 3. Measures to prevent recurrence are established. 4. No product that is injurious to health or adulterated is sold.	Weekly product temperature in cooler. Weekly calibration of temperature recording device.	Time/ Temperature Log Deviation/ Corrective Action Log Temperature Recording Device Calibration Log
			Time at specified temperature	Observe temperature during specified time intervals.	Largest roast of each lot.	Deli manager			

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

HACCP PLAN
(Cooked Roast Beef)

CCP	Hazard	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Display	Pathogens	Product internal temperature 41°F.	Product temperature	Recording thermometer	Several times each day	Dei manager	1. Identify & eliminate cause of deviation. 2. Bring the CCP under control after corrective action is taken. 3. Measures to prevent recurrence are established. 4. No product that is injurious to health or adulterated is sold	Daily product temperature in cooler. Weekly calibration of temperature recording device.	Time/ Temperature Log Deviation/ Corrective Action Log Temperature Recording Device Calibration Log

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
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HACCP PLAN FORM
(Vacuum Packaged Hot Smoked Salmon)

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4)			(6) Frequency	(7) Who	(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How						
Brining	C. botulinum toxin production in the finished product	a) Minimum 24 hour soaking time b) Minimum salt content of 60° salometer at start of process c) Minimum 2:1 ratio of brine to fish (weight to weight)	a) Time in brine b) Salt content of brine c) Weight of fish and brine	a) Visual time checks b) Salometer c) Weight of fish (scale) Weight of brine (calibrated mark on tank)	a) Each batch before removing fish b) Each batch at start of process c) Each batch	a) Production employee b) Quality control person c) Production employee	a) Hold longer in brine solution b) Add salt c) Adjust amount of fish or brine	a) Daily review record b) Study showing brining method provides at least 3.5 percent water phase salt	a) Processing record b) Processing record c) Processing record	
<i>Explanatory Note: In many cases, it will be necessary to control the drying step to achieve the desired water-phase salt content in finished product.</i>										
Smoking/ Cooking	Bacterial pathogen survival	Minimum internal temperature of fish of 145°F for 30 minutes	Fish internal temperature and time	Thermocouple probes in the three thickest fish in the coldest part of oven	Continuous with visual check at the end of each batch	Smoker operator	Recook, destroy or hold product and evaluate.	- Daily record review - Study identifying cold spot in the smoker - Calibration of the recording device at the beginning and end of each day - Quarterly testing of water phase salt content	Thermocouple recording chart	

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

HACCP PLAN FORM
(Vacuum Packaged Hot Smoked Salmon)

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4)				(7)		(8) Corrective Action(s)	(9) Records	(10) Verification
			What	How	Frequency	Who					
Vacuum/ Packing Labeling	Growth of proteolytic <i>C.</i> <i>botulinum</i>	Presence of appropriate label statement	Product label	Visual	Pre-operational checks	Packing supervisor			Reject packages without label statement and replace with appropriate packages.	Weekly record review	Rack room log
Cooler storage	<i>C. botulinum</i> (proteolytic) toxin production during storage	Maximum cooler temperature of 50°F	Cooler temperature	Recorder thermometer	Record continuously; check chart every 12 hours.	Quality control person			- Readjust cooler thermostat. - Hold and evaluate based on time and temperature of exposure.	- Daily record review - Weekly calibration of recording thermometer	Cooler temperature chart

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

HACCP PLAN FORM
(Apple Cider)

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) (5) (6) (7)			(8) Corrective Action(s)	(9) Verification	(10) Records
			What	How	Frequency	Who		
CCP 1 (chemical) Sorting	Patulin	No moldy, rotten apples (max. Patulin level of 50ppb)	Presence of rotten apples	Culling	Continual on inspection belts	Operator	Visual inspection of sorted apples by supervisor Record review and signature by trained HACCP coordinator	Sorting logs Visual inspection logs
CCP 2 (physical) Filtration	Materials other than Cider (MOCs)	No MOCs	Filter (100 mesh)	Visual inspection of filter integrity	Beginning and end of each batch filtration - prior to filling	Operator	Record review and signature by trained HACCP coordinator	Filter inspection logs
CCP 3 (biological) A. Pasteurize	Pathogens (<i>E. coli</i> 0157:H7)	Minimum of 160°F for a minimum of 6 sec.* or 11 sec. if more than 50% Red Delicious	Temperature and Time	Temperature recorder on pasteurizer at the end of holding time. Pump flow Flow diversion valve working properly	Continual recording At Start up At Start up	Operator Operator Operator	Monthly thermometer calibration Record review and signature by trained HACCP coordinator	Pasteurization logs Recorder chart Calibration records Flow rate log Flow diversion valve check log

*Reference: Splitstoeser et. Al. Heat Resistance of *Escherichia coli* 0157:H7 in Apple Juice. Journal of Food Protection. 59 (3):226-229.1995

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

HACCP PLAN FORM
(Apple Cider)

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4) (5) (6) (7)				(8) Corrective Action(s)	(9) Verification	(10) Recordkeeping
			What	How	Frequency	Who			
CCP 3 (biological) A. UV Treatment	Pathogens (<i>E. coli</i> 0157:H7)	14,000 uWatts ultraviolet light exposure	Uwatts of ultraviolet light exposure	Alarm error on unit for: UV lamps or ballast pump drive fault sensor failure	Automatic continual monitoring	Operator	Check error code for specific action Replace UV lamp or ballast Restart machine or replace pump Replace sensor	Self diagnostic check prior to start of processing run Record review and signature of processing records by trained HACCP coordinator	Operator log Print out from unit Validation form

SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035

Performance of HACCP Inspections

When conducting HACCP inspections, the major focus of the inspection is to be placed on the HACCP plan, its accuracy, and industry's compliance with it. The following guidelines apply to which deficiencies are to be scored as critical or general deficiencies. Additionally, Food Inspectors should complete a Report of Seafood/Juice HACCP Operations (FSI-891) so we can maintain a data base of HACCP operations.

Inspection Scoring

“Specialized food processing requiring a HACCP Plan”

Critical Deficiencies

5B/24A – Establishment lacks required **HACCP Plan for [product].**

5B/24B – Significant (biological, chemical, physical) hazard(s) associated with [product] is/are not identified on HACCP Plan.

5B/24B – Critical Control Point(s) – CCP(s) – for (biological, chemical, physical) hazard(s) not identified in HACCP Plan.

5B/24B – Inadequate or no Critical Limit(s) are established for CCP(s).

[Critical Limit: A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.]

5B/24B – Establishment is operating outside critical limit(s).

5B/24B – Required monitoring of CCP(s) is inadequate or not performed.

- A) Monitoring equipment is not available or operating accurately.
- B) Monitoring intervals are inadequate or not in accordance with HACCP plan
- C) Monitoring is not performed by appropriate personnel.
- D) Required monitoring records are not available.

5B/24B – Inadequate or no record of corrective action(s) available based on deviation from critical limit(s).

- A) Affected products are not isolated for safety evaluation.

**SANITARY INSPECTIONS
HACCP (HAZARD ANALYSIS CRITICAL CONTROL POINT)
SUB-SECTION 2035**

- B) Affected products are not properly diverted or reprocessed.
- C) Record of final disposition for affected product not accomplished.

5B/24B – Required verification activities are not performed..

[Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that verify the system is operating according to the plan.]

Inspection Scoring

“Specialized food processing requiring a HACCP Plan”

General Deficiencies

13A/24C – HACCP training requirements are not met.

- A) The establishment lacks proof of HACCP training for required individuals.
- B) Weekly review, signing and dating of CCP monitoring records is not being conducted by a person trained in HACCP principles.
- C) Establishment lacks HACCP trained individual for record review and plan revision.

13A/24C – Other required records are not maintained or complete.

Records do not include all required information.

- A) Records not completed at time of activity.
- B) Records not signed or initialed by operator or observer.
- C) Records not retained for specified periods of time.
- D) Records not available for review.

13A/24C – Verification is not conducted in accordance with HACCP plan.

13A/24C – HACCP plan review and/or revision not performed at adequate intervals.

13A/24C – Juice manufacturer lacks hazard analysis and/or written SSOP's.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SANITARY INSPECTIONS
VARIANCE/ALTERNATIVE PROCESS REQUESTS
SUB-SECTION 2040**

VARIANCES

Lack of water, a service sink, toilet and handwash facilities within a food handling establishment constitute violative conditions and should be reported as such on the Sanitary Inspection Report. However, the operator may request an exemption, PROVIDED the Inspector has determined that an alternate source of water, toilet, handwash facilities and waste water handling procedures are conveniently located, easily accessible and satisfy the requirements set forth in Section 261 and Part 271 of 1NYCRR.

When the Inspector has determined the alternate facilities satisfy the requirement cited above and are within the parameters of the **VARIANCE GUIDELINES** listed below, he/she may grant such a variance.

VARIANCE GUIDELINES

Facilities/Equipment Variances

A Facilities/Equipment Variance Request form (FSI-855, Attachment 1) is to be completed by the Inspector and forwarded for comment by the Zone Supervisor and Region Chief Inspector. The form is then forwarded to the Central Office for approval. Facilities/Equipment Variances include variance numbers 1-5 and 0.

1. Water Supply: Drop ship or other warehouses, handling only cased, packaged foods where personnel spend only limited time, may request an off-premise water supply variance.
2. Service Sink: Retail food stores using a working toilet to dispose of wastewater may apply.
3. Off-Premise Toilet with Handwash Facilities: Establishments handling only packaged food products may request a variance, provided the off-premise facility is accessible to employees during hours of operation. If not, the variance will be revoked.
4. Handwash Facility: A handwash sink in a toilet facility may substitute for a handwash sink in a processing area if **all** of the following criteria is met:
 - A. The establishment's processing operations are restricted to only low volume manufacturing of cold sandwiches, making peanut butter, roasting or repacking nuts, repacking dry fruit or repacking grain.
 - B. No more than three (3) employees are present in the establishment at any one time.
 - C. The establishment has adequate equipment wash facilities (at least a two-compartment sink).

SANITARY INSPECTIONS
VARIANCE FROM REQUIRED FACILITIES AND CONTROLS
SUB-SECTION 2040

D. The toilet facilities are suitably equipped for handwashing and in the Inspector's view, in close proximity and convenient to the processing area.

5. One Bay of a Three-Bay Sink: Retail food stores may request a variance to use one bay of a three-bay sink for a handwash facility, provided, the handwash sink is posted and adequate soap and a hand-drying device is available.
0. Other: This category covers situations other than the foregoing and the Inspector feels that the condition may warrant a variance. The Inspector must follow the guidelines as outlined in the third paragraph of this section.

Note: Before considering a category No. 0 variance the Inspector shall contact the Food Safety Compliance Unit for approval.

PROCESSING VARIANCES

6. Processing Variance Request: The Department may approve a processing variance by modifying or waiving the requirements of a selected part9s0 of the Retail Food Store Sanitation Regulations, Article 17, Part 271, if in the opinion of the Department a health hazard or nuisance will not result from the approval. If the processing variance is approved, the Department shall retain the information in its records for the food establishment.

Before a Processing Variance Request from a requirement of the Retail Food Store Sanitation Regulations is approved, the information provided by the person requesting the Processing Variance shall be submitted on a form approved by the Department (including or limited to Department form FSI-855a and FSI-855b, Attachments 2 and 3, Processing Variance Request) and shall include:

- (a) A statement of the proposed processing variance citing the relevant section numbers.
- (b) An analysis of the rationale for how the potential public health hazards and/or insanitary conditions addressed by the relevant sections will be alternatively addressed by the proposal.
- (c) A HACCP plan, if required as specified under the Section 271-2.23 or Section 271-2.24 of the Retail Food Store Sanitation Regulations. The plan must include the information specified under Section 271-9.6 and/or supporting studies and scientific data relevant to the request.

All Processing Variance Requests will be filed first through field supervisory staff for comment and recommendation. Upon completion they are to be submitted to the Albany office for final approval.

SANITARY INSPECTIONS
VARIANCE FROM REQUIRED FACILITIES AND CONTROLS
SUB-SECTION 2040

7. Curing and Smoking Meats: Retail food stores may request a variance to cure and/or smoke meats. Before a variance to cure or smoke meats is approved, the applicant must submit a Processing Variance Request form (FSI-855) as described in exemption guideline No. 6.

The applicant must also meet the requirements for cured and/or smoked meats in Section 14, Sub-section 6050 – Scheduled Process/Variance/Recordkeeping Requirements.

8. Specialized Vacuum Packaging: Retail food stores may request a variance to vacuum package foods in a manner which does not meet the requirements as specified under Section 271-2.24 of the Retail Food Store Regulations. Before a variance to vacuum package foods in such a manner is approved, the applicant must submit a Processing Variance Request form (FSI-855) as described in exemption guideline No. 6.
9. Processing of Game Animals: Retail food stores may request a variance to process game animals. Before a variance to process game animals is approved, the Inspector must submit a completed Game Animal Custom Processing Variance for Retail Food Stores form (FSI-856, Attachment 4) through field supervisory staff for approval. Upon completion they are to be submitted to the Albany Office.

**SANITARY INSPECTIONS
VARIANCE FROM REQUIRED FACILITIES AND CONTROLS
SUB-SECTION 2040**

FSI-855 (6/06)

New York State Department of Agriculture & Markets
Division of Food Safety & Inspection
10B Airline Drive
Albany, NY 12235

DATE: _____

EST # _____

FACILITIES/EQUIPMENT VARIANCE REQUEST

OWNER _____

TRADE NAME _____

STREET _____

CITY _____

ZIP _____

COUNTY _____

VARIANCE TYPE

☐

1. WATER SUPPLY

☐

3. OFF PREMISES TOILET w/ HANDWASHING FACILITY

☐

5. ONE BAY OF 3 BAY SINK

☐

2. SERVICE SINK

☐

4. OFF PREMISES HAND WASH FACILITY

☐

0. OTHER

☐

I recommend that this request not be granted.

☐

I recommend that this request be granted with the following conditions:

Name Supervisor _____
Signature

Name Chief _____
Signature

CENTRAL OFFICE APPROVAL:

Name Title _____
Signature

SANITARY INSPECTIONS
VARIANCE FROM REQUIRED FACILITIES AND CONTROLS
SUB-SECTION 2040

Attachment #2

FSI-855a (1/06)

DATE: _____

New York State Department of Agriculture & Markets
Division of Food Safety & Inspection

VARIANCE REQUEST # _____

EST # _____

PROCESSING VARIANCE REQUEST

OWNER _____

TRADE NAME _____

STREET _____

CITY _____

ZIP _____

COUNTY _____

VARIANCE REQUEST DESCRIPTION: A statement of the proposed Processing Variance citing specific part and section numbers.

RATIONALE FOR VARIANCE: An analysis of the rationale for how the potential public health hazards and insanitary conditions addressed by the relevant sections will be alternatively addressed by the proposal.

SUPPORTING ATTACHMENTS:

☐

HACCP PLAN (See Section 271-9.6: Contents of HACCP Plan)

☐

SUPPORTING STUDIES / DATA

NAME

TITLE

SIGNATURE

SANITARY INSPECTIONS
VARIANCE FROM REQUIRED FACILITIES AND CONTROLS
SUB-SECTION 2040

Attachment #3

FSI-855b (1/06)

DATE: _____

New York State Department of Agriculture & Markets
Division of Food Safety & Inspection

VARIANCE REQUEST # _____

EST # _____

PROCESSING VARIANCE REQUEST

OWNER _____

TRADE NAME _____

STREET _____

CITY _____ ZIP _____ COUNTY _____

☐ I recommend that this request not be granted:

☐ I recommend that this request be granted with the following conditions:

Remarks:

NAME SUPERVISOR: _____ SIGNATURE

CENTRAL OFFICE APPROVAL:

☐

VARIANCE GRANTED

☐

VARIANCE IS NOT GRANTED

NAME TITLE SIGNATURE

SANITARY INSPECTIONS
VARIANCE FROM REQUIRED FACILITIES AND CONTROLS
SUB-SECTION 2040

Attachment #4

FSI-856 (1/06)

New York State Department of Agriculture and Markets
Division of Food Safety and Inspection
10B Airline Drive
Albany, New York 12235

GAME ANIMAL CUSTOM PROCESSING VARIANCE
FOR RETAIL FOOD STORES

Owner: _____ Date:

Trade Name: _____ Est No.

Address: _____

1. What type of game animals will the firm be processing? _____
2. How will the game animal carcasses be received: Whole _____ Parted _____ Both _____
3. What are the planned processing activities? (Check all that apply)
Cut-up _____ Grinding _____ Sausage making _____ Cooking/Smoking _____
Other _____ (describe in detail)
4. During what months will the processing of game animals take place? _____
5. At what time of day does the game animal processing generally take place? _____
6. At any time does the firm shut down to process game animals only? Yes _____ No _____
If Yes, when? _____
7. Does the firm have ample space to accommodate planned game animal processing operations?
Yes _____ No _____

Inspection Conducted ☐ _____ Food Inspector – I.D. # _____

Inspector's Recommendation:

Grant Variance _____ Do Not Grant Variance _____
Comments:

Supervisor's Approval:

Variance Granted _____ Variance Not Granted _____

Name	Supervisor/Chief	Signature

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SANITARY INSPECTIONS
OCR (OPERATION CHANGE REPORT)
SUB-SECTION 2045**

GENERAL INFORMATION

The Operation Change Report is the method used by Division field personnel to provide accurate and timely establishment information to the Central Office in Albany. This information is important to properly communicate with the establishment in the performance of our regulatory functions.

It is imperative that all Inspectors continually review establishment information and operations and report changes promptly and accurately.

Whenever the Inspector observes a change in the current establishment information or operations from that listed in the current establishment printout, or notes errors or omissions in establishment information documents provided by the Central office (printouts, memos, legal papers, etc.), an OCR is to be submitted.

Presently this information is forwarded to the Central Office electronically via OCR email.

OPERATION CHANGE REPORT

Note: All numbering and lettering in this section correlates with the Operation Change Report example form, Exhibit #1.

- A. Address Correction: Enter the date, the establishment number and the new, corrected or modified address information in the affected section (i.e.: correcting a number in ZIP Code, Street Number, P.O. Box or adding a P.O. Box #).

Make an entry in “Remarks” if it will clarify the modification (i.e.: 911 address change or street re-named, etc.).

Note: When an establishment physically moves, submit a “New Business/Out of Business OCR”. A new establishment number will generally be assigned.

- B. Operation Change: An “Operation Change” would be any information changes not directly and clearly attributable to one of the other categories in the OCR section.
- C. Owner Change: Check this box, enter the date, the establishment number and the new, corrected or modified owner's name. List the prior owner's name and explain the changes in the “Remarks” section.

Owner changes may include: Correcting spelling, changing a maiden name to a married name or modifying a corporate name (must mail a copy of the Cer-

SANITARY INSPECTIONS
OCR (OPERATION CHANGE REPORT - FSI-151)
SUB-SECTION 2045

tificate of Corporate Amendment or a similar official document). If the ownership name was incorrect a full explanation is required along with documents or statements from the owner in the "Remarks Section".

1. County – Enter County Code
2. Social Security Number or Tax Payer ID's 9 digits, unless it has a temporary filing (TF) status, than it is 7 digits.
3. Owner's Name: - There are three common forms of establishment ownership:

A. Sole proprietorship (one person)

Enter the LAST NAME, first name, middle initial; i.e., Jones, John E.; Sanchez, Jose B.; Hussien, Ali A.

B. Partnerships (two or more persons)

Enter the last names, first names, middle initial as given, (not necessarily in alpha order) i.e., Corbin, Paul E. & Brown, Allen P. If the partners names are too long to fit into the spaces provided enter the last name and the initial of the first name. List the correct full names of all partners in the "Remarks Section".

C. Corporations (can be listed as Jones, Inc., Jones Corp., Jones Ltd., or, Jones, LLC.)

List the Corporate name exactly as it appears on the Corporate Seal or other official document. If "The" is the first word of a corporate name, put it at the end (i.e., Jones Corp., The).

Any ownerships differing from the above (such as religious groups) should be discussed with your Supervising Inspector before being submitted.

Note: Most cultures write/give the first name first and the family name (surname, last name) second. Most Asians write/give the last name first. This often causes confusion and results in incorrect entries. Be sure to carefully ascertain that the last name is properly entered as the last name. Asian names containing a Christian given name are to be entered last name first; (i.e., Choy, John).

4. Trade Name:

A. Trade names must be entered as they normally appear, EXCEPT: put "The" at the end of the name; i.e., Country Store The.

B. Enter the store number after the trade name; i.e., A & P 105.

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OCR (OPERATION CHANGE REPORT - FSI-151)
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C. Do not use terms such as “T/N” or “D/B/A” in the trade name line.

5. Street:

- A. The street address indicates the actual physical location of the inspected establishment.
- B. If a box number is used; a street, road or RD number must also be used to indicate the establishment's physical location.
- C. Standard abbreviations should not be used for the full name of the street; (i.e., 25 Fort St. NOT 25 Ft. St).
- D. Write a number and alpha together if it occurs; (i.e., 12A 5th Ave).
- E. Acceptable abbreviations are: North = N, South = S, East = E, West = W, Route = Rt, Street = St, Avenue = Ave, Parkway = Pkwy, Boulevard = Blvd, Lane = Ln, Terrace = Ter
- F. Do not abbreviate in cases such as: 261 Avenue U or 10 East St: (NOT 261 Ave U or 10 E St).
- G. Write location names or abbreviations (Street/St, Avenue/Ave etc.) after a location number and suffix; (i.e., use 92 6th St., not 92 6th).
- H. “Mailing Address” - See #9.

6. City:

- A. In New York City use Borough listings for “city” entries EXCEPT Queens where the Post Office areas should be used, i.e., Flushing, Woodhaven, Jackson Heights, etc., otherwise, New York for Manhattan Borough, Staten Island for Richmond, Brooklyn for Kings.
- B. If the city name includes a “direction”, write it out in its entirety: i.e., Northville, Southampton.
- C. If the city name contains a connecting word, write it in its entirety, without hyphens, i.e., Castleton on Hudson.

7. ZIP Code: - Five numeric digits must be entered.

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8. Telephone: - Enter the area code and 7 digit number without hyphens. Do not enter "1" before the area code.
9. Mailing Address: If the establishment has a separate mailing address such as, PO Box, etc., write it in the "Remarks Section" and enter #### (four pound signs) after the physical street location on Line 6.
10. Fax: If firm has a fax machine, enter the area code and 7 digit number without hyphens. Do not enter "1" before the area code.
11. E-mail: Enter as -----@aol.com For example: SmithJohn@aol.com
12. Relationship of new to prior owner: Father, Mother, Son, etc.
13. A & B. OOB/Replaces Establishment
14. Indicator of Potential Hazard (IPH): Refer to the IPH Categories and Inspection Rate.
15. Type: Refer to the back of the OCR form (Exhibit #1A) to determine the establishment type(s). If it is a single operation such as a "Bakery", enter a single letter, (i.e. "B") in the left most box. If there are two or more operations, enter a "J" in the left most box followed by the designating letters in alpha order, i.e., JABC. Refer to Establishment Type Definitions (Exhibit #1C). Do not leave spaces between letters nor use punctuation marks. Establishment Type Codes that relate to an Agriculture and Markets License shall only be assigned when the establishment requires that License (Exhibit #1D). For an Establishment type "G," always list with type "C" so that the 20-C License can be sent to the Processing Plant. Retail food stores that require an Article 28-A license, should be entered or are to be entered as an "A3".
16. Codes: Processing Operations, Food Storage and Commodities: Refer to the back of the revised OCR to determine the Activity and Commodity Codes. Enter the code or code combination(s) in the boxes without hyphens, i.e., A06, E41, G35, X13.

Approved food processes or those being planned will be explained in the memo section of the Sanitary Inspection Report and when acceptable, these process codes will be added via the OCR and reported on a Sanitary Inspection Report.

Provide information on commodities in storage for Establishment Type Codes: D (Food Warehouse), I (Refrigerated Warehouse), L (Produce Refrigerated Warehouse), N (Wholesale Packer), O (Grower Packer/Broker, Storage) and if applicable, Z (Farm Products only).

SANITARY INSPECTIONS
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When recording the X-Storage code with a commodity identity code on the OCR it is important to list the most potentially hazardous food commodities first, then those that make up the majority of the foods in storage. In a case such as a supermarket distribution warehouse where many types of food commodities are stored, identify the predominate products and hazardous foods in the first five spaces, then enter X-67 - (General Commodity Storage), thus providing information on the wide variety of foods stored at this facility.

For multiple type establishments such as a "JACD", the codes entered shall first show processing operations, then storage commodities. For N (Wholesale Packers) or O (Grower Packer Broker/Storage), enter the codes that represent the activity(s) conducted, i.e., N63 (packing onions), N64 (packing lettuce), R39 (waxing vegetables), X60 (storage of apples). An OCR shall be submitted showing these activity and commodity codes whenever the actual activities being conducted differ from that which shows on the Inspection Rate Printout or Establishment List.

17. Water Supply: Check the type(s) of water supply(s) this establishment is on. Private certificate on file – If the establishment is on a private water supply, check the appropriate box.
18. Coliform Certificate Date: Enter the date of the water certificate, i.e. 02/04/95. If the certificate is more than 1 year old, see "Critical Deficiencies, Item 1-B".
19. Variance Granted: If granting a variance, refer to the back of the OCR form for the appropriate variance code number(s) and review Sub-Section 2040, "Variance from Required Facilities and Controls." Enter the variance number(s) in the box(s). Explain in "Remarks" section. Variance 6 through 9 can only be entered by Central Office.
20. Date of Nitrate Test: Yearly
21. Date of Nitrite Test: One time or initially for new businesses
22. Usual Days of Operation: Enter "1" under the days of operation an inspection could be conducted.
23. If Seasonal, Months Operated: If the establishment operates seasonally, print the month-from to month-to, using numbers only. Put a zero in front of single-digit months, i.e., from 04 to 09.
24. Hours of Operation: Immediately following this statement on the OCR form, enter the normal hours of operation, i.e., 9:00AM-5:00PM. For establishments open 24 hours a day, enter "12:00 A to 12:00 A."
25. Full-time - Part-time : Fill in the number of full and part-time employees.

SANITARY INSPECTIONS
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26. Checkouts : Enter the number of checkout counters in the establishment.
27. Square feet : Fill in the approximate square footage of the establishment.
28. Scanners: Enter “1” if the establishment has any scanners at checkout counters. If not, check “no”.
29. Chain Store: If a chain store, put a check. If not, leave blank.
30. Unit Pricing Required: Check appropriate box.
31. Eggs in Establishment: Check appropriate box. Available at Retail.
32. Produce in Establishment: Check appropriate box. Available at Retail.
33. Name of Person Interviewed: Print the first and last name and title of the person interviewed.
34. Remarks: Enter clear, concise statements in the “Remarks Section” when required, appropriate or helpful (i.e. other firms at this address, location change, name change only, explain relationship to prior owner, etc.)

SANITARY INSPECTIONS
OCR (OPERATION CHANGE REPORT - FSI-151)
SUB-SECTION 2045

EXHIBIT #1

Establishment OCR to E-mail			
SSN or Taxpayer ID: 2		County: 1	
Owner Name: 3 Trade Name: 4 Street: 5 City: 6 Zip: 7 Phone: 8		OOB Date 13 A Replaces Estab No. 13 B	
		Establishment Types	
		IPH 14 15	
		Processing Operations, Food Storage and Commodities	
		Water Supply	
Mailing Address Attn: 9 Addr Ln1: Addr Ln2: City: State: Zip: Fax: 10 Email: 11 Relationship of New to Prior Owner: 22 Days of S M T W T F S Operation: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ Seasonal Operation 23 - Operation Hours Employees Check Outs 26 From 24 Full Time 25 To Part Time Sq.Ft. 27 Scanners? ☐ 28		1 16 2 3 4 5 6	
		☐ Municipal ☐ NPWS 17 ☐ PWS ☒ None ☐ Treated NPWS	
		Coliform Date 18	
		Variance 19	
		Nitrate Date 20	
Nitrite Date 21			
Chain Store? ☐ 29 Eggs? ☐ 31 Unit Price Required? ☐ 30 Produce? ☐ 32		Person Interviewed: 33 Title:	
Remarks: 34			

SANITARY INSPECTIONS
OCR (OPERATION CHANGE REPORT - FSI-151)
SUB-SECTION 2045

FSI-151 BACK (Rev. 11/05)

ESTABLISHMENT CODES, ESTABLISHMENT TYPES AND LICENSE OR FEE ARTICLES			
<u>EST. CODES & TYPES</u>	<u>ARTICLES</u>	<u>EST. CODES & TYPES</u>	<u>ARTICLES</u>
A(3)-Store	28-A	N - Wholesale Produce Packer	
B - Bakery	20-C	O - Produce Grower/Packer/Broker, Storage	
C - Food Manufacturer	20-C	P - C.A. Room	
D - Food Warehouse	28-D	Q - Feed Mill/Medicated	8
E - Beverage Plant	20-C	R - Pet Food Manufacturer	8
F - Feed Mill/Non-Medicated	8	S - Feed Warehouse and/or Distributor	8
G - Processing Plant	20	T - Disposal Plant	5-C
I - Refrigerated Warehouse	19	U - Disposal Plant/Transportation Service	5-C
J - Multiple Operations		V - Slaughterhouse	5-A
K - Vehicle		W - Farm Winery-Exempt 20-C, for OCR Use	
L - Produce Refrigerated Warehouse	19	Z - Farm Product Use Only	
M - Salvage Dealer	17-B		

<u>COMMODITY AND PRODUCT CODES</u>		
01 - Soft Drinks, Water	22 - Shellfish, Crustaceans, Etc.	43 - Cured, Proc. Vegetable Prods.
02 - Beverage Bases	23 - Smoked Fish	44 - Dry Dessert, Pudding Mixes
03 - Coffee, Tea, Cappuccino	24 - Spices, Salt	45 - Prepared Multiple Foods
04 - Alcoholic Beverages	25 - Extracts, Flavors	46 - Misc. Food Use Items
05 - Bread, Rolls, Buns, Sweet Goods	26 - Dressing, Condiments	48 - Food Chemicals
06 - Custard, Cream-Filled Sweet Goods	27 - Fresh Fruits, Juices (except apple cider)	49 - Infant, Jr., Geriatric Foods
07 - Macaroni, Noodle Products	28 - Frozen Fruits, Juices	50 - Dietary Specialties,
08 - Breakfast Cereals, Ready-to-Eat	29 - Canned Fruits, Concentrates, Nectars	Artificial Sweeteners
09 - Whole Grains, Beans-Bulk	30 - Dried Fruits	51 - Other
10 - Pretzels, Chips, Specialty Items	31 - Jams, Jellies, Preserves, Butters	52 - Soy Products
11 - Proc. Grain, Starch Prods.-Human	32 - Fruit Products	53 - Apple Cider
12 - Prep. Mixes, Dry Flour/M meal Base	33 - Animal Feeds	60 - Apples
13 - Candy, Gum, Choc., Cocoa Products	34 - By-Products for Animal Feeds	61 - Grapes
14 - Honey, Syrup, Sugar	35 - Meat, Meat Products	62 - Potatoes
15 - Butter, Butter Products	36 - Nuts, Nut Products	63 - Onions
16 - Cheese, Cheese Products	37 - Veg. Oil Seed, Oil Stock, Crude Oil	64 - Lettuce
17 - Milk, Milk Products	38 - Ref. Veg. Oil, Shortening, Oleo	65 - Maple Syrup
18 - Dried Milk, Dried Milk Products	39 - Fresh Vegetables	66 - All Commodities 60 thru 64
19 - Ice Cream, Related Products	40 - Frozen Vegetables, Veg. Juices	67 - General Commodity Storage
20 - Eggs, Egg Products	41 - Canned Vegetables, Veg. Juices	91 - Medicated Feed
21 - Fish, Fish Products (not smoked)	42 - Dried, Dehydrated Vegetables	

<u>FOOD PROCESSING OPERATIONS OR STORAGE CODES & ACTIVITIES</u>		<u>VARIANCE CODES & EXEMPT. GUIDELINES</u>
A - Baking	L - Grinding	1 - Water Supply
B - Blending	M - Mixing	2 - Service Sink
C - Brewing	N - Packing	3 - Off Premise Toilet w/Handwash Facility
D - Bottling	O - Pickling	4 - Off Premise Handwash Facility
E - Canning	P - Roasting	5 - One Bay of Three Bay Sink
F - Chemically Treating	Q - Smoking	6 - Alternate Process
G - Cooking or Other Heat Treatment	R - Waxing	7 - Curing & Smoking Meats
H - Curing	S - Vacuum Packaging	8 - Specialized Vacuum Packaging
I - Dehydrating	T - Catering	9 - Processing of Game Animals
J - Fermenting	U - Slicing	0 - OTHER
K - Freezing	X - Storage	

**NYS Department of Agriculture and Markets
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**SANITARY INSPECTIONS
IPH CATEGORIES AND INSPECTION RATE GUIDELINES
SUB-SECTION 2050**

IPH 1 ESTABLISHMENTS:

1. Low acid canned food manufacturers
2. Acidified food manufacturers
3. High volume food salvagers
4. High volume wholesale manufacturers of potentially hazardous foods, i.e., cream-filled pastries, filled macaroni products
5. High volume smoked and salt cured fish manufacturers
6. Vacuum Packers at wholesale

Rate: 3 inspections per calendar year

Reinspect: 30 days

IPH 2 ESTABLISHMENTS:

1. Manufacturers of potentially low acid foods
2. "Super" supermarkets with many complex food manufacturing operations (curing and smoking meats, elaborate deli preparation, food service areas, etc.)
3. Vacuum packaging operations at retail
4. Low volume food salvagers
5. Low volume smoked and salt-cured fish manufacturers-air pack

Rate: 2 inspections per year

Reinspect: 30 days

IPH 3 ESTABLISHMENTS:

1. All other food manufacturers requiring Article 20 or 20-C licenses (includes low volume manufacturers of potentially hazardous foods)
2. Refrigerated warehouses with Article 19 licenses
3. Non-licensed stores handling exposed foods; Farm Winery
4. High volume food warehouses
5. Retail food stores handling potentially hazardous foods

Rate: 1 inspection per year

Reinspect: 60 days

IPH 4 ESTABLISHMENTS:

1. Low volume food warehouses
2. Grocery stores not handling potentially hazardous foods
3. Retail food stores exempt from Article 28 license

Rate: 1 inspection every 2 years

Reinspect: 90 days

**SANITARY INSPECTIONS
IPH CATEGORIES AND INSPECTION RATE GUIDELINES
SUB-SECTION 2050**

IPH 5 ESTABLISHMENTS:

1. Disposal plants/Transportation Services

Rate: 3 reviews per calendar year

2. Poultry and small animal slaughterhouses (Article 5-A Establishments)

Rate: 3 inspections per calendar year (if seasonal, once before and once after opening)

Reinspect: 5 days

IPH 6 ESTABLISHMENTS:

1. Feed mills
2. Honey processors (Apiaries)
3. Maple syrup processors
4. Home processors
5. Beverage distributors - "D", No Retail Sales
6. Ice cream depots
7. Retail candy stores and kiosks (if not licensed)
8. Delivery vehicles
9. Produce warehouses – "N", "O" and "P"
10. Drug stores or Department stores which do not require licensing
11. Food Pantries

Rate: Complaint basis

Reinspect: 90 days

Note: FDA and USDA Contract reinspections will be scheduled, by memo, from the central office.

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**SANITARY INSPECTIONS
ESTABLISHMENT TYPES
SUB-SECTION 2055**

ESTABLISHMENT TYPE	LICENSE OR FEE ARTICLE
A – Store (Retail)	Art 28 A
B - Bakery	20 - C
C - Food Manufacturer	20 - C
D - Food Warehouse	Art 28 D
E - Beverage Plant	20 - C
F - Feed Mill - Non Medicated	8
G - Processing Plant	20
H - Home Processor	
I - Refrigerated Warehouse	19
J - Multiple Operations	
K - Vehicle	
L - Produce Refrigerated Warehouse	19
M - Salvage Dealer	17 - B
N - Produce Wholesale Packer	
O - Produce Grower Packer/ Broker, Storage	
P - Produce C.A. Room	12 - A
Q - Feed Mill-Medicated	8
R - Pet Food Manufacturer	8
S - Feed Warehouse/Distributor	8
T - Disposal Plant	5 - C
U - Transport Service	5 - C
V - Slaughterhouse	5 - A
W - Farm Winery	20 - C Exempt
Z - Farm Products Use Only	

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**SANITARY INSPECTIONS
ESTABLISHMENT TYPE DEFINITIONS
SUB-SECTION 2060**

<u>CODE</u>	<u>TYPE</u>	<u>DEFINITION</u>
A	Store Retail Food Store	Facility selling packaged food and food products (i.e., supermarket, grocery, market, mall kiosk or food section of a large store, conducting retail or wholesale food sales).
B	Bakery	Wholesale facility or section of a store or other food manufacturer that bakes bread, rolls, cakes, cookies, pies, sweet goods, etc., and requires an Article 20-C License.
C	Food Manufacturer	Establishment that conducts any type of food processing or preparation activities that qualify as licensable under Article 20-C. Does not include establishments coded as Bakery (B) or Beverage Plant (E).
D	Food Warehouse	Food storage establishment that store refrigerated, frozen and/or unrefrigerated food products other than their own fresh produce and are not required to be licensed under Article 19.
E	Beverage Plant	Establishment that produces and/or bottles carbonated and non-carbonated beverages (soft drinks, soda, seltzer, wine, beer, juice or flavored water). An Article 20-C License is required.
F	Feed Mill Non-Medicated	Firm blends grains, vitamins, minerals, forage products, meat by-products, etc., without drugs or antibiotics into feed for cattle, poultry, swine, equine, etc. Requires registration of the premises with the Department and the payment of tonnage fees, per Article 8.
G	Processing Plant	Establishment that purchases raw agricultural products from New York State producers for processing or packing as defined by Article 20. An Article 20-C License is also required and is to be coded Type (JCG).
H	Home Processor	A private home or residence being used to produce non-potentially hazardous foods, using only the ordinary kitchen facilities of that home and is exempt from Article 20-C licensing.
I	Refrigerated Warehouse	Establishment that rents space or lockers to others for the storage of refrigerated or frozen foods except exclusively raw fruits or vegetables, for a period over 30 days. Licensable under Article 19.

**SANITARY INSPECTIONS
ESTABLISHMENT TYPE DEFINITIONS
SUB-SECTION 2060**

<u>CODE</u>	<u>TYPE</u>	<u>DEFINITION (continued)</u>
J	Multiple Operations	Use as the first letter when more than one establishment type is assigned to an establishment.
K	Vehicle	Used to identify all vehicles transporting foods: Delivery vehicles or common carriers, transient or semi-permanent vendor vehicles. If licensable operations are conducted that type code shall also be assigned (i.e., JACK).
L	Produce Refrigerated Warehouse	Establishment that rents refrigerated storage space for the exclusive storage of raw produce for 30 days or more. An Article 19 License is required.
M	Salvage Dealer	Establishment that receives damaged or distressed food and reconditions or culls the food products for human or animal consumption. An Article 17-B License is required.
N	Produce Wholesale Packer	Establishment that purchases only whole fresh produce directly from brokers, or growers for repackaging and distribution. No FSI License is required.
O	Produce Grower/Packer Broker, Storage	A facility that stores, packages and/or distributes only produce of their own production.
P	Produce C.A. Room	Controlled atmosphere storage facilities that meet the specific requirements for this type of storage. FSI Article 12-A registration is required.
Q	Feed Mill Medicated	Firm combines grains, vitamins, minerals, forage products, by-products, etc. with drugs or antibiotic products referred to as medicated supplements, concentrates, premix feeds, base mixes and finished feeds for cattle, poultry, swine, equine, etc. The premises must be registered with the Department and tonnage fees paid as per Article 8.
R	Pet Food Manufacturer	Firm produces food for dogs, cats and domesticated pets. The firm must register each of its products with the Department as per Article 8.
S	Feed Warehouse and/or Distributor	Firm handles/stores/distributes non-medicated feed, medicated feed and pet food. The premises and the products handled are not usually registered by this establishment.
T	Disposal Plant/Vehicle	Dead animal rendering or processing facility and its vehicles used in producing grease, hides, offal, skins and meat for non-human consumption. An Article 5-C License is required.

**SANITARY INSPECTIONS
ESTABLISHMENT TYPE DEFINITIONS
SUB-SECTION 2060**

<u>CODE</u>	<u>TYPE</u>	<u>DEFINITION (continued)</u>
U	Transportation Service/Vehicle	Service provider and their vehicles used to transport, within New York State, unprocessed animal bodies, carcasses or parts and meat or meat products which are not intended for human consumption. An Article 5-C License is required.
V	Slaughterhouse	Establishment that slaughters animals or fowl that are exempt from the Federal Meat Inspection Act or Federal Poultry Inspection Act. In most cases, an Article 5-A License is required.
W	Farm Winery	Winery that is licensed by the New York State Liquor Authority as a Farm or Special Farm Winery and does not conduct other food processing activities that are licensable under Article 20-C.
Z	Farm Products	Establishment not subject to routine sanitary inspection, but produce or eggs are inspected at this location. This code is not to be used in combination with any other establishment type code.

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**SANITARY INSPECTIONS
PHOTOGRAPHIC REPORTS
SUB-SECTION 2065**

OVERVIEW

Photographs of deficient conditions found in establishments under this Division's jurisdiction have proven to be of major value in our enforcement efforts.

The United States Supreme Court has ruled the taking of photographs during an inspection or investigation is a legitimate enforcement activity. Never ask an establishment representative for permission to take photographs. Tell the representative you are going to take pictures to supplement your written report. They will seldom object. If they should refuse advise them, politely and professionally, you have the authority to take pictures and their refusal may be construed as interference with an Inspector in the performance of his duties. If they still refuse, do not take photos. Immediately call your Supervising Inspector or the Food Safety and Compliance Unit for instructions. Document the incident in a Report of Investigation.

When photographs are taken during sanitary inspections, special investigations, or at the request of the Central Office, the photos will be submitted using digital images as follows:

COMPLETION OF DIGITAL PHOTOGRAPHIC REPORT (FSI-825)

A. Submission of digital photographic report:

1. Est. No.: Enter the establishment number if known. If not known, enter the county code only.
2. Owner Name: Enter the ownership name of the establishment where the photos were taken.
3. Inspector: Enter the name and I.D. # of the Inspector completing the report.
4. Photo of: Enter a sequential number for each photo in the left space and the total photos submitted in the right space.
5. Photo: Paste the selected photo image into the selected box.
6. Deficiency #: Enter the related violative item number(s) from the sanitary inspection report checklist.
7. Description: Enter a concise, accurate description of the violation(s) depicted in the photo.

Enter the next photo image, repeating steps 4-8 above, until the report is complete.

**SANITARY INSPECTIONS
PHOTOGRAPHIC REPORTS
SUB-SECTION 2065**

The page number and date will be entered by default.

Submit the completed report via electronic mail to the Compliance Unit.

**SANITARY INSPECTIONS
PHOTOGRAPHIC REPORTS
SUB-SECTION 2065**

Est. No.
Photo of

Owner Name:

Insp:

PHOTO

Deficiency #

Description:

Photo of

PHOTO

Deficiency #

Description:

**NYS Department of Agriculture and Markets
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**SANITARY INSPECTIONS
FIELD TESTS
SUB-SECTION 2070**

OVERVIEW

The qualitative analysis of foodstuffs starts with an organoleptic examination based on odor and appearance. The following field tests are used as adjuncts to the organoleptic evaluation to confirm an analysis.

It must be emphasized; these are field tests and must not be used alone as a basis for condemnation or legal action. Confirmation samples must be obtained and submitted for laboratory examination while the suspected material is detained under seizure. The purpose and the intention of the field tests is to assist the inspectors organoleptic senses and is not meant to supplant the more critical examination of foods by trained chemists.

SULFITE IN MEAT PRODUCTS

Sulfite is illegally added to ground meat to mask decomposition, to deodorize and to restore the bright red color characteristic of fresh meat. To prepare the test solution:

1. Unplug the empty bottle (1190), add one Malachite Green Tablet (4239), and fill the bottle to the black line with de-ionized water. Replace plug and cap and shake bottle to dissolve tablet. If stored out of direct sunlight, the solution should be good for at least 3 months.
2. Transfer 1/2 teaspoon of suspected meat to a piece of the filter paper or other white paper.
3. Add 10 drops of the Malachite Green Solution to the meat and thoroughly mix the dye with the meat for several minutes, using the stirring rod (0519).
4. If the green color disappears, the meat probably contains sulfite. If the green color is retained, sulfites are not present.

AVAILABLE CHLORINE IN DISINFECTANT SOLUTIONS

1. Fill a 10-ml test tube (0775) to the line with the sanitizing rinse water to be tested.
2. Add one Chlorcol Tablet. Cap tube and shake to disintegrate the tablet.
3. Compare the sample color with the tablet below to determine the approximate available chlorine content.

**SANITARY INSPECTIONS
FIELD TESTS
SUB-SECTION 2070**

Color	Chlorine (ppm)
None	Absent
Faint pink to pink	0.2 - 1.0
Pink to red	1 - 5
Red to purple	5 - 10
Purple to Blue	10 - 20
Blue to gray green	20 - 30
Gray green to yellow	30 - 50
Brown	Over 50

If the test result is over 50 ppm, the test may be repeated on a 1/10 diluted sample. Use the 1-ml pipette (0354) to transfer 1.0 ml of the sanitizing rinse water to a 10-ml test tube. Fill the tube to the 10-ml line with chlorine-free water. Follow steps 2 and 3 above and multiply result by 10.

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**SANITARY INSPECTIONS
COMPLIANCE SESSIONS
SUB-SECTION 2075**

OVERVIEW

An industry compliance session is an educational meeting which is held between an Agriculture and Markets Food Inspector and a representative of a firm that has repeat violations in an attempt to get the firm into compliance with our regulations prior to requesting legal action. Compliance sessions are usually conducted at the establishment as a result of multiple reports with critical deficiencies. They may also be requested when an establishment has a history of recalls and/or numerous economic violations.

Based upon the violations noted, an industry compliance session will be requested by the Food Safety and Compliance Unit following a third consecutive failing inspection or as deemed necessary in response to recalls and economic violations. A letter of notification that a compliance conference has been requested will be mailed to the establishment and a copy sent to the Zone Supervisor. Compliance conferences will be held at the establishment whenever possible, but may be held at a Regional Office or in certain situations, over the phone. Bilingual inspectors should be utilized when necessary.

If the conference is to be held at the establishment, the inspector assigned to conduct the conference will phone the establishment and arrange the date and time of the conference. The conference should be held within two weeks of the date of the conference notification letter. If the establishment cannot be reached by phone to schedule the conference, the Inspector will visit the establishment and attempt to conduct the conference. If the store is visited and management is unreceptive to the compliance session, the Inspector will conduct the session as fully as possible and note the circumstances on a compliance session worksheet.

If during the initial telephone contact, the firm representative states that a single, easily correctable deficiency has already been corrected, establish a reinspection date at that time. This procedure can only be utilized when one easily corrected critical deficiency existed on the latest inspection report. This phone call would be considered the industry compliance session and would be reported as such.

If the session is scheduled to be held in the Regional Office and a firm representative fails to appear, note this on the conference worksheet and schedule a post session inspection.

When conducting the compliance session, the Inspector or Supervising Inspector should focus on the critical deficiencies present during the most recent inspection. However, all previous inspections must be reviewed. Impress upon management that further failing inspections may lead to a hearing, injunction, or other legal action. Educational handouts shall be distributed and reviewed as necessary. Corrective actions must be noted along with the expected date of completion. A follow-up reinspection will be arranged no later than 30 days from the date of the compliance session.

If during the course of the session it is determined that the store is free of critical deficiencies, a reinspection may be conducted if the establishment requests it.

**SANITARY INSPECTIONS
COMPLIANCE SESSIONS
SUB-SECTION 2075**

The Inspector or Supervising Inspector must forward the completed industry compliance session form to the Sanitation Compliance Unit by e-mail the same day as the session. The Compliance Unit will then generate a post-conference letter which will be mailed to the establishment and a copy forwarded to the Zone Supervisor.

If during the compliance session, the firm representative complains about or has questions regarding penalties, instruct them to call the Food Safety and Compliance Unit at (518) 457-2840. Do not inform the establishment representatives that penalties will be waived or reduced.

COMPLIANCE SESSION FORM (Attachment #1):

Open the blank word document template for the industry compliance session.

1. Owner: Enter the establishment's name.
2. Est. No.: Enter the establishment number.
3. Street, City and Zip Code: Enter the street address, city, and zip code of the establishment.
4. Date Held and Where Held: Enter the date the compliance session was held and where the session was held, for example "at firm" or "Brooklyn office".
5. Est Representative and Title: Complete the name and title of the representative of the firm present for the compliance session.
6. Department Representative and Title: Complete the name(s) and title(s) of the Inspector(s) conducting the compliance session.
7. Dates of Inspections reviewed: Enter the date of each inspection that was reviewed during the compliance session.
8. Firm Processes Meat and/or Poultry and Meat & poultry Safety Guide Issued(Attachment #2): Double click on the highlighted boxes. A message box will pop up. Click on "checked" for "yes" or "not checked" for "no" then on "OK" to save information.
9. Deficiency table: For each deficiency reviewed, enter the deficiency number and letter under "Item #", a brief description of the deficiency under "Deficiency", what actions the firm is taking to correct the deficiency under "Corrective Actions" and the date the deficiency will be or has been corrected under "Correction Date". Additional text boxes will appear as needed for additional deficiencies. Use the tab key to move from one box to another in this table.
10. Comments: Enter any additional information, such as if license application and fee were collected, in the comments box.
11. Reinspection is scheduled for the week of: Enter the week scheduled for the reinspection. The reinspection should be scheduled no later than 30 days from the date of the conference.

Once the information has been entered into the compliance session worksheet, it must be e-mailed as an attachment, to the Compliance Unit (Attachment #3). The Sanitation Compliance Unit will then mail a post conference letter to the store.

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**SANITARY INSPECTIONS
COMPLIANCE SESSIONS
SUB-SECTION 2075**

Attachment #1

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE
ALBANY, NEW YORK 12235

INDUSTRY COMPLIANCE SESSION

Owner: ①		Est. No.: ②	
Street: ③		City:	Zip Code:
Date Held: ④		Where Held:	
Est. Representative: ⑤		Title:	
Dept. Representative: ⑥		Title:	
Dates of Inspections Reviewed: ⑦			

☒ Firm Processes Meat and/or Poultry ⑧

☒ Meat & Poultry Safety Guide Issued

ITEM #	DEFICIENCY	CORRECTIVE ACTION	CORRECTION DATE
⑨			

COMMENTS: ⑩

REINSPECTION IS SCHEDULED FOR THE WEEK OF: ⑪

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SANITARY INSPECTIONS
COMPLIANCE SESSIONS
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Attachment #2

To move from cell to cell click, do not tab

To mark a box, double click on the box, then click on "checked" in the pop-up window

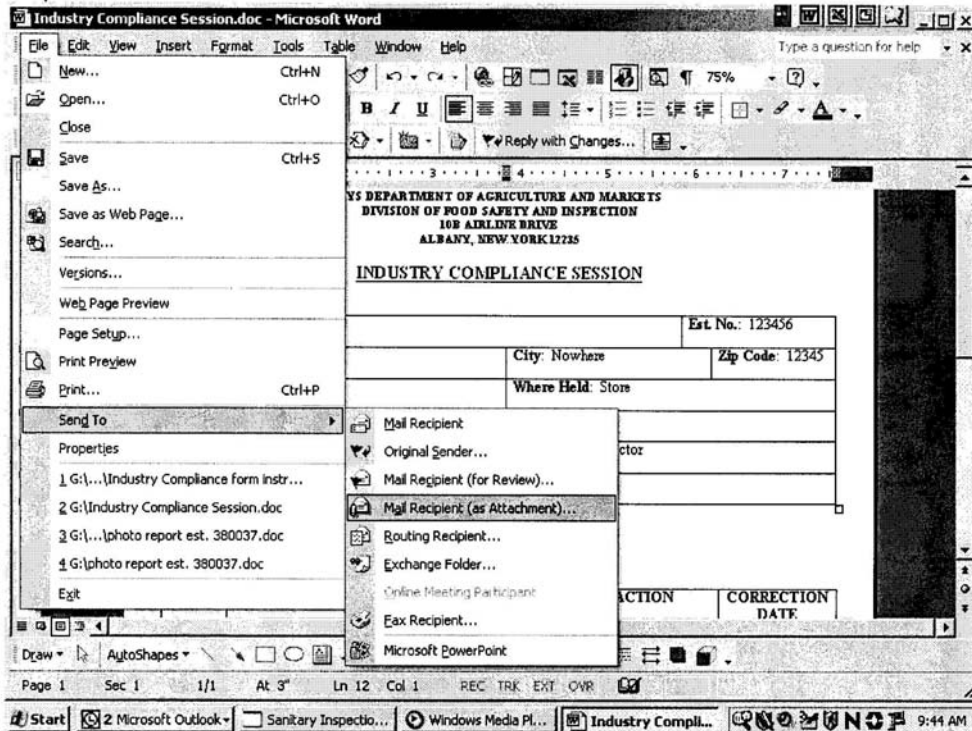
To create a new deficiency cell, click in the bottom right cell and click on the "Tab" key

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Attachment #3

Click on the file menu and move to the bottom of the menu until the extended menu appears. Move cursor to the “Send To” option. Move cursor to “Mail Recipient (as Attachment)” and click. The session report will be sent as an attachment in an email message.



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**FOOD SAFETY EDUCATION
SUB-SECTION 2080**

AUTHORITY

Agriculture and Market Law requires the applicant for a food processing establishment license to furnish evidence of competency to maintain the premises with adequate facilities, equipment and in such a state of cleanliness so that the product produced within the establishment will not become adulterated. Persons-in-charge of retail food stores may be required to complete food safety training at any time the Commissioner is not satisfied with his or her competency. The license application shall be accompanied by documentation that an individual in a position of management or control has completed a food safety program.

OVERVIEW

Food safety training is paramount in the prevention of unintentional contamination of food produced in food processing establishments and in the transmission of pathogens that caused foodborne illnesses.

DEMONSTRATION OF KNOWLEDGE

The person-in-charge of a retail food store or a representative may be directed by the Commissioner to attend a food safety course approved by the Department at any time critical deficiencies are noted on three consecutive sanitary inspections. The Commissioner may require the person-in-charge or a representative to attend an approved food safety course as often as deemed necessary.

Persons in charge of establishments that do not fall under the purview of the Rules and Regulations Relating to Retail Food Stores are not required to attend an approved food safety course. An industry compliance conference is conducted at those establishments.

Attendance at an approved food safety course does not preclude an industry compliance session being held at an establishment.

**FOOD SAFETY EDUCATION
SUB-SECTION 2080**

FOOD SAFETY EDUCATION CERTIFICATION PROGRAM

A retail food store is defined, in accordance with Agriculture and Markets Law §251-z-12, as an establishment or section of an establishment, licensed by the Department, where food and food products are offered to the consumer and are intended for off premises consumption.

Every retail food store shall employ an individual in a position of management or control that has completed eight hours of food safety training over a biennial license period before a food processing license can be issued. Documentation of attendance to an approved food safety education certification program shall accompany the application and renewal application for a food processing license in the form of a certificate of completion issued by the program provider. The certificate shall consist of a form approved by the Commissioner and shall be posted in the individual's place of business.

Individuals who have completed eight hours of training shall only be assigned to one retail store for the purpose of compliance with the New York State Department of Agriculture and Markets Law. A certificate of completion will remain valid for the individual for the biennial license period even if there is a change of employment to another licensee. A certificate of completion from a course or courses in an approved food safety education program is issued to the individual not to the licensee, unless he or she is the individual owner of the retail food store.

Re-certification shall occur every two years by attending a course or courses in an approved food safety education program.

The licensee shall have a period of up to thirty days to come into compliance where the person assigned to the retail food store who has been certified as having completed training in an approved food safety education program separates from his or her place of employment.

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**INVESTIGATIONS
REPORT OF INVESTIGATION (FSI-30)
SUB-SECTION 2090**

OVERVIEW

The Report of Investigation (ROI) is, primarily, an electronically typed description of facts gathered by an Inspector in a variety of situations. The form must be properly completed to enable the matching of related reports and to facilitate routing and filing.

Do not complete a Report of Investigation when samples are taken or Seizure/Waivers completed while conducting consumer complaint or illness investigations or sanitary (re)inspections. Use only the forms specifically designed for those purposes.

DISTRIBUTION

The Report of Investigation is completed electronically. The word template of the Report of Investigation (FSI-30) should be saved to your F: Drive or "My Documents." When you need to complete it, simply click on the box and type in the information. Double-click on the smaller boxes (i.e. investigation, follow-up, etc.) to check them. Once completed, it is to be E-mailed as an attachment to your Supervisor. The supervisor will review it, type his/her name in the "review by" box at the bottom, and forward it to the appropriate Central Office Personnel and CC: the Region Chief.

FORM COMPLETION

The numbers and/or letters preceding the form completion descriptions refer to those on the sample Report of Investigation form in this section:

1. Investigation/Follow-Up Investigation: Check the appropriate box. After the initial investigation, all subsequent investigations on the same matter, involving the same establishment, are marked "follow-up", unless it was closed out and is now being reopened, in which case, mark the report as an investigation. A reference should be made to the previous investigation at the beginning of the Remarks section.
2. Date: Enter the date the investigation was conducted. If the investigation covers more than one day, type in "day 1 of N days" over the date box. Subsequent pages would be marked "day 2 of N days", etc.
3. Owner: There are three common forms of establishment ownership:
 - A. Single proprietorship (one person)
 - B. Partnership (two or more persons)
 - C. Corporation (can be listed as Jones, Inc., Jones Corp. or Jones, Ltd., etc.)

**INVESTIGATIONS
REPORT OF INVESTIGATION (FSI-30)
SUB-SECTION 2090**

For establishments with an assigned establishment number, enter the ownership name as it appears on the establishment printout. If an establishment number is not assigned, determine the ownership from other licenses, tax certificates or operator statements.

One of the three ownership categories should be entered. If an owner's name is not known or would not be appropriate or informational, the full name of the consumer, the custodian of the merchandise or other responsible person interviewed may be entered.

4. Est. No.: Enter the assigned Establishment Number, if known. If not known or no number has been assigned, enter the County Code. Leave the remaining boxes blank.
5. Trade Name: Enter the trade name of the establishment, if applicable.
6. Street: Enter the physical street address at which the investigation took place.
7. City: Enter the name of the city (town, village, etc.) where the investigation took place.
8. County: Enter the name of the county where the investigation took place.
9. Zip Code: Enter the correct five-digit Zip Code.
10. Interviewed: Enter the full first and last name of the person interviewed.
11. Title: Enter the title of the person interviewed.
12. Time In/Time Out: Enter the exact times of the day (or night) the investigation began and the time it is completed.
13. Nature of Investigation: Mark an X in the appropriate box.
 - A. Licensing: Use this category whenever the primary purpose of the of the report relates to a Licensing Unit matter.
 - B. Refrigerated Warehouse Extension: Used when reporting the results of a Refrigerated Warehouse Extension investigation. One report will suffice for each extension investigated at the same establishment.

**INVESTIGATIONS
REPORT OF INVESTIGATION (FSI-30)
SUB-SECTION 2090**

- C. Miscellaneous Investigation: Use this category when the purpose of the report does not relate to the other categories. Appropriate entries may be: recall activities, conferences with industry, special projects, etc.
- D. Disaster: This category is used when reporting the results of a fire, flood, wreck or other disaster. If a seizure, waiver or sample is executed as a result of a disaster mark an X in both the disaster and/or seizure/waiver, sample box and enter the seizure/waiver and/or sample numbers.
- E. Food Sample: If a Food Sample is taken during the course of an investigation, enter the FL-number in this space.
- F. Unit Pricing Survey: Used when reporting results of a unit pricing survey.
- G. Seizure/Waiver: If a Seizure is made but the product is not waived, enter the seizure number and indicate seizure is open in Remarks Section. If you are documenting Product Destroyed, enter the original seizure number and indicate seizure closed out in the Remarks Section.
- H. Product Destroyed: If there is product destroyed during an investigation, enter the number of pounds and units destroyed in the appropriate box. Enter only the amount on the date of this Report of Investigation.
14. Remarks: Type a descriptive, factual and concise narrative of the results of your investigation in this space.
15. Inspector's Name: The Inspector(s) conducting the investigation type their name(s) in the box.
16. Inspector's I.D.: Enter the Identification Number(s) of the Inspector(s) conducting the investigation in this box.
17. Reviewed By: The Supervisor reviewing the report will type his/her name in this box.

**INVESTIGATIONS
REPORT OF INVESTIGATION (FSI-30)
SUB-SECTION 2090**

FSI-30 (Rev. 3/06)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE, ALBANY, NEW YORK 12235

REPORT OF INVESTIGATION

☐ INVESTIGATION ☐ FOLLOW-UP INVESTIGATION
(1)

(2) DATE:

OWNER: (3)		(4)	EST. NO.:						
TRADE NAME: (5)									
STREET: (6)			CITY: (7)		COUNTY: (8)		ZIP (9)		
INTERVIEWED: (10)			TITLE: (11)		TIME IN: (12)		TIME OUT:		
NATURE OF INVESTIGATION: (13)									
(A) ☐ LICENSING (B) ☐ REF. W'HSE EXT. (C) ☐ MISC. INVEST. (D) ☐ DISASTER (E) ☐ FOOD SAMPLE: (F) ☐ UNIT PRICING SURVEY (G) ☐ SEIZURE/WAIVER: # # FL#(S): PRODUCT DESTROYED: (H) LBS.: UNITS: 									
REMARKS: (14)									
INSPECTOR: (15)							ID NO.: (16)		
REVIEWED BY: (17)									

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Field Operations Manual

INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095

OVERVIEW

Seizures and Quarantines

Paragraph one of Article 17 - Section 202-b (below) clearly states that a food or food product which is **“unfit or unsafe for use as a food”** is required to be placed under **“seizure,”** e.g., “the taking possession of by a legal process.”

Paragraph two of the same section states that any food or food product which is **“adulterated or misbranded”** shall be placed under **“quarantine,”** e.g., an enforced isolation or restriction of movement.

To comply with these requirements of the Law, the following procedure will be followed: Consider if a food product is “unfit” or “unsafe,” thus, to be “seized” or similarly, “adulterated” or “misbranded” and, therefore, to be “quarantined.” When this determination is made, follow the Food Seizure / Quarantine Notice completion instructions found on page 3 of this Sub-Section.

Note: In the preparation of Seizure / Quarantine related reports, for the sake of clarity and brevity, the terms “seize”, “seized” or “seizure” will be used generically in place of the word “quarantine” in the preparation of all written narratives.

STATUTORY AUTHORITY FOR SEIZURE / QUARANTINE ACTION

Article 17 - Section 202-b - Seizure and Quarantine

Whenever the Commissioner or his/her duly authorized representative shall find distributed, offered or exposed for sale within this State, a food or food product which is unfit or unsafe for use as food, and its condemnation is required to protect the public health, he/she may seize, destroy or denature such product so that it cannot thereafter be used for food.

Whenever the Commissioner finds, or has probable cause to believe, that any food or food product is adulterated or misbranded within the meaning of this article, he may affix to such food or food product a tag or other appropriate marking, giving notice that such food or food product is, or is suspected of being, adulterated or misbranded and has been quarantined, and warning all persons not to remove or dispose of such food or food product by sale or otherwise until permission for removal or disposal is given by the Commissioner or his/her duly authorized representative. It shall be a violation of this article for any person to remove or dispose of such quarantined food or food product by sale or otherwise without such permission.

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
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Before destruction of a food or food product following seizure or quarantine, the Commissioner shall give the owner, proprietor or custodian of such food or food product ten days' notice in writing, to be served either personally or by mail, of a hearing for said owner, proprietor or custodian to show cause why such food product should not be destroyed in accordance with the provisions of law.

Following such hearing, the Commissioner shall make a determination in accordance with the provisions of this chapter. The determination of the Commissioner may be reviewed in the manner provided by Article seventy-eight of the Civil Practice Law and Rules, and such determination shall be final unless within thirty days from the date of service of a copy thereof upon the owner, proprietor or custodian a court proceeding is instituted to review such determination.

Whenever following seizure or quarantine, a food or food product is found to be unfit or unsafe for use as food, the destruction and disposition of such food or food product, as well as any necessary storage, handling, or other incidentals between the time of seizure or quarantine and the destruction and disposition thereof, shall be the responsibility, both financially and otherwise, of the owner or other person having custody of such food or food product; provided, however, that such destruction and disposition shall be carried out only under the direction and immediate supervision of the Commissioner or his/her duly authorized representative. Nothing in this section shall be construed as preventing the Commissioner or his duly authorized representative from destroying and disposing of such food or food product found to be unfit or unsafe, where such procedure is warranted.

WHEN SEIZURE / QUARANTINE AUTHORITY SHOULD NOT BE EXERCISED

Liquor involved in fires, floods, wrecks, etc., (wine and beer is subject to seizure except as described below). Food Products (including beer and wine) involved in fires (except under special circumstances to be determined by the Division administration). The Inspector is, however, required to visit the scene of a fire and advise the operator of his/her responsibilities concerning any distressed food products present. In addition, he/she will provide the operator with a copy of the Damaged - Seized Food Notice (FSI-868), a preprinted set of guidelines specifically drawn for such circumstances along with a list of licensed salvage dealers. This fact should appear on a Report of Investigation listing the establishment representative who received the preprinted guidelines. No seizure or waiver will be executed. The Inspector will, following his/her initial visit, simply spot check the progress of the cleanup operation to assure the proper disposal of any distressed foods. If the spot checks reveal the establishment's handling of such distressed merchandise is not in keeping with Agriculture and Markets regulations, the Inspector is authorized, and in most situations should, place such products under seizure. When notified of a fire after normal working hours on a weekday or on a holiday or weekend the Inspector should visit the scene of the fire, as soon as possible, during his or her next regularly scheduled workday.

INSTRUCTIONS - SEIZURE / QUARANTINE NOTICE AND FOOD SEIZURE / QUARANTINE HEARING WAIVER SECTION (FSI-865)

The Seizure / Quarantine Notice (FSI-865) (see example, Page 11) and the Food Seizure / Quarantine Hearing Notice section of this form is completed after an Inspector places food or ingredients under seizure, when food or ingredients already under seizure are to be destroyed or otherwise disposed of, or when it becomes necessary for the Inspector to leave seized items. A commodity is legally under Seizure / Quarantine as soon as the Inspector so states. Therefore, the Seizure / Quarantine Notice does not have to be completed prior to commodity being placed under Seizure / Quarantine.

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095**

FOOD SEIZURE / QUARANTINE NOTICE COMPLETION INSTRUCTIONS

1. Seizure / Quarantine - Determine if a food product is “unfit” or “unsafe” thus, to be “seized” or, “adulterated” or “misbranded” and, therefore, to be “quarantined.” When this determination is made, put a check mark in the seizure box or quarantine box.

Note: In the preparation of Seizure / Quarantine related reports, for the sake of clarity and brevity, the terms “seize”, “seized” or “seizure” will be used generically in place of the word “quarantine” in the preparation of all written narratives.

2. Date - Fill in as indicated (calendar date on which product is placed under Seizure / Quarantine).
3. Inspection, Complaint, R.O.I. - Check the appropriate box.
4. “Project No.” - is only to be filled in when such a number is specifically assigned by the Albany Office. Seizures assigned Recall Project Numbers are usually made in conjunction with the general recall of a potentially adulterated or mislabeled product.
5. Custodian, Trade Name, Address and Establishment Number - This information should properly reflect the business entity responsible for operating the regulated establishment. This would be an individual, a partnership (which may be composed of two or more persons), or a corporation. In the case of a truck wreck, list the county code (first two digits of the county where the accident took place in the Establishment Number space. (The same procedure should be used in the case of a custodian who does not have an Establishment Number assigned).
6. Owner Name, Trade Name, Address and Establishment Number - If different than the custodian. If the custodian and the owner are one and the same, write “same as custodian” under the owner's name.
7. Person Interviewed and Title - Fill in the name and title of the most responsible industry representative present even if most of your contact had been with a less responsible person.
8. Seized Product Made or Distributed By - When several distributors or manufacturers are involved, write “various manufacturers” or “various distributors” in this space.
9. Seized Products Received or Purchased From - If same as No. 6, write “same as above.”
10. Invoice/Bill of Lading No. and Date - Enter date and number of invoice or bill of lading which accompanied product upon delivery.
11. No. of Samples - Indicate number of samples submitted.

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FOOD SEIZURES, QUARANTINES AND WAIVERS
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12. FL No. - List FL numbers from Reports of Sampling and Analysis submitted. If more than four FL reports are submitted and they are consecutively numbered, enter the first, second and last numbers in the spaces provided.
13. Date Samples Shipped to Lab - Enter information requested.
14. Product Withheld From Sale or Use Prior to Seizure / Quarantine - Check "Yes" or "No."
15. If "Yes," Explain Why - Describe apparent conditions of product placed under Seizure / Quarantine; e.g., bulged cans, dented seams, fire, water or smoke damaged, insect infested, rodent defiled, mislabeled as to grade, contents, size, or excessive decomposition, etc.
16. Describe Product, Reason For Seizure / Quarantine and Location Prior to Seizure / Quarantine - If disposition of product is yet to be determined also describe location of seized product. If same as prior to Seizure / Quarantine, so state.
17. Signature of Representative, Title and Date - Obtain signature and title of the most responsible establishment representative present (this is usually the same person listed in #5) - and enter date.
18. Inspector(s) Signature(s) and Date - Enter information requested.
19. To Contact this Department Concerning this Seizure / Quarantine - The Inspector making the seizure will enter the names and phone numbers for two of the following: the Inspector, the Regional Supervisor, or the Chief Inspector. Home telephone numbers of Department employees will not be given unless prior permission has been obtained. The appropriate Region telephone number should be listed here.

FOOD SEIZURE /QUARANTINE HEARING/WAIVER SECTION

20. Name of Representative, Home Address, Title and Trade Or Corporate Name - A responsible establishment representative should sign their name after the Inspector enters the signer's name, home address, title and trade or corporate name.

This part should be completed if the owner or custodian agrees to waive his/her right to a hearing as described in Section 202-b and agrees to the destruction of the seized product. Should the establishment representative agree to sign a waiver, it is still necessary for the Inspector to complete the "Food Seizure / Quarantine" and "Seizure / Quarantine Information and Inventory Control" portion of the Seizure / Quarantine Notice (FSI-865).

When the establishment representative signs a Food Seizure / Quarantine Hearing Waiver, he/she is agreeing to the destruction of the product involved. Such destruction and disposition shall be carried out only under the direction and immediate supervision of the Inspector. The waiver must be signed prior to any ordered destruction of a food or food product. The Inspector should not

INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095

personally participate in such destruction. However, as indicated above, he/she must observe and direct the destruction.

Whenever all or any portion of the goods described under the "Seizure / Quarantine Notice" portion of the FSI-865 are waived, that particular Seizure / Quarantine Notice (FSI-865) is complete. In such cases, the "... (of seizure no. _____) ..." portion of the "Food Seizure Hearing Waiver" should be struck out so the waiver reads, "...reverse side (hereof) should not be destroyed....". If, at this point, all of the product originally placed under seizure is accounted for, either via destruction or release, the seizure is closed and the original and second carbon copy of the completed report should be submitted together, via supervisory channels, to the Albany Office with the first carbon copy going to the custodian. However, if some product remains under seizure, the Inspector should submit only the second carbon copy to Albany, retaining the original until all of the product is accounted for.

If, at this point, the custodian of the product refuses to waive his right to a hearing, the Inspector should give the establishment operator the first carbon copy of the report and immediately mail the second carbon copy, via supervisory channels, to Albany. The Inspector will keep the original copy until the seizure is closed out, at which time it will also be mailed without delay to Albany through channels.

If, at some subsequent date, the establishment operator agrees to waive the right to a hearing on an additional portion of the seized product, the Inspector would fill out the Food Seizure / Quarantine Hearing Waiver portion of a new Seizure / Quarantine Notice (FSI-865) striking out the Food Seizure and Seizure Information and Inventory Control portions (see Sample 2). In this circumstance, the Inspector would strike out the "(here of)" statement on the report so the waiver reads, "reverse side of seizure no. (list the no. of the original FSI-865) should not be destroyed...." Additional Seizure / Quarantine Notice forms (FSI-865's) must be made out in similar fashion for each separate date on which additional product is waived. A running account of the product disposition will be kept on the "Seizure Inventory Control" portion of the original Seizure / Quarantine Notice (FSI-865) as per instructions numbered 26 through 37 in this Sub-Section.

At such time as all of the product is accounted for as the result of destruction via waiver or release, the original Seizure / Quarantine Notice forms (FSI-865's) made out as the result of additional product destruction, will be attached together and forwarded through channels to the Albany Office, along with Reports of Investigation which should be submitted for each date product was either seized, destroyed, released or the establishment simply visited to check the status of the seized goods. If a sanitary inspection is performed and a Sanitary Inspection Report is submitted on a date when product is either seized or destroyed, a Report of Investigation for that date is not necessary.

INSPECTOR/NOTARY STATEMENT

This section is to be filled in and signed by an Inspector or a Notary Public when a responsible establishment representative has signed the Establishment Representative Consent Section.

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
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21. County of - Enter the name of the county where the document is completed.
22. Day, Month, Year - Enter the date on which the operator waived his/her right to a hearing. There may be two or more dates on which waivers pertaining to portions of the same seized/quarantined lot of product are signed. (See instruction number 19 (above) on the completion of the "Food Seizure / Quarantine Hearing Waiver" section of the FSI-865).
23. Before Me Personally Appeared - Enter the name of the responsible establishment representative.
24. Inspector(s), I.D. No.(s) - Print the Name(s) and I.D. No.(s) of the Inspector(s) who made the original seizure. However, on occasion, when the follow-up investigations and subsequent disposition of products are handled by another Inspector, his/their name(s) and I.D. No.(s) should appear in this space. This, of course, will be the case when the seized product is shipped to another zone or region in the state for salvage.
25. Signature of Inspector or Notary Public - The lead Inspector or Notary Public should sign their name.
26. Central Office Use Only - Do not write in this area.

SEIZURE / QUARANTINE INVENTORY CONTROL INSTRUCTIONS

This part of the report is on the reverse side of the Seizure / Quarantine Notice (FSI-865). (See example, page 12). Its purpose is to keep a running, checkbook-type, account of the seizure and disposition of all products placed under seizure.

27. Commodity and Brand Name - Enter the commodity (common name) and brand name of the product seized.
28. Type - Enter "type" of container - cans, jars, poly bags, bulk, etc.
29. Weight - Enter weight to the nearest 1/2 lb. or to the nearest ounce for those items weighing less than one pound.
30. Number - Enter number of containers.
31. Code(s) - Enter code number(s) (if any) of product as it appears on the container.
32. "Seized"- Lbs. and Mo./Day - Enter total lbs. of product seized and the date.
33. "Destroyed"- Lbs. and Mo./Day - Enter total lbs. of product destroyed and the date.

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095**

34. “Released” - Lbs. and Mo./Day - Enter total lbs. of product released and the date.
35. Bal. Remaining - It is always necessary following each entry in the “Seized,” “Destroyed” or “Released” columns to calculate and enter a new balance in lbs. in the “Balance Remaining” column along with the date.

When the balance reaches zero, the seizure is closed and the remaining paperwork should be forwarded immediately, through supervisory channels, to the Albany Office.

36. Telephone Report Made? “Yes”-“No” - Answer this question every time a Food Seizure and/or Food Seizure Hearing Waiver is completed. If the seizure/waiver information was called in to a regional office, circle “Yes” and show to whom report was made - if not, circle “No.” See the “Telephone Reporting Procedures” instructions on page 9 of this section for additional information.
37. Describe Methods of Destruction - e.g., buried in landfill, container opened and emptied, product denatured with ammonia, etc.
38. Explain Reasons for Release of Seized Goods - e.g., laboratory results indicate product not adulterated, product properly relabeled, undented portion of lot sorted under Inspector's supervision and released, etc.

DAMAGED - SEIZED FOOD NOTICE (FSI-868)

Whenever product is placed under seizure and left in the custodian's care a copy of the Damaged - Seized Food Notice (FSI-868) (see example, page 16) must be presented to the custodian. His/Her name and the fact that he/she received the notice should appear on the Report of Investigation or on the Supplemental Sanitary Inspection Report.

SEIZURE TAGS, PLACARDS & SEALS

Embossed ball type seizure seals must be used on all entranceways to cargo area of any vehicle used to transport seized product. These seals may also be used (at the custodian's request or with his permission) to seal product in a room, refrigerator, freezer, etc. Red “Seizure Notice” placards (FSI-860) (see examples; front, page 13 and back, page 14) and “Seizure Notice” tags (FSI-861) (see example, page 17) should be displayed in close proximity to any seizure seal. Whenever seals are used, their serial number should be recorded on the Report of Investigation or on the Supplemental Sanitary Inspection Report.

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095**

SEIZURE SAMPLING

When seizure samples are taken, do not submit a copy of the Notice of Seizure / Quarantine (FSI-865) with the samples to the Food Laboratory.

DISTRIBUTION INSTRUCTIONS

The first carbon (white copy) will be given to the custodian or establishment representative who signed the report at the time of the seizure.

The second carbon is to be sent to the Central Office, through supervisory channels, immediately. If the seizure is resolved on the day the seizure is made, the second carbon and the original are to be sent together, through supervisory channels, with no delay on the part of the Inspector or Supervising Inspector.

The Supervising Inspector will forward the second carbon, accompanied by a Seizure Routing Slip (FSI-803) bearing the Supervisor's comments and recommendations and routing choices. The Seizure Desk option must always be checked.

The original will be retained by the Inspector as a working copy for all seizures which are not closed on the day of the seizure.

When the seizure is closed, the Inspector will submit the original through supervisory channels immediately. The Supervising Inspector will use the same routing choices for the original as he/she did for the second carbon as described in paragraph 3 of this section.

TELEPHONE REPORTING PROCEDURES

All open seizures, regardless of product value, will be reported by telephone. As used here, open seizures are those where waiver and destruction and/or release of the seized product is not accomplished on the day the seizure is made.

All Recall Project seizures, regardless of product value, will be reported by telephone.

Telephone reporting of seizures will be done as soon as possible on the day the seizure is made.

All telephone reports will be made to the Inspector's assigned Regional Office. The Seizure Clerk will receive telephone or FAX reports from each Regional Office weekly.

The Inspector whose name and number appear on the form first is to be the person responsible for telephone reporting.

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095**

TRANSPORTATION OF SEIZED / QUARANTINED PRODUCT

Except in emergency situations, prior approval for the movement of seized product shall be obtained from the appropriate Zone Supervisor.

In those cases where shipment of the seized product out of State is contemplated, approval shall be obtained from one of the following: the appropriate Chief Inspector, the Director of Field Operations, the Assistant Director or the Division Director.

When product is moved within the State, but across zone or regional boundaries, the Regional Supervisor of the area to which the product is being shipped shall be notified, via telephone, of all the particulars concerning the seizure, along with the destination and estimated time of arrival of the vehicle. The Central Office copy of the Food Seizure / Quarantine Hearing Waiver Report (FSI-865 - pink copy) along with a copy of the Report of Investigation (FSI-30) should be sent with the driver of the vehicle, in a sealed envelope, marked "New York State Food Inspector". The inspector's work copy of the Seizure / Quarantine Notice (FSI-865 - yellow copy) should be forwarded through supervisory channels to the Central Office.

If the custodian or owner of the product remains unchanged, then the Inspector at the receiving point should utilize the copy of the Seizure / Quarantine Notice (FSI-865) which he/she receives from the driver to close out the seizure (when appropriate). He/She should also sign and date the report next to the signature of the Inspector who originally made the seizure, in the area set aside for "Signatures of Inspector and Date."

If the custodian or owner of the product changes when the product reaches its destination, then a new Seizure / Quarantine Notice (FSI-865) should be completed in the name of the new custodian or owner by the Inspector at the receiving point.

When seized product is to be shipped out of State, the Chief Inspector, Director of Field Operations, Assistant Director or Division Director will contact the appropriate governmental authorities in the receiving State advising them of the circumstances surrounding the shipment of the product involved, including the destination, estimated time of arrival, and the seizure seal numbers. They will also request confirmation that the product arrived intact and request the return of the New York State seizure seals and tags. Do not ship a copy of our Food Seizure / Quarantine Report/Food Seizure Hearing Waiver Report (FSI-865) with product being shipped out of State.

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095**

030124 Q

FSI-865 (REV. 2/96) pm5

NYS AGRICULTURE & MARKETS
10B AIRLINE DRIVE
ALBANY, NY 12235

SEIZURE ☐ 1
QUARANTINE ☐

SEIZURE / QUARANTINE NOTICE

PROJECT NO: 4		INSPECTION ☐		COMPLAINT ☐		R.O.I. ☐		DATE: 2	
CUSTODIAN: 5				TRADE NAME:				EST. NO:	
STREET:				CITY:		ZIP:		COUNTY:	
OWNER'S NAME (If different from custodian): 6				TRADE NAME:				EST. NO:	
STREET:				CITY:		ZIP:		COUNTY:	
PERSON INTERVIEWED: 7								TITLE:	
SEIZED PRODUCT MADE OR DISTRIBUTED BY: 8									
SEIZED PRODUCT(S) RECEIVED OR PURCHASED FROM: 9									
NO. OF SAMPLES: 11		FL-NO: 12		FL-NO:		FL-NO:		FL-NO:	
PRODUCT WITHHELD FROM SALE OR USE PRIOR TO SEIZURE: 14		YES ☐ IF YES, EXPLAIN WHY: 15				INVOICE/BILL OF LADING NO. AND DATE: 10		DATE SAMPLES SENT TO LAB: 13	
DESCRIBE PRODUCT, REASON FOR SEIZURE AND LOCATION AT TIME OF SEIZURE: 16									
It is a violation of the Agriculture and Markets law for any person to remove or dispose of such seized food or food products by sale or otherwise without the permission of the Department of Agriculture and Markets. You may wish to review these matters with your legal representative. Your signature indicates you have received a copy of this notice.									
SIGNATURE OF REPRESENTATIVE: 17				TITLE:		DATE:			
INSPECTOR(S) SIGNATURE(S): 18						DATE:			
TO CONTACT THIS DEPARTMENT CONCERNING THIS SEIZURE, CALL: 19 AT: () OR AT: ()									
FOOD SEIZURE/QUARANTINE HEARING WAIVER									
ESTABLISHMENT REPRESENTATIVE CONSENT SECTION. Execution of this waiver must always be acknowledged before an Inspector, Notary Public or other authorized person.									
I, 20, residing at (Name) (Street, City, State, Zip)									
the (Owner, Manager, Agent or Other Title) of (Trade or Corporate Name) hereby waive a notice and a hearing, as provided in Section 202-b of the Agriculture and Markets law, as to why seized products designated as waived on the reverse side (hereof) (of Seizure no.) should not be destroyed and hereby consent that such goods be destroyed and further agree to destroy such goods forthwith without the hearing therein provided for.									
Signature of Representative: _____									
STATE OF NEW YORK SS:									
County of 21									
On this 22 day of (Month) (Year), before me personally appeared 23, to me personally known and known to me to be the individual described in and who executed the foregoing instrument for the purpose stated therein and that he executed the same before me, and he, being by me, duly sworn, deposes that he has read the foregoing waiver and the same is true in every respect.									
Inspector(s) name(s) (Print): 24				ID No(s.):		25			
						Signature of Inspector or Notary Public			
Central Office Use Only									
1. In: Seized		Destroyed		26		Released			

DISTRIBUTION: Yellow; Inspector's work copy (To Central Office when action complete); white; to the establishment; Pink; to the Central Office.

FSI-865B (Rev. 2/96) pm5

[illegible]

INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095

SEIZURE NOTICE

RETAINED FOR FURTHER DETERMINATION

This food or product is suspected of being misbranded or adulterated

COMMODITY _____

AMOUNT _____ SEIZURE No. S-_____

OWNER OR
CUSTODIAN _____
(Name and Address)

This food, food product or related articles are not to be removed
or disposed of by sale or otherwise without permission of the New
York State Department of Agriculture and Markets.

Removal is a violation of the Agriculture and Markets Law.

DATE _____ INSPECTOR _____

FSI 860

INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095

SEIZURE NOTICE

**New York State
Department of Agriculture and Markets**

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095**

FSI-864 (REV. 6/06)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE, ALBANY, NY 12235

**FIRE - FLOOD - WRECK
NOTICE**

PLEASE CALL

INSPECTOR _____ TEL. NO: _____
OR
SENIOR INSPECTOR _____ TEL. NO: _____

CONCERNING

FOODS INVOLVED IN FIRES, FLOODS OR WRECKS IN YOUR AREA

TO PERMIT OFFICIAL INSPECTION FOR POSSIBLE CONTAMINATION.

THANK YOU FOR HELPING US KEEP ONLY SAFE, PURE FOODS ON THE MARKET IN NEW YORK STATE

FSI-864 (REV. 6/06)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE, ALBANY, NY 12235

**FIRE - FLOOD - WRECK
NOTICE**

PLEASE CALL

INSPECTOR _____ TEL. NO: _____
OR
SENIOR INSPECTOR _____ TEL. NO: _____

CONCERNING

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TO PERMIT OFFICIAL INSPECTION FOR POSSIBLE CONTAMINATION.

THANK YOU FOR HELPING US KEEP ONLY SAFE, PURE FOODS ON THE MARKET IN NEW YORK STATE

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095**

FSI-868 (REV. 6/92)

**NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION**

DAMAGED - SEIZED FOOD NOTICE

DAMAGED FOOD

IT IS ILLEGAL FOR ANY PERSON WITHIN THE STATE OF NEW YORK TO
POSSESS, SELL, OFFER OR EXPOSE FOR SALE ADULTERATED OR
MISBRANDED FOOD.

FOOD AND FOOD PRODUCTS WHICH HAVE BEEN INVOLVED IN A FIRE, FLOOD, WRECK OR
OTHER DISASTER MAY HAVE BECOME ADULTERATED AND MUST BE CAREFULLY EXAMINED
AND, IF NECESSARY, RECONDITIONED BEFORE BEING OFFERED FOR SALE.

RECONDITIONING MAY ONLY BE DONE BY THE OWNER AND HIS EMPLOYEES OR BY A
LICENSED FOOD SALVAGER.

A LIST OF LICENSED FOOD SALVAGERS IS ATTACHED

RECONDITIONING AND LABELING

All metal cans offered for sale shall be free from rust and rim and/or seam dents. Springers, flippers and swells shall be deemed to be unfit for sale or use. Food containers having press caps or screw caps that have been totally immersed in water as the result of fire, flood or similar mishap shall be deemed unfit for sale or use.

All metal cans or tins of food which have been partially or totally submerged in water as the result of flood, sewer backup or other reasons shall, after cleaning, be subjected to a sanitizing rinse of a concentration of 200 PPM available chlorine for a minimum period of one minute, or shall be sanitized by other approved methods. They shall subsequently be treated to inhibit rust formation. All other types of packages so damaged shall be deemed unfit for use or sale.

Any cans or tins showing excessive rust shall have labels removed, the outer surface reconditioned by buffing, a protective coating applied where necessary and shall be relabeled. Relabeling of other types of containers shall be required where the circumstances require.

All salvaged foods and food products in containers are to be provided with labels meeting the requirements of Section 201 of Article 17 of the Agriculture and Markets Law. Where original labels are removed from containers which are to be resold, salvager replacement labels must show the name of the salvager as the distributor.

SEIZED FOOD

DEPARTMENT OF AGRICULTURE AND MARKETS EMPLOYEES ARE AUTHORIZED BY LAW TO SEIZE
FOOD OR FOOD PRODUCTS WHICH ARE SUSPECTED OF BEING ADULTERATED OR MISBRANDED.

IT IS A VIOLATION OF THE AGRICULTURE AND MARKETS LAW TO REMOVE OR DISPOSE OF SEIZED
MERCHANDISE WITHOUT PERMISSION OF THE COMMISSIONER OF AGRICULTURE AND MARKETS OR HIS
AUTHORIZED REPRESENTATIVES.

THE OWNER OR CUSTODIAN OF SEIZED FOOD HAS THE RIGHT TO A FORMAL HEARING PRIOR TO
THE DESTRUCTION OF SEIZED PRODUCT. THE HEARING MAY BE WAIVED BY THE OWNER OR CUSTODIAN
WHERE THERE IS A VOLUNTARY WRITTEN AGREEMENT TO PROPERLY DESTROY THE SEIZED MERCHAN-
DISE.

**INVESTIGATIONS
FOOD SEIZURES, QUARANTINES AND WAIVERS
SUB-SECTION 2095**

FRONT

FSI-861 (Rev. 1/96)pm5

SEIZURE NOTICE
RETAINED FOR FURTHER EXAMINATION

Commodity _____

Amount _____

Dealer _____

Not to be removed until released by N.Y. State Department of
Agriculture and Markets

Date _____ Inspector _____

BACK

SEIZURE NOTICE

N. Y. STATE DEPARTMENT OF AGRICULTURE
AND MARKETS

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**FIELD OPERATIONS MANUAL
MULTI-ESTABLISHMENT PROJECT REPORT (FSI-27)
SUB-SECTION 3000**

OVERVIEW

The purpose of this report form is to provide a procedure to document official visits to a number of establishments for a common purpose, such as: damage assessments, recall advisories, product surveys, etc.

ADMINISTRATIVE RESPONSIBILITIES

When an event occurs that should be responded to by investigations or surveys at a number of establishments a responsible person at or above the level of Zone Supervisor will initiate a multi-establishment activity. The Supervising Inspector shall be kept fully informed of the project activity. The Zone Supervisor or Chief Inspector assigned to head the project will have several important tasks to complete:

1. Request a "Project Number" from the Director of Field Operations.
2. Assign a "Project Name" to the task.
3. Compose a "Job Description" to fully explain to the field staff assigned to the project what is required to properly complete the project. It would be helpful if the responsible person provided an example of the reporting format that would best suit the circumstances.
4. Compose a brief and concise "Task" statement describing what the project is and why it is being done, i.e., Newburgh water supply contaminated by a parasite, Giardia Lamblia, ordering food dealers to boil water; or Hurricane damaged Long Island on 10/1/89, conducting damage assessment survey; or a Fire at Logan Circle Mall on 11/2/89, conducting damage survey and initiating appropriate action as required.
5. Give the Project Number, Project Name, Job Description and the "Task" statement to the assigned Inspector(s) during a pre-project discussion.
6. Monitor the progress and completion of the project.

FIELD STAFF RESPONSIBILITIES

1. The assigned Inspector(s) should make sure they have received a Project Number, a Project Name, a Job Description and a "Task" statement.

FIELD OPERATIONS MANUAL
MULTI-ESTABLISHMENT PROJECT REPORT (FSI-27)
SUB-SECTION 3000

2. Complete the project using the information provided.
3. The multi-establishment project report is completed electronically. The word template of the multi-establishment project report (FSI 127) should be saved to your "My Documents" file or the F: Drive. Once that is done you can complete it on the computer. Just click on an information box and type in the requested information. Then proceed with E-mailing it as an attachment to the Supervising Inspector, who will type his/her name in the "reviewed by" section at the bottom. They will then forward it on to the Chief Inspector for review. The Region Chief, after review, will forward it by E-mail to appropriate Central Office Personnel.

PROJECT NUMBER

A six-digit Project Number is assigned for each separate multi-establishment activity through the Director of Field Operations. Call and advise the Director of Field Operations of the nature of the project and a Project Number will be assigned.

The first two digits represent the project category (see the chart below). The second two digits represent the number of times the project category has occurred to date.

The third two digits represent the year the activity takes place, i.e., the Project Number 012590 means twenty-five recall projects were completed, to date, in 1990. The number 040290 means two flood damage assessments or surveys were completed, to date, in 1990.

The Project Numbers are the primary identifier for data entry, filing and statistical analysis and are issued sequentially. Hence, a recall project number of 010190 might be assigned to a project in the city of Utica, 010290 may be in use in all of Long Island and 010390 may be assigned to a statewide project. All separate projects, but, all occurring during the same time period.

An emergency, requiring a multi-establishment activity, may occur at anytime. The Zone Supervisor or Chief Inspector should not wait to get a Project Number before initiating action. This can be done later. However, a written or verbal Project Name, Job Description and Task Statement must be provided to the field staff so they will understand what needs to be done.

<u>Project Categories And Numbers</u>

FIELD OPERATIONS MANUAL
MULTI-ESTABLISHMENT PROJECT REPORT (FSI-27)
SUB-SECTION 3000

Project	No.	Project	No.
Recall	01	Other Disasters	06
Advisory	02	Licenses	07
Fire	03	Economics	08
Floods	04	Compliance	09
Storms	05	Other	10

PROJECT NAME

A “Project Name” is always used in conjunction with the “Project Number” for filing, processing, etc. The “Project Name,” designated by the Zone Supervisor or Chief Inspector should be simple, concise and descriptive of the activity, i.e., Long Island Hurricane Damage Survey, Chinese Mushroom Recall Advisory, Egg Breaking Machine Use Investigation.

JOB DESCRIPTION

The “Job Description” is an outline, prepared by the Zone Supervisor or Chief Inspector, specifying what needs to be done to properly complete the multi-establishment project. It should include, if possible, an example of the reporting format to be used. The example should make a logical listing of information required.

Since the “Job Description” and the example (if included) will determine the quality and accuracy of information returned from the field, it is important these sections are clearly and carefully structured. The circumstances of the activity will dictate whether a job description and the example will be simple or relatively complex.

TASK

A Task statement is a brief, concise description of what the project is and what is being done. This information is provided by the project leader and is entered in the TASK area of the report form by the Inspector.

A SAMPLE MULTI-ESTABLISHMENT PROJECT

FIELD OPERATIONS MANUAL
MULTI-ESTABLISHMENT PROJECT REPORT (FSI-27)
SUB-SECTION 3000

A fire occurs in a large shopping center. There are many stores and kiosks in the center under FSI jurisdiction. The Zone Supervisor and/or Chief Inspector determines a multi-establishment fire damage survey would be the appropriate action. The Director of Field Operations is contacted and assigns the Project Number 030190. The Project Name of "Logan Circle Mall Fire Damage Survey" is given by the Zone Supervisor or Chief Inspector. The Job Description prepared by the Zone Supervisor, or Chief Inspector says: "Visit each establishment in the mall under FSI jurisdiction. If there is no damage present at an establishment enter "No Damage" following the establishment information. If damage has occurred, type a concise description of the extent of damage, the corrective action by the establishment and Division action, if any."

The Task statement says: "Fire at Logan Circle Mall on 11/2/89. Conducting a damage assessment survey and initiating appropriate action as required."

The Example given shows:

010666, Brown Deli, Inc., John Brown, Pres. - No damage
010787, Brown, Peter, John Jones, Asst. Mgr.
Est. suffered moderate smoke damage. Store crew busy cleaning canned and packaged foods. No exposed foods. Left copy of FSI-868 with the Asst. Mgr.

The assigned Inspector completes the project using the Project Number, the Project Name, the Job Description, the example and the Task Statement provided by the Zone Supervisor or Chief Inspector.

FORM COMPLETION (FSI-27)

(see Example Form FSI-27 on Page 7)

1. Project Number - Enter this number here when received.
2. Project Name - Enter the name here.
3. Day of - Use a new form each day if the project goes beyond one day. Type in this box on each form to indicate the sequential number of each day and the total number of days involved.
4. Page N of N - If more than one form of the Multi-Establishment Project Report form (FSI-27) is used, whether on one day or more, type in this box to indicate the sequential number of each form and the total number of forms involved.
5. Region and Zone Numbers - Enter the appropriate numbers.

FIELD OPERATIONS MANUAL
MULTI-ESTABLISHMENT PROJECT REPORT (FSI-27)
SUB-SECTION 3000

6. Date - Enter the date the activity takes place. If the activity goes beyond one day a new cover form, listing the correct date, will be filled out for each subsequent day.

If more than one form is needed to complete a project subsequent form headings will be completely filled out as indicated in Items 1 through 6.

7. Task - When starting a project the Inspector should enter in the Task section of the first page only (regardless of how many subsequent forms there may be) a brief, concise synopsis of the project, i.e., "Fire occurred at Logan Circle Mall on 11/2/89. Conducting damage survey and initiating appropriate action as required."
8. Remarks - All establishment information will be entered in the Remarks section of the report form. The Inspector will enter only:

- A. The establishment number
- B. The owner's name
- C. The name and title of the person interviewed

If the facility does not have an establishment number then it will be necessary to enter:

- D. The county code of the establishment
- E. The owner's name
- F. The trade name
- G. The street, city and ZIP code
- H. The name and title of the person interviewed

Complete the project using the information and example provided. All narrative information should be typed concisely using repetitive phrases where possible in each establishment entry to facilitate review.

If a seizure or sanitary inspection or other activity takes place requiring completion of other documents relating to the project enter a concise notation in the Remarks Section; e.g., "See the Report of Investigation (ROI)," "See S-145666-A," "See the Sanitary Inspection Report (SIR)," etc.

These documents should be paper clipped to a hard copy of the Multi-Establishment Project Report form. The Project Name and Project Number should be entered in the upper right edge of the attached reports.

FIELD OPERATIONS MANUAL
MULTI-ESTABLISHMENT PROJECT REPORT (FSI-27)
SUB-SECTION 3000

If the other activity requiring completion of other reports does not relate to the project the completion of these reports should not be mentioned in the Project Report unless the Inspector feels there is a compelling reason for doing so.

9. Initial - Check this box if this report constitutes an original multi-establishment project.
10. Follow-Up - Check this box if this report follows after the original multi-establishment activity.

A follow-up should be conducted only when two or more establishments involved in the original activity are revisited in connection with conditions or circumstances related to the original action. In this case, the Project Number and Project Name would be the same as the original.

The Job Description may be a modification of the original, i.e., revisit each establishment involved in the “Logan Circle Mall Fire Damage Survey” to determine compliance with Department regulations. If not in compliance take appropriate action.

The responsible Zone Supervisor or Chief Inspector may provide a format for the Inspector to follow when reporting this follow-up activity.

On a follow-up activity the Task statement may also be modified, i.e., Logan Circle Mall fire follow-up to determine if damaged foods are properly handled.

If “appropriate action” taken during a “follow-up” activity requires completion of other documents relating to the project enter a concise notation in the Remarks Section, i.e., See the Report of Investigation (ROI), See S-145666-A, See the Sanitary Inspection Report (SIR). These documents should be paper clipped to the rear of an electronic copy of the Multi-Establishment Project Report form. The Project Name and Project Number should be entered in the right upper edge of the attached reports.

If the action taken during the “follow-up” activity requiring completion of reports does not relate to the project the completion of these reports should not be mentioned in the “follow-up” report unless the Inspector feels there is a compelling reason for doing so.

A Multi-Establishment Project follow-up is not appropriate when the Inspector is returning to an establishment to continue an activity not related to the project purpose that was started during the original visit.

11. Inspector's Name and Number - Type your name and assigned Inspector's I.D. Number.
12. Hours Spent - Enter the total time spent each day on the project. Do not include travel time.

**FIELD OPERATIONS MANUAL
MULTI-ESTABLISHMENT PROJECT REPORT (FSI-27)
SUB-SECTION 3000**

13. Reviewed By: The Supervisor reviewing the report will type his/her name in the box.

FIELD OPERATIONS MANUAL
MULTI-ESTABLISHMENT PROJECT REPORT (FSI-27)
SUB-SECTION 3000

FSI-27 (Rev. 3/06)

PROJECT NUMBER **1**

9 ☐ INITIAL ☐ FOLLOW-UP **10**

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE, ALBANY, NEW YORK 12235

MULTI - ESTABLISHMENT PROJECT REPORT

DATE: 6	REGION: 5	ZONE:	DAY 3 OF	PAGE 4 OF
PROJECT NAME: 2				
TASK: 7				
REMARKS: 8				
INSPECTOR:		ID NO.: 11	HOURS SPENT: 12	
REVIEWED BY: 13				

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**INVESTIGATIONS
RECALL ACTIVITIES
SUB-SECTION 3005**

OVERVIEW

The removal from distribution or a field correction of a marketed food product, including its labeling, that this Agency considers to be in violation of the laws that it administers, and against which we would initiate legal action and seizure, is a Recall.

The recall of a food product from market distribution, and sometimes even from the purchaser, can be extremely difficult, costly and could involve litigation. A product recall may be initiated on a voluntary basis (1) by the company or (2) by result from a regulatory agency or (3) by a court order.

The Department does not have the authority to order a firm to initiate a recall of a violative product.

RECALL DISTRIBUTION

Class I

This is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. A Class I Recall necessitates the following:

1. Notification of FDA
2. Recall to consumer or user level
3. Product placed on FDA's public recall list
4. Public warning be used via news media
5. 100% removal from all direct accounts and sub-accounts and if necessary, from the possession of consumers

Examples of Class I Recalls: Products found to contain undeclared sulfites, products contain *Listeria Monocytogenes*, product contains undeclared peanuts; uneviscerated processed fish.

Class II

This is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class II Recall necessitates the following:

1. Notification of FDA
2. Recall product to retail or dispensing level

**INVESTIGATIONS
RECALL ACTIVITIES
SUB-SECTION 3005**

3. Product placed on FDA's public recall list
4. Press release announcing the recall, when public interest requires
5. "Effectiveness check" varies according to the degree of consumer hazard associated with the product

Examples of Class II Recalls: Products found to contain undeclared Yellow #5; product did not receive a complete thermal process; cans are detinning; potential microbiological contamination exists.

Class III

This is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. A Class III Recall necessitates the following:

1. Notification of FDA
2. Recall product to wholesale level
3. Product mentioned on FDA's public recall list
4. Ordinarily, no press release; company may be contacted by news media because of FDA's public recall list mentioning
5. "Effectiveness check" varies according to degree of consumer hazard associated with the product

Examples of Class III Recalls: Product is contaminated with yeast or mold; product is off color possibly due to the presence of *Aspergillus niger*; product is adulterated due to decomposition.

DEPTH OF RECALL

Depending on the product's degree of hazard and extent of distribution, the recall strategy should specify the level in the distribution chain to which the recall is to extend.

Recall depth is defined as:

1. Consumer or user level: product in consumer's hands or home shelves. The levels below are included in this level.
2. Retail level: product in possession of retailer, in immediate retailer warehouse or storage. The level below is included in this level.
3. Wholesale level: product in possession of wholesaler and not in direct control of manufacturer.

EFFECTIVENESS CHECKS

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The purpose of effectiveness checks is to assure that all receivers, purchasers or users of the product at the recall depth specified by the strategy have received notification of the recall and have taken appropriate action. Individuals should be contacted by personnel visits, telephone calls, letters or any combination thereof. The recall strategy will specify the method(s) to be used and the level of effectiveness check as follows:

Level A - 100 percent of the total number of users, etc., contacted

Level B - a percentage of users contacted to be determined in each recall, less than 100 percent but greater than 10 percent

Level C - 10 percent of total number of users contacted

Level D - 2 percent of total number of users, etc., contacted

Level E - No effectiveness check

RECALL PROCEDURE

1. Identification of Potential Recall Situation:

All consumer complaints, notifications from a distribution channel/co-packer; communications from a regulatory agency or a company discovery in its own records (indicating product that should be withdrawn from distribution) shall be channeled to the Recall Coordinator. The Recall Coordinator in most cases, will be the Zone Supervisor.

2. Assessment of Potential Recall Situation:

A. The Recall Coordinator shall substantiate that a problem exists by obtaining relevant facts via:

1. Inspection or investigation results
2. Laboratory results on the suspect product
3. Examination of other lots, shipments, labels and records

B. The Recall Coordinator shall immediately assess the situation and determine whether a recall is appropriate and should determine:

1. The Recall Class
2. The Depth of the Recall
3. Type of public warning (if appropriate)
4. Methods and the appropriate level of "effectiveness check"

C. After discussing the matter with the Chief Inspector and/or Director of Field Operations, the Zone Supervisor shall proceed in conducting the Recall.

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3. Steps to Conduct a Recall:

- A. Notify the FDA district office in your area if they are not aware of the problem. Have the following information prepared as completely as possible but do not delay FDA notification if all information is not immediately available:
 - 1. Identity of the product involved
 - 2. Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
 - 3. Evaluation of the risk associated with the deficiency or possible deficiency
 - 4. Total amount of such products produced and/or the time span of the production
 - 5. Total amount of such products estimated to be in distribution channels
 - 6. Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts. This is to include name, address, and telephone number.
 - 7. A copy of the firm's recall communication, if any have been issued, or a proposed communication, if none have been issued (see Recall Letter Requirements on Page 7)
 - 8. Proposed strategy for conducting the recall
 - 9. Name and telephone number of the firm official who should be contacted concerning the recall
 - 10. For imported product(s), obtain pertinent invoice(s), bill of lading(s), and custom entry summary form(s)
- B. Notify appropriate local/state regulatory agency, i.e., State Health Department, State Agriculture Department (out of state).
- C. Notify all distribution points by telephone, or in person, regarding all suspect product codes/label brands/package sizes, etc.
- D. Maintain a running record of the recalled units accounted for as a check on the effectiveness of their removal from the distribution chain. Compare the recalled tally to the total number of units manufactured.

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- E. Notify the FDA District Office of the effectiveness check results on product removal from distribution.
- F. Make sure products to be disposed of are done so in an appropriate fashion.
- G. Coordinate all reports including inspection/investigation reports, food sampling reports, recall letters, invoices, distribution records, etc., and submit them along with a completed NYS Recall Tracking Report to the Director of Field Operations through normal supervisory channels.

FORM COMPLETION

(See Example NYS Recall Tracking Report Form (FSI-) on Page 8)

- 1. Project No.: - Enter this number here when received (if applicable).
- 2. Date: - Enter the date the recall was completed.
- 3. Recalling Est.: - Enter the name of the establishment recalling the product.
- 4. Est. No.: - Enter the assigned Establishment Number, if known. If not known or no number has been assigned, enter the County Code. Leave the remaining boxes blank.
- 5. Trade Name: - Enter the trade name of the establishment, if applicable.
- 6. Street: - Enter the physical street address at which the investigation took place.
- 7. City: - Enter the name of the city (town, village, etc.) where the investigation took place.
- 8. Zip Code: - Enter the correct five-digit Zip Code.
- 9. Est. Rep.: - Identify the responsible person from the recalling establishment charged with completing the recall. For Class I recalls, the name of the corporate president shall be identified.
- 10. Title: - Enter the title of the establishment representative.
- 11. Telephone: - Indicate the telephone number of the establishment representative from the recalling firm.
- 12. Inspector's: - The recall coordinator signs his/her name on this line.

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13. ID No.: - Enter the Identification Number of the recall coordinator conducting the recall.

Numbered Sections of the Report as Follows:

1. Product: - Identify the brand name along with the product, package type, and net weight (i.e., ABC corn in 16 oz. cans). Check whether the product is imported or domestic. Identify sample number.
2. Code: - List the container code(s) if available.
3. Importer/Manufacturer: - List the name and address of the importer and/or manufacturer if different from the recalling firm.
4. Reason for Recall: - Describe the product defect and violation. Check the appropriate sub-sections and/or provide explanations relative to lab reports, inspection findings, injuries or complaints and audit checks.
5. Distribution Pattern: - Indicate the number of direct accounts, type of consignee, number of sub-accounts, and type of sub-account.
6. Volume of Product in Commerce: - Indicate the volume of product in commerce.
7. Volume Recovered and Status: - Indicate the volume of product recovered and its status.
8. Disposition of Product Under Recall: - Check the appropriate section concerning product disposition, return or correction. Indicate the appropriate dates.
9. Date and Method of Notification: - Indicate the date and method that accounts were notified of the recall.
10. Establishment's Planned Recall Procedure: - Describe firm's planned procedure. Comment on the adequacy of this strategy and evaluate the firm's ability to effect recall.
11. Audit Program: - State what actions have already been taken (inspections, sample collections, etc.). Provide specific recommendations for action where indicated. Provide details of any publicity issued whether by the firm, the state, or local government.

**INVESTIGATIONS
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All reports relative to the Recall investigation shall be submitted to the Director of Field Operations in the Albany Office.

RECALL LETTER REQUIREMENTS

The following information is required on all Recall letters:

1. Recalling firm's name, address and telephone number
2. Product(s) being recalled
3. Product packaging and container size
4. Product manufactured/distributed by
5. Container coding affected by the recall
6. Reason for the recall
7. Procedures for returning the recalled product
8. Sub Recall action
9. Requested response
10. Notation "Urgent" Food Recall

[illegible]

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**CONSUMER COMPLAINT INVESTIGATIONS
RECEIVING, PRIORITIZING, ASSIGNING AND INVESTIGATING
COMPLAINTS
SUB-SECTION 3020**

OVERVIEW

New York State takes pride in the safety and wholesomeness of foods consumed by its residents. The Division of Food Safety & Inspection plays a vital role in monitoring the safety and wholesomeness of food products produced and purchased in New York State. To ensure the continued safety of our food supply it is the responsibility of every Inspector to thoroughly investigate allegations of food borne illness or injury, and sanitation concerns as they relate to establishments regulated by our Division.

RECEIVING COMPLAINTS

All consumer complaints will be received and recorded by Regional Office Support Staff and/or Supervisory personnel (Supervising and Chief Inspectors) using the Electronic Consumer Complaint Tracking System – Central Office Version.

The recorder shall obtain and document the minimum necessary contact information, i.e. name, address, telephone number of the complainant, establishment information, and the complaint description and assign the complaint (as dictated by the Inspector establishment territories established within the zone) to an Inspector(s) by full completion of the Complaint Information Tab field and required fields to receive an auto-generated Case Number.

The complaint report will be sent electronically to the assigned Inspector(s) by checking the Send To Inspector box. The Inspector will receive the complaint upon the next synchronization of the Consumer Complaint Tracking System – Field Version.

ASSIGNING AND MONITORING COMPLAINTS FOR INVESTIGATION

Supervising Inspectors shall monitor all complaints that require investigation and provide additional recommendations as warranted in the Supervisors Tab of the Electronic Complaint Report. Complaints should be prioritized using the following criteria:

- Complaints involving a food illness shall be investigated immediately.
- Complaints that involve critical deficiencies in establishments under our jurisdiction shall be investigated as soon as possible.
- In most cases, complaints involving establishments where critical deficiencies are pending need not be investigated until the next scheduled reinspection unless at the

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discretion of the Region Chief or Zone Supervisor the allegations warrant immediate action.

- Complaints involving general deficiencies shall be handled promptly by conducting an investigation at the establishment. Supervisors shall periodically monitor complaints within their Zone, and shall obtain a status of the complaint investigation for any complaints that have not been completed in a timely manner, as based on the nature of the complaint allegations.
- Complaints that are handled by contacting the establishment's management via telephone, in lieu of an investigation at the establishment will be documented in the appropriate sections on the Electronic Consumer Complaint Report.

HEALTH DEPARTMENT NOTIFICATION

The Supervisor shall provide notification of any reported illness to the appropriate health agency for their information and to obtain the complainants' food history. Documentation shall be made in the Referral Tab of the complaint report that includes the *Date* and *Agency*, and method of notification. A printed copy of the initial complaint report shall be made available to the appropriate Health Agency.

The appropriate city, county, or state health department will always be advised immediately if the following criteria are present:

1. The circumstances seem to support the complainant's supposition that a food caused the illness,
and/or
2. The illness is confirmed by a physician's diagnosis,
3. In the case of chemical poisonings, one or more people are involved,
4. In the case of any other type of food borne illness, two or more people are involved.

The name of the health *Agency*, the name of the *Contact* person, and *Contact Date* will be entered in the Referral Tab of the Electronic Complaint Investigation Report.

INVESTIGATING COMPLAINTS

If an establishment which is the subject of the complaint is due for a full inspection it shall be completed in conjunction with the complaint investigation. If an establishment, which is the subject of the complaint, is due for a reinspection, a full or limited

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reinspection (as dictated by Compliance Unit parameters regarding reinspection protocol) shall be conducted along with the investigation of the complaint.

If the establishment is not due for an inspection, a limited in scope inspection may be conducted which is restricted to the investigation of the alleged deficiencies. This inspection should be identified as an “Inspection” and the memo section of the inspection report should state as follows: “Limited in scope inspection pursuant to consumer complaint involving (list issues). If during the course of the limited inspection, one or more critical deficiencies are noted, then a full inspection is to be conducted.

When the complaint involves a food product issue that is likely to be unrelated to sanitation at the establishment, an inspection is not warranted (i.e. a sealed food container that has a foreign object, where the problem is likely to have originated at the manufacturer), unless they are due for a routine sanitary inspection.

COMPLAINANT INTERVIEW

The complainant shall be interviewed as soon as possible after receiving the complaint. In most cases, this can be accomplished by telephone. Information obtained during the interview of the complainant shall be documented in the Complainants Investigation within the Electronic Consumer Complaint Report. If after several attempts contact cannot be made (no answer, busy, left message), your efforts to contact the complainant shall be documented in the complainant investigation within the electronic consumer complaint report. The Inspector shall document a reason that contact was not made with the complainant in the Text Box of the complaint.

Do not choose sides while conducting the investigation. You should not act as a go-between for the complainant or the establishment. If the complainant wants reimbursement for a product, or seeks legal relief, it is their responsibility to initiate these actions, not yours.

Do not make any statements regarding an establishment's history or conditions.

Complaints that are the responsibility of other agencies shall be forwarded to the appropriate agency as soon as possible and documented in the referral tab of the complaint report. This can be accomplished via telephone, FAX or mail.

SUBMITTING SAMPLES WITH A COMPLAINT

When it is necessary to submit food products to the Food Laboratory for analysis a Report of Investigation that provides sufficient detail regarding the circumstances

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concerning the complaint and requested analysis or a copy of the printed complaint report shall accompany the FL Report. It is necessary that the complaint case number is documented on the FL Report and accompanying Report of Investigation.

When it is necessary to examine the complainant's food product:

1. Examine the product organoleptically. If it contains foreign matter - worms, insects, metal, straw, etc. which you can identify, there is no need to send the consumer sample to the laboratory for analysis.
2. Obtain all necessary information concerning the product from the product label i.e.. Name and address of the manufacturer and/or distributor, container codes, USDA establishment number, date of purchase etc., and document this information in the appropriate fields on the electronic consumer complaint report.
3. If you cannot identify the foreign material or problem with the product, a sample of complainant's product may be submitted to the laboratory for analysis. Inform the complainant that the laboratory analysis may be considered unofficial since the product container has been opened prior to submission for analysis. If the complainant requests their consumer sample and/or product container be returned to them, document this on the FL Report as well as the ROI or complaint report submitted with the sample.
4. If the complaint involves a foodborne illness outbreak, you should coordinate the taking of consumer samples with the responsible health agency.
5. In cases where it is necessary to conduct a follow up investigation at the establishment, you should look for the same coded product. Examine the product organoleptically. If it is found to be adulterated or misbranded, it should be placed under seizure and the custodian notified of their right to a Hearing to consider the disposition of the seized product. If the custodian waives the right to a Hearing and voluntarily destroys the product, samples need not be sent to the laboratory for analysis. If the same coded product is not available, in most cases, it is not necessary to submit similar coded product to the laboratory for analysis.
6. When submitting samples in other than manufacturer's container, indicate whether or not the sample was selected from the manufacturer's sealed or open container or obtained from a container packed by the retailer.

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7. When the complaint involves deteriorated ground meats, you should take a sample of the product in question for analysis. However, sampling alone is not enough - you should conduct a sanitary inspection of the meat department and report any deficiencies found.
8. When the complaint involves spoiled, decayed, rotten or off-condition produce, it should be forwarded to the appropriate Farm Products Unit.
9. If your investigation reveals product contamination by insects or rodents, your report should show whether examination of adjoining products on the shelf and in the storage area revealed contamination. In the case of canned products, you should indicate whether examination of like product on the shelf, storage area and morgue area revealed evidence of swells, flippers, leakers, etc.
10. If your investigation reveals a suspect food tampering problem, refer to the Reference/General Information Section, Sub-Section 6040, Consumer Product Tampering, for procedural information.
11. Prior to conducting an inspection you should identify yourself to the manager or most responsible person present and state the nature of your visit. **Never reveal the name and address of the complainant to establishment representatives.**

FOLLOW-UP ACTIVITY

If your investigation reveals that the product was likely to have become adulterated prior to entering the retail establishment you should follow through by visiting the distributor and/or manufacturer, if located in your area. If they are located elsewhere, notify your Supervisor right away for appropriate follow-up action to be arranged.

The Supervisor, utilizing the Central Version of the Consumer Complaint Tracking System can assign additional follow-up investigations, if the product is manufactured or distributed by an establishment in New York State under our jurisdiction. In cases where follow-up investigations are required out of the Supervisors assigned Zone, the investigation shall be assigned to the Chief or Supervisor in the appropriate Region or Zone. A follow-up e-mail shall be made by the Supervisor requesting the follow-up to the Chief Inspector and/or Supervisor responsible for the establishment requiring follow-up such that the investigation may be appropriately reassigned within the Zone.

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RECORDING INVESTIGATION RESULTS

The details of the complaint investigations are to be recorded in the assigned case number of the Electronic Consumer Complaint Report utilizing the Consumer Complaint Tracking System - Field Version.

It is important that the information obtained is documented in the appropriate investigations within the complaint report. Information obtained from contact or visit with the Complainant shall be recorded in the Complainant Investigation and information obtained from the investigation of the complaint at the establishment shall be recorded in the Establishment Investigation.

REVIEW OF INVESTIGATION RESULTS

The case will be automatically forwarded to the Supervisor for review when all investigations within the complaint case (Complainants Investigation, Establishments Investigation, and Additional Assigned Investigations) are checked completed as “Y”.

Supervisors shall review the reports for completeness, spelling and grammar as well as the content of the investigation to determine that the complaint has been satisfactorily investigated. Modifications to the report may be made by the Supervisor, in the case of minor spelling and/or grammatical errors. The Supervisor will check the “Reviewed by Supervisor” box only when satisfied that the report has been satisfactorily completed and the complaint has been satisfactorily investigated.

RETURNED REPORTS

After review of the report the Supervisor may require that additional information to be provided. The Supervisor may change the status of an investigation within the complaint report by changing the *Investigation Completed* box from “Y” to “N” to return this complaint to a status of “uncompleted”. The Supervisor will provide an email to the Inspector detailing the case number and the additional information requested.

RESUBMITTED REPORTS

When the additional information requested is obtained and recorded by the Inspector, the Inspector will once again check the *Investigation Completed* box to “Y”. The report will then be electronically forwarded to the Supervisor for review upon the next synchronization of the Inspector’s complaint program.

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REFERRALS TO OTHER AGENCIES

The Zone Supervisor shall determine if a referral is warranted and to make and document any referrals that may be made for the complaint investigation. The Supervisor shall record referrals made to other agencies or divisions, for the purpose of providing information and seeking additional follow-up.

FINAL CLOSURE

When all investigations within the complaint have been checked “Y” as completed, and the Reviewed by Supervisor box has been checked, the complaint will be sent electronically to the Complaint Coordinator for final closure. A letter to the complainant shall be generated from the information provided by the Inspector in the text box of the Establishment Investigation. As such, it is important that this information is accurate and free from subjective statements regarding either the complainant or the establishment operators.

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INVESTIGATION OF COMPLAINTS

Prior to the investigation, review the complaint information and, as needed, review the Department's Laws, Rules and Regulations, Field Operations Manual or consult with your Supervising Inspector. If the investigation requires that the complainant be interviewed it should be done as soon as possible. In most cases, this can be accomplished by telephone.

It is important to take a neutral stance and not take sides. Do not make any statements regarding an establishment's history or conditions.

You shall not act as a go-between for the complainant and the establishment. If the complainant wants reimbursement for a product, it is their responsibility to contact the establishment, not yours.

Complaints that are the responsibility of other agencies shall be forwarded to the appropriate agency as soon as possible. This can be accomplished via telephone, FAX or mail.

The following procedures should be followed when it is necessary to examine the complainant's food product:

1. Examine the product organoleptically. If it contains foreign matter - worms, insects, metal, straw, etc. which you can identify, there is no need to send the consumer sample to the laboratory for analysis.
2. Indicate your findings on the Complaint Investigation Report (FSI-550) as well as the name and address of the manufacturer and/or distributor, container codes, USDA establishment number, etc., if appropriate.
3. Enter the name and address of the establishment from which the consumer purchased the product and the date of purchase.
4. If you cannot identify the foreign material or problem with the product, a sample of complainant's product should be submitted to the laboratory for analysis. Inform the complainant that the laboratory analysis may be considered unofficial since the product container has been opened prior to submission for analysis.

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5. Always ask the complainant if they want their consumer sample and/or product container returned to them. Write their response in the written narrative portion of the Consumer Complaint Investigation Report (FSI-550).
6. If the complaint involves a foodborne illness you should coordinate the taking of consumer samples with the responsible health agency. You should also complete the Illness Complaint Investigation Report (FSI-551).
7. In cases where it is necessary to conduct a follow up investigation at the establishment, you should look for the same coded product. Examine the product organoleptically. If it is found to be adulterated or misbranded, it should be placed under seizure and the custodian notified of their right to a Hearing to consider the disposition of the seized product. If the custodian waives the right to a Hearing and voluntarily destroys the product, samples need not be sent to the laboratory for analysis. If the same coded product is not available, in most cases, it is not necessary to submit similar coded product to the laboratory for analysis.
8. When submitting samples in other than manufacturer's container, indicate whether or not the sample was selected from the manufacturer's sealed or open container or obtained from a container packed by the retailer.
9. When the complaint involves deteriorated ground meats, you should take a sample of the product in question for analysis. However, sampling alone is not enough - you should conduct a sanitary inspection of the meat department and report any deficiencies found.
10. When the complaint involves spoiled, decayed, rotten or off-condition produce, it should be forwarded to the appropriate Farm Products Unit.
11. If your investigation reveals product contamination by insects or rodents, your report should show whether examination of adjoining products on the shelf and in the storage area revealed contamination. In the case of canned products, you should indicate whether examination of like product on the shelf, storage area and morgue area revealed evidence of swellers, flippers, leakers, etc.
12. If your investigation indicates that the product became adulterated prior to entering the retail establishment, you should follow through by visiting the distributor and/or manufacturer, if located in your area. If the distributor and/or manufacturer are located elsewhere, notify your Supervisor, who will refer your investigation to the appropriate agency.
13. If your investigation reveals a suspect food tampering problem, refer to the Reference/General Information Section, Sub-Section 6040, Consumer Product Tampering, for procedural information.
14. In most cases, complaints involving critical deficiencies will require a complete sanitary inspection of the establishment. This will involve the completion of the Sanitary Inspection Report forms (FSI-894 and FSI-898) and the Consumer Complaint Investigation Report (FSI-550).

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15. However, it is not necessary to complete the Sanitary Inspection Report forms (FSI-894 and FSI-898) and/or the Consumer Complaint Investigation Report (FSI-550) when the Consumer Complaint/ Inquiry Form (FSI-553) is used and the complaint is resolved on the telephone without a field investigation.
16. Prior to conducting an inspection you should identify yourself to the manager or most responsible person present and state the nature of your visit. **Never reveal the name and address of the complainant to establishment representatives.**

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ELECTRONIC FORM COMPLETION



1. All complaints will be received at the Zone Offices and recorded electronically by Supervisors or office support staff utilizing the Consumer Complaint Tracking System – Central Office Version.
2. Complaints will be forwarded electronically to inspectors, who will receive the complaint by utilizing the Consumer Complaint Tracking – Field Version. **As such, it is important that the field version is synchronized at the start of each workday.**
3. Each Complaint is assigned a unique case number. New complaints can be viewed by selecting *Inspector Investigations New/Open*.

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4. An investigation will be conducted, and all pertinent information gathered will be recorded in the appropriate fields within the electronic complaint report. It is important that only information relevant to the complaint is entered. The report is broken down into a series of Tabs to include a Complaint Information, Product, Illness, Supervisor Recommendations and/or comments, Referrals To, and Investigations. The Consumer Complaint Field version allows for the retrieval and entering of data without being connected to the servers in Albany.
5. Each Complaint Case may contain one or more investigations (Complainants Investigation, Establishment Investigation (primary), and other follow-up investigations as assigned by the Supervisor. Investigations within a specific case may be assigned to different inspectors and/or different Regions/Zones, as warranted.
6. When all investigations are completed within the complaint case, (*Investigation Complete* = Y for all investigations) the completed complaint case will automatically be forwarded to the Ready for Supervisor Review Box, for the zone in which the primary establishment investigation is recorded.
7. The Supervisor will open and review the complaint, and check the *Review by Supervisor* box when satisfied that the investigation was satisfactorily completed.
8. The complaint case is then sent to the Complaint Coordinator for final review and closure which may include a response letter to the Complainant.

MAIN SCREEN

1. The main screen is set up with a number of buttons to allow for the receipt of new or edited complaints for each inspector as well as the retrieval previously assigned complaint cases.
2. Search criteria include the following:
 - *Inspector Investigations Edited:* This will reveal a list of investigations that have been started by the inspector but have not been completed.
 - *Inspector Investigations New/Open:* This will reveal a list of the new complaint cases with an investigation assigned to the inspector showing in the inspector field above.

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- Inspector Investigations Completed: This will reveal a list of all closed complaint cases that have an investigation completed by the inspector showing in the inspector field above.
 - Inspector Investigations All: This will reveal all the complaint cases that have an investigation assigned to the inspector showing in the inspector field above.
 - All Open Complaints: This will reveal a list of all open complaints that currently entered into the Consumer Complaint Tracking System. This may be utilized to determine if there are other similar open complaints (product or illness related) within the state.
 - All Closed Complaints: This will reveal a list of all closed complaints that are currently entered into the Consumer Complaint Tracking System. This may be utilized to determine if there are other similar complaints that have been investigated (product or illness related) within the state.
 - All Complaints: This will reveal a list of all open and closed complaints that are currently entered into the Consumer Complaint Tracking System. This may be utilized to determine if there are other similar complaints (product or illness related) within the state.
 - Search by Case Number: This will reveal the investigation for the specific case number entered.
 - Search by Complainant: This will reveal all of the Complaint Cases that have been recorded for a specific complainant. This can be utilized to determine a past history of complaints recorded by the same individual. You may also search for the complainant using a last name, telephone number, street address, or city.
 - Search by Establishment: This will reveal all of the complaint investigations recorded for a specific establishment. You may search for the establishment by trade name, address or city. This search may be useful for identifying a history of complaints for a specific establishment or repetitive complaints concerning an establishment.
3. Synchronization of the Field Version of the Consumer Complaint Program, shall be completed each work day by connecting to the Departments server via phone, cable connection (WAN), or a dedicated T-1 Line by selecting the *Synchronize with AS/400* button (You must be connected to the Albany server to synchronize the program). The synchronization process will allow the uploading and downloading of data that has been entered or removed from the Consumer Complaint Tracking system (Field and Central Office Versions) to and from the AS/400.

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ENTERING INFORMATION

1. The electronic complaint form is intended for use for non-illness related complaints as well as illness related complaints. The fields provided are intended to accommodate each type of complaint that may be received. If the field category does not apply, it may be left blank. Field labels in red are required fields. These fields must contain information if the tab is used. For example, if the product tab is used; information in the Commodity Type, Product Disposition, and Brand/Product fields must be entered before the information can be saved.
2. It is necessary to save any data entered by selecting the save button, prior to switching between tabs, within a complaint investigation. **Failure to save information entered before switching tabs may result in the loss of the information entered for this tab.**
3. To preview or print the complaint in a report format, select *Preview*.

The screenshot displays the 'Complaint Entry Screen' for Case No. 22543. The interface includes a top navigation bar with tabs for 'Complaint Inf.', 'Product', 'Illness', 'Supervisor', 'Referred To', and 'Investigation'. The 'Complaint Inf.' tab is active. The form contains the following fields:

- Complainant:** Linda & Mark Desiderio, 933 Route 31, Bridgeport NY 13030, (315) 633-8368(h)
- Establishment Number:** 310654
- Zone:** 02
- Last Inspection Date:** 02/10/2006 (highlighted with a red box)
- Inspector Assigned to Complainant:** Gregory Slivinski
- Inspector Assigned to Establishment:** Gregory Slivinski
- Recorded by:** William J. Kalabanka
- Record Date:** 04/28/2006
- Complaint Codes:** (empty field)
- Complaint Description:** Foodborne illness from the consumption of 100% carrot juice (Bolthouse Farms). Both alleged illness (diarrhea) after consumption. Product was a replacement bottle for a bottle that was returned on 4-25-06, with an off odor "chlorine like" and had exceeded its expiration date by two days. Mark took a sip of replacement bottle, to "check it", after returning. Then consumed the product again on 4-26-06. Mark also noticed a "fermented" type taste, after the second consumption.

At the bottom of the screen, there is a red box stating '*red denotes required field', a 'Preview' button, and a 'Main Menu' button.

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1. Zone Office Supervisors and support staff will obtain at minimum, sufficient information from the initial contact with the complainant to begin the investigation to include the name of the *Establishment*, *Complainant* information, *Complaint Description*, Complaint Category*, the *Inspector(s) Assigned*, the *Recorder* and the *Record Date*.
2. Where applicable, the inspector will contact the Complainant to obtain additional details concerning the investigation (ie. Product information, codes etc.). This information shall be recorded in the appropriate investigation (Complainants Investigation) in the Investigation Tab.

*Note: The primary complaint category code (entered by the Recorder in the Central Office Version) is the code that is considered the highest priority of multiple complaint allegations. For example, if a complainant alleges an illness from the consumption of a food product, but also indicates that he/she noted that the floors are dirty. The primary complaint category would be Unconfirmed Illness. A secondary complaint category may be entered by the inspector, by selecting the Complaint Code Button, ie. Insanitary Conditions – Physical Facilities.

CONSUMER COMPLAINT INVESTIGATIONS ELECTRONIC FORM COMPLETION SUB-SECTION 3030

The screenshot displays the 'Complaint Entry Screen' for Case No. 22543. The 'Product' tab is selected, showing a form with the following fields and values:

- Commodity Type:** Frozen Vegetables, Vegetable Juices
- Product Disposition:** Complainant has product
- Brand/Product:** Bolthouse Farms 100% Carrot Juice
(Ex. 1: Carnation Hot Chocolate with Marshmallows
Ex. 2: Nature Valley Trail Mix)
- Additional Label Information:** Keep Refrigerated
- Container Code:** Use by May 23 06
- Container Size:** 1 liter
- Container Type:** Plastic Bottle
- Date Purchased:** 04/25/2006
- Date Used:** 04/26/2006
- Primary Suspected Product:** ☒
- Product Eaten by Others:** ☐

On the right side, there are dropdown menus for **Manufacturer** and **Distributor**, each with an 'Update List' button below it. At the bottom right of the form are 'Delete Product' and 'Save' buttons. A red text box at the bottom left states '*red denotes required field'. At the bottom center are 'Preview' and 'Main Menu' buttons.

PRODUCT TAB

1. If the complaint involves a food product, the inspector shall obtain the pertinent information concerning the *Product Description*, including the exact description of the product from the label (ie. Bolthouse Farms 100% Carrot Juice), any *Additional Label Information* that may help further identify the product (ie Vitamin C added, USDA Insp. #), the *Container Code*, *Container Size*, *Container Type*, the *Date Purchased*, and *Date Used*.
2. The inspector shall obtain information regarding the *Manufacturer* and/or *Distributor*, including name, address, city, state and zip code. The distributor that is entered shall be the name of the firm from which the establishment / corporate warehouse receives the product. It may be necessary for the establishment management to contact the corporate warehouse for information concerning the distributor of the product as most larger chains have a corporate warehouses from which the products are distributed to their stores. This information may become important when referrals are made to other Federal/State/Local agencies for follow-up.

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3. Enter a *Commodity Type* from the commodity drop down list that best describes the commodity.
4. The product tab allows for multiple food products to be listed. To enter another product, select the *Add Product* button. This will bring up a blank product information screen.
5. Check the *Primary Suspected Product* box for the product most likely to be suspected if multiple products are involved in an illness complaint investigation.
6. Check the *Product Eaten by Others* box, if the product listed is alleged to be involved in an illness complaint investigation.

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Complaint Entry Screen Case No. 22543

Complaint Info | Product | **Illness** | Supervisor | Referred To | Investigation

Add Symptom(s)

Symptom	Date	Incubation	Duration	
Abdominal Cramps	04/27/2006	4	hour(s)	Delete
Diarrhea	04/27/2006	4	hour(s)	on-going Delete

2 Symptom(s) Recorded

Details

Husband (Mark) became ill approximately 4 hours after consumption of the product at 11:30 pm on 4-26-06. Husband also had a sip of the product on 4-25-06 around the time of purchase.
Linda (Wife) also consumed the product at 11:30 pm on 4-26-06, she became ill approximately 13 hours later on 4-27-06 at 12:30 pm.
No doctors were visited.

Visit to Doctor ☐
Visit to Hospital ☐

Save

*red denotes required field

Preview Main Menu

ILLNESS TAB

1. The inspector shall record all illness symptoms reported by the complainant by selecting the appropriate *Symptom* from the dropdown menu. In addition, details concerning the *Date* of the illness, the approximate *Incubation* period (the time period from consumption of the suspected food product to the time of onset of illness symptoms) and the *Duration* of the illness shall be recorded.
2. Record any additional details related to the illness, in the *Detail* text box. This may include a food history, medications taken by the complainant, names of doctors or hospitals visited, names of additional people that may have experienced illness symptoms from the consumption of a common food.
3. Check *Visit to Doctor* and/or *Visit to Hospital* boxes, if it is reported that the complainant sought medical attention through a physician or hospital. Enter the name, address, telephone number of the physician or hospital visited and any pertinent details of the visit (tests performed, diagnosis) in the details text box.

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The screenshot shows a web application window titled "[Complaint Information]". The main header is "Complaint Entry Screen" with "Case No. 22543" on the right. Below the header is a navigation bar with tabs: "Complaint Inf.", "Product", "Illness", "Supervisor", "Referred To", and "Investigation". The "Supervisor" tab is selected. The main content area is titled "Supervisor Recommendations" and contains two paragraphs of text. Below the text is a "Suggested Response Time" dropdown menu set to "Immediate" and a "Supervisor" dropdown menu set to "William Kalabanka". At the bottom of the screen, there is a red text box that says "*red denotes required field", a "Preview" button, and a "Main Menu" button.

Supervisor Recommendations

Contact the complainant to arrange to pick up sample. Has 1/3 of the product, and will hold for sampling. Complainants also have consumed common foods at the Great Wall Chinese Restaurant, RT 11, North Syracuse on 4-25-06, including salad greens, soup, and salmon.

Contacted Price Chopper Manager (Sue Hainey) on 4-28-06. She indicated that there have been no complaints regarding this product. Requested that she look for product coded use by May 23, 06 and remove product from sale and hold for sampling.

Suggested Response Time Immediate **Supervisor** William Kalabanka

*red denotes required field Preview Main Menu

SUPERVISOR TAB

1. The Supervisor may provide additional direction or guidance in the *Supervisors Recommendations* text box on how the complaint should be investigated or document actions that may have been taken by the supervisor to assist in the investigation (ie. Phone contact to the store's management to remove product from sale or hold product for sampling). It is important that the inspector review this tab prior to conducting the investigation.
2. The Supervisor may also choose a *Suggested Response Time* from the dropdown menu, if warranted.

CONSUMER COMPLAINT INVESTIGATIONS ELECTRONIC FORM COMPLETION SUB-SECTION 3030

Complaint Entry Screen Case No. 22543

Complaint Inf. | Product | Illness | Supervisor | Referred To | Investigation

Referrals

Agency
Madison County Department of Health
1064 Northside Shopping Center
Oneida, NY 13421
Phone: 3153662526

Contact Environmental Health
Contact Date 04/28/2006

Notes:
Via FAX for food history and possible stool samples.

*red denotes required field Preview Main Menu

REFERRAL TAB

1. It is the responsibility of the Zone Supervisor to determine if a referral is warranted and to make and document any referrals that may be made for the complaint investigation. The Supervisor shall record referrals made to other *Agencies* or Divisions, for the purpose of providing information and seeking additional follow-up.
2. While in the Central Office Version, the Supervisor may select an *Agency* from the dropdown list. If the agency is not available in the dropdown list, select *New Agency*, and provide the name of the agency, street address, city, zip, phone and fax numbers. This information will then be available as part of the dropdown list for future referrals.
3. Enter the *Contact Information* (name of the Division or person the referral was sent to and the *Date* the referral was made.
4. Provide any additional information in the *Notes* text box.

CONSUMER COMPLAINT INVESTIGATIONS ELECTRONIC FORM COMPLETION SUB-SECTION 3030

- Agency information (address, telephone numbers) may be edited in the Central Version, after the referral has been saved within the complaint tab.

Complaint Entry Screen Case No. 22543

Complaint Inf. | Product | Illness | Supervisor | Referred To | Investigation

Investigation Date 05/01/2006 [1 of 2 Investigations Recorded](#) [Sample Form](#)

Inspector Gregory Slivinski

Owner Linda & Mark Desiderio

Address 333 Route 31
Bridgeport NY 13030
(315) 633-8368(h)

Complainant Contacted Visit **Investigation Complete?** Y

Complainant's residence was visited on the above date and details of complaint were reviewed. Mark Desiderio explained that he and his wife became ill after consuming the carrot juice product on Wed evening at 11:30pm on 4/26/2006. Mark explained that his symptoms did not start getting better until the next Sunday. Mr. Desiderio provided me with what was left of the carrot juice in its original container. There was about 1/4 of the carrot juice left in the original container. The carrot juice container was labeled FL 295466 placed into a plastic bag, sealed, and sent to the NYS Food Laboratory for pathogen and mold bacterial analysis.

[Save](#)

[Preview](#) [Main Menu](#)

*red denotes required field

Start | [Main Menu] | [Complaint Informa...] | Sub-Section 3035 - Revis... | 12:49

INVESTIGATION TAB

Complainant Investigation

- The investigation tab may be split into two or more separate investigations within the Complaint Case (anonymous complaints will have one or more). Investigations within a complaint case can be toggled by selecting the *up or down arrow* to the right of the investigation text box.

**CONSUMER COMPLAINT INVESTIGATIONS
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2. If the complainant is known, an investigation will be generated for the complainant. The inspector shall provide any pertinent information provided by the complainant. In most cases contact with the complainant is necessary to confirm the complaint information that has been provided and to obtain any additional information (ie. Product codes, labeling information, illness symptoms and onset times etc.). The inspector shall document the *Date of Investigation* and the type of contact; *Complainant Contacted* (ie, phone, visit). If the complainant was not contacted, or attempts to contact the complainant were unsuccessful, select “none” from the dropdown list, and provide a brief notation in the text box regarding the reason that no contact was made (ie. Three attempts to contact via phone, no answer).

The screenshot shows a web form titled 'Samples' with a subtitle 'Samples from Linda Mark Desiderio'. It features three main input fields: 'Sample No' (containing 'FL-'), 'Sample Description' (empty), and 'Analysis Required' (empty). To the right of these fields are 'Save' and 'Clear' buttons. Below these is a section titled 'Existing Samples' containing a table with one row of sample data and a 'Delete' button to its right.

Sample No	Sample Description	Analysis Required
FL-		

Save Clear

Existing Samples

FL-295466	100% Pure Carrot Juice, Bolthouse Farms Inc. is the brand name	Pathogen and Mold bacterial analysis

Delete

Close

3. When consumer samples are taken during the complaint investigation, select *Sample Form*, and enter the *Sample Number*, the *Sample Description* and the *Analysis Required*. It is important that this sample information (Complainant's Sample) is documented in the complaint report, as this will flag this report as a Complaint Case that has pending samples. These complaints will be closed by the Complaint Coordinator only after results are received. The FL Report that is completed should cross reference the Case Number of the complaint.

**CONSUMER COMPLAINT INVESTIGATIONS
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4. All complaint samples must be accompanied either by a hard copy of the complaint case printed out utilizing “Print *Preview*” or an ROI that cross references the Case Number / FL Number(s), with a brief summary of the nature of complaint allegations, and rationale for the requested sample and the FL Sample Report.
5. The inspector shall document any additional information in the text box of the complainant’s investigation.
6. When the investigation is completed for the complainant, select “Y” in the *Investigation Complete* box.

Primary Establishment Investigation

1. The primary establishment investigation is the establishment in which the complainant has made the observation or purchased product from. Additional follow-up investigations can be assigned by the Supervisor, utilizing the Consumer Complaint Central Version at the same establishment (different investigation date) or at another establishment in which the Division has jurisdiction. If a follow-up investigation is required in another Region or Zone, the Supervisor will assign the investigation to the Chief or Supervisor in the Region/Zone where the follow-up investigation is to be conducted, and send a notification e-mail to the Chief / Supervisor that a follow-up to the complaint investigation has been requested. The Supervisor will then reassign the investigation to the appropriate inspector, who will receive the complaint in the “*New/Open Investigations*” box (Main Screen) upon the next synchronization. The inspector will need to open the complaint case and look for the follow up investigation that is assigned (The case will show up with the primary establishment and the inspector assigned to the primary investigation).

CONSUMER COMPLAINT INVESTIGATIONS ELECTRONIC FORM COMPLETION SUB-SECTION 3030

Complaint Entry Screen Case No. 22543

Complaint Inf. | Product | Illness | Supervisor | Referred To | Investigation

Investigation Date 05/01/2006 **2 of 2 Investigations Recorded** **Sample Form**

Inspector Gregory Slivinski **Establishment Number** 310654 **Seizure Form**

Owner PRICE CHOPPER 199
Address PRICE CHOPPER OPERATING CO INC
5701 E CIRCLE DR, CICERO NY 13039
(315) 458-2056

Person Interviewed Sue Hainey
Title Manager
Inspection Type None
Complaint Related Deficiencies Noted N
Tampering N
Investigation Complete? Y

Complaint was followed up on at the above-named establishment and date. Store Manager Sue Hainey indicated that they have not received any complaints involving the Bolthouse Farms Inc. Carrot Juice product. On Friday 4/28/06 Sue Hainey had removed all the Bolthouse brand carrot juice from sale at the store code dated 05/23/06 and put them in the back produce room cooler to hold for sampling. On 05/01/06 during investigation Sue Hainey indicated that there was only 3 containers of the carrot juice product left in retail cooler on Friday 04/28/06 when she pulled them from sale. I purchased one of the containers of Bolthouse Farms 100% carrot juice on hold from Friday labeled it FL 295467 and sent it to NY's Food Laboratory for pathogen and mold bacterial analysis.

***red denotes required field** **Preview** **Main Menu**

2. All complaint cases will have an investigation generated for the primary establishment. The inspector shall document the *Date* of the Investigation, and the *Inspection Type* (ie, limited, full, none), the *Person Interviewed* and *Title*. .
3. The inspector shall document any pertinent information gathered during the investigation at the establishment within the Text Box, for the investigation. **It is extremely important that only factual information that pertains to complaint investigation is documented as this information is imported into the text of an auto-generated Complaint Response Letter, and is sent to the Complainant.**

**CONSUMER COMPLAINT INVESTIGATIONS
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Samples

Samples from Price Chopper 199

Sample No	Sample Description	Analysis Required	
FL-			Save Clear

Existing Samples

FL-295467	100% Carrot Juice, Bolthouse Farms Inc. is brand name	Pathogen and Mold bacterial analysis	Delete

4. When establishment samples are taken during the complaint investigation, select *Sample Form*. Enter the *Sample Number*, the *Sample Description* and the *Analysis Required*. It is important that this sample information (establishment's sample) is documented in the complaint report, as this will flag this report as a Complaint Case that has pending samples. These complaints will be closed by the Complaint Coordinator only after results are received. The FL Report that is completed should cross reference the Case Number of the complaint.
5. All complaint samples must be accompanied either by a hard copy of the complaint case printed out utilizing "Print *Preview*" or an ROI that cross references the Case Number / FL Number(s), with a brief summary of the nature complaint allegations, and rationale for the requested sample and the FL Sample Report.

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Seizures

No Seizures from Price Chopper 199

Seizure No **Seizure Description**

6. When a seizure is made at the establishment of product that is related to the complaint investigation, select *Seizure Form* and enter the *Seizure Number*, and the *Seizure Description* to include the product/brand, size, number of pounds seized and the reason for the seizure.
7. When an inspection is conducted in conjunction with the complaint investigation, Enter “Y” in the box *Complaint Related Deficiencies Noted* **only if** inspection deficiencies are documented that are **related to the complaint allegations.**
8. If the complaint involves a *Tampering* incident. (generally these are investigated only upon request or first refusal of law enforcement) check as “Y”.
9. When the investigation is completed for the establishment select “Y” in the *Investigation Complete* box.

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COMPLAINT WRITING TIPS

1. Do not use “first person” writing style; for example statements such as: “I went to the establishment”, “We met with the manager”, etc., do not flow well when they are incorporated in the text of the complainant letter..
2. When information is already provided in the fields within the complaint, it is not necessary to repeat this information in the text of the complaint. For example, “Discussed the complaint with Manager Jim Jones”, is not necessary, if Jim Jones is already documented as the *Person Interviewed* or “A full sanitary inspections was conducted on 5-11-06”, since the *Date* of the investigation and the *Inspection Type* are already filled in.
3. Do not report deficiencies that may have been documented during the inspection which are not related to the complaint. If during the course of your inspection you discover that the establishment has a rodent problem, this should not be documented in the text of the complaint if the complaint was not related to rodents.
4. Report only the facts of the investigation. Conjecture, allegations or suspicions, are inappropriate and should not be written in the complaint investigation.
5. Remember that the thoroughness of the report, grammatical and spelling errors, and abbreviations reflect upon you, the Inspector. Check your report for errors prior to checking the investigation as completed.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**CONSUMER COMPLAINT INVESTIGATIONS
ILLNESS COMPLAINT INVESTIGATION REPORT (FSI-551)
SUB-SECTION 3035**

OVERVIEW

New York State takes pride in the safety and wholesomeness of foods consumed by its entire people. To ensure the continued safety of our food supply it is the responsibility of every inspector to thoroughly investigate allegations of foodborne illness or injury, to remove dangerous food from the market place and to report all contributing factors.

The Illness Complaint Investigation Report (FSI-551) will be completed when investigating complaints alleging a foodborne illness or injury.

A foodborne illness is a sickness caused by the ingestion of a food contaminated with a pathogenic bacteria, virus, toxin, chemical, insect or other harmful agent.

A foodborne injury is a cut, laceration, abrasion, chemical burn or other physical damage caused by the consumption of foreign substances or objects in a food.

Use the Complaint Investigation Report (FSI-550) and the Consumer Complaint Report (FSI-553), where appropriate, for all other consumer complaint investigations other than Illness Complaint Investigations.

Review the complaint carefully prior to interviewing the complainant. If you lack experience in the matter you should refer to the Inspector's Manual, the FDA Investigations Operations Manual or consult with your Supervising Inspector.

COMPLAINANT INTERVIEW

The complainant should be interviewed as soon as possible after receiving the complaint. Do not choose sides while conducting the investigation. You should not act as a go-between for the complainant or the establishment. If the complainant wants reimbursement for a product, or seeks legal relief, it is their responsibility to initiate these actions, not yours.

It is very important to obtain a detailed description of all foods eaten up to 72 hours prior to the onset of symptoms. Every reasonable effort should be made to help refresh the complainant's memory.

Most people will not remember all of the foods eaten in the past 72 hours. The Inspector should help stimulate recall during the interview by asking questions relating to specific foods eaten, normal dietary habits, unusual foods eaten, recent unusual or special events and, generally, helping the complainant reconstruct the people, places, and events of the prior 3 days.

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A working knowledge of the more common foodborne illness symptoms may help to focus on the cause of the illness; e.g., nausea, and vomiting could indicate the foods most recently eaten; diarrhea and abdominal cramps point to foods eaten 6 to 20 hours earlier; chills, fever, and diarrhea implicate foods consumed 20 to 72 hours before symptoms appear. Other illness such as typhoid fever and Hepatitis A have incubation periods greater than 72 hours. See Sub-Section 3040, Illness Analysis Guidelines.

When it is necessary to conduct a follow-up investigation at the establishment where the product was purchased the inspector shall look for the same coded product. If located, the product should be submitted to the Food Laboratory for analysis.

If an establishment representative takes a sample for you from a bulk master container or bulk display or prepares a sample; e.g., makes a chicken salad sandwich, carefully observe the procedure to determine if the product might be contaminated by improper food handling practices.

If product is placed under seizure, samples must be submitted.

Exercise judgment as to the necessity of inspecting the establishment where the product was procured. If a sanitary inspection is indicated, HACCP procedures should be utilized as fully as possible.

FOLLOW-UP ACTIVITY

If your investigation indicates the product became adulterated prior to entering the retail establishment you should follow through by visiting the distributor and/or manufacturer, if located in your area. If they are located elsewhere, notify your Supervisor right away for appropriate follow-up action to be arranged.

HEALTH DEPARTMENT NOTIFICATION

The appropriate city, county, or state health department will always be advised immediately if the following criteria are present:

1. The circumstances seem to support the complainant's supposition that a food caused the illness,
- AND/OR,**
2. The illness is confirmed by a physician's diagnosis,
3. In the case of chemical poisonings, one or more people are involved,
4. In the case of any other type of foodborne illness, two or more people are involved.

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The name of the health agency and the name of the person contacted will be entered in the Illness Complaint Investigation Report, (FSI-551), #27 - Complaint Referred To, and in the Remarks section, if appropriate.

FORM COMPLETION (FSI-551)

See report exhibits on pages 8 and 9.

1. Inspector's Number: Enter your assigned number.
2. Date: Record the date of the investigation.
- 3-7. Consumer Information: Fill in all information concerning the identity and location of the complainant in spaces 4-8. The consumer's name is to be recorded with the last name first; e.g., Tollman, James R. Also include the title of the complainant; e.g., Ms., Mr., Mrs., Rev., etc.

The name and address of a complainant should never be revealed to an establishment representative.

- 8-16. Establishment Information: Fill in this section as you would the heading on the Sanitary Inspection Report Cover Sheet (FSI-894). If a complainant names two or three establishments in which the product may have been obtained and a sample is found in one, use this as the establishment on the report and indicate in the narrative, the other stores checked. If the complainant specifies a particular establishment, that establishment must be listed, even if the product is not available.
17. Product: Use this space to describe the product involved in the complaint using the true or common name followed by the brand name; e.g., Chicken Soup, Campbell's.

Although the consumer may implicate a particular product as causing their illness, the Inspector should review all evidence. This would include comparing foods eaten, symptoms, and incubation periods with the listings in Sub-Section 3040, "Illness Analysis Guidelines." If the evaluation indicates another product may be implicated, the investigation should be completed following the chain of evidence. See procedural guidelines in Sub-Section 3040, Illness Analysis Guidelines.

18. Manufacturer/Distributor (Mfg./Dist.): List the name of the manufacturer, packer or distributor of the product involved; e.g., Duval Canning Co., Inc.

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If the producer is a USDA inspected establishment, include the USDA establishment number in this space.

- 19-21. Street, City, State and ZIP Code: Record the complete address of the producer if available. Some containers may only list the city, state and ZIP code. If so, record this information in the appropriate space.
22. Date of Purchase: List the actual or approximate date the consumer purchased the product.
23. Container Size and Type: Record the size and type of the container in this area; e.g., 12-fl. oz. plastic bottle, 1 lb. pasteboard box. When the container sizes are too long to be placed here, enter the size in the space provided by converting the size from lbs. & oz. to # & Z, or oz. Ex: 10 lb., 2 oz. = 10 # 2 Z, or 162 oz., or 162 Z.
24. Container Code: List the manufacturer's code that appears on the consumer's product in this space.
25. Complaint Referred By: List the agency and person who notified our Department about the complaint; e.g., Albany County Health Dept., John Smith. If we received the complaint directly from the consumer, this should be noted in this area.
26. Complaint Referred To: List the agency and person this complaint was referred to if:
- A. The circumstances meet the "Health Department Notification" criteria.
 - B. An action or follow-up by this department is not appropriate; e.g., NYC Health Dept., Joseph Roe.
27. Suspected Tampering: If your investigation reveals a suspected food tampering problem, refer to the Reference/General Information Section, Sub-Section 6040, Consumer Product Tampering, for procedural information.
28. Nature of Complaint: Give a brief description of the nature of the complaint; e.g., "consumer became ill after eating hamburger" or, "consumer's lips & tongue blistered after eating popsicle."
29. Illness History: Enter the date and time the suspect food(s) were eaten by the consumer.
30. Onset of Illness: Enter the date and time the illness symptoms began and the number of days and/or hours the symptoms lasted.

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31. Signs & Symptoms: Mark an "X" next to each symptom reported by the consumer. Explain in "Other" those symptoms not listed.
32. Sanitary Inspection: If a sanitary inspection is conducted as a result of the complaint, put an "X" in the "YES" box. If not, put an "X" in the "NO" box.
33. Limited Inspection: If a limited inspection was conducted, put an "X" in the "YES" box. If not, put an "X" in the "NO" box.
34. Consumer Contacted: Check appropriate method of contact - telephone or personally. If the initial attempt is unsuccessful, several documented attempts must be made.
35. Seizure Number(s): If the investigation resulted in the seizure of product, record the seizure number in the box provided. If more than one seizure was made, list these seizure numbers in the space at the bottom of the form.
36. Sample Numbers: If any samples were obtained, record the sample number(s) in the spaces provided. If more than 3 samples were taken, list the additional FL numbers in the space at the bottom of the form. When product placed under seizure during an illness investigation is destroyed or released at a later date, that action should be reported on a "Report of Investigation" rather than another "Illness Complaint Investigation Report."
37. Analysis Requested: Enter a brief description of the laboratory analysis requested; e.g., Salmonella, chemicals, etc.
38. Inspector's Signature: Sign your name here.
39. Hours Spent on Investigation: Record all time spent on this investigation. This would include the time spent with the consumer, the referral agency, the hospital, etc. **(Do not include travel time)**.
40. Investigation: Check this box if the report constitutes an original investigation of this complaint.
41. Follow-ups: Check this box when your investigation follows an original investigation of a complaint. This is to be done whether the follow up is done in the same zone or outside the zone in another part of the state.
42. Medical Attention Tendered By: This section should include the name of the hospital or clinic and/or the name and title of the responsible provider as well as the address and phone number; e.g., St. Mary's Hospital Emergency Room, Joan Smith, R.N., 1254 E. Division

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St., Amherst, NY 16604, 518-672-9544, or Dr. John Smith, 15 Main St., Glenmont, NY 16244, 518-472-9612.

43. Is Consumer on Medication(s): If the complainant has taken any prescribed or over-the-counter medication during or shortly before the period covered by the reported illness, put an "X" in the "YES" box. Describe these medications and the reason taken in the Remarks section. If not on medications, put an "X" in the "NO" box.
44. Does Consumer Have Allergies: If the consumer has any allergies put an "X" in the "YES" box. Describe these allergies and the medication being taken for them in the Remarks section. If no allergies, put an "X" in the "NO" box.
45. Prior Meals: **A detailed description of all meals and snacks eaten up to 72 hours prior to the onset of the illness symptoms is critical to the success of the investigation.** These meals and snacks should be listed in the spaces provided starting with those nearest to the beginning of symptoms and working backwards. Careful attention should be given to gathering complete and accurate information. (See "Complaint Interview").
46. Have Others Eaten the Same Food: If the answer is no put an "X" in the "NO" box and continue on to the "Remarks" section. If the answer is yes put an "X" in the "YES" box and indicate the number in the space marked "how many." If there were no other illnesses put an "X" in the "NO" box and proceed to "Remarks." If there were other illnesses put an "X" in the "YES" box and indicate "how many." List the name(s) and address(es) of these other illness victims in "Remarks" and follow through with separate, cross-referenced investigations.
47. Remarks: This section should include a factual reporting of information not reported in the preceding sections of the report. The details should be concise and should clearly explain the complaint with the inclusion of pertinent information. Unless an explanation is given concerning missing portions in the report, the report will be assumed to be incomplete and may be returned for correction. Unusual circumstances and your evaluation and interpretation of the investigation, if reported, must be based on factual evidence. As with other reports, do not include personal opinions and/or feelings in the report. Any information in these categories shall be in memo form and attached to the report. If more space is needed for additional remarks, use and attach a Supplemental Sanitary Inspection Report (FSI-898).

GENERAL INFORMATION

1. On all illness complaint investigations, only one original Illness Complaint Investigation Report (FSI-551), printed in ink, is to be sent to the Albany Office or the Food Laboratory.

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ILLNESS COMPLAINT INVESTIGATION REPORT (FSI-551)
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2. When samples are taken as a result of the complaint, the original Illness Complaint Investigation Report (FSI-551) shall go with the sample(s) and the sample report(s) to the Food Laboratory and no FSI-551 will be sent to the Albany Office. If the field Supervisor wants a copy for their files they may request one from their Inspectors.
3. Do not write in any section marked "For Office Use Only." Use only one character per box in all boxed areas. Do not use punctuation in boxed areas. Leave one blank box between words or initials.
4. It is sometimes difficult for the Laboratory to determine what the sample is to be specifically analyzed for unless explained in the "Examine for" space on the sample report. Example: Consumer complains of nausea, vomiting and diarrhea after swallowing a lump from a soda can. Enter Code 17 in the "Test Code" box of the sample report and write: "Filth/Foreign Material - Mold" in "Examine for:" box on the same sample report.
5. Always ask the complainant if they want their consumer sample returned to them (if there is any remaining product or residue). Enter their response in the written narrative and on the sample report.

CONSUMER COMPLAINT INVESTIGATIONS
ILLNESS COMPLAINT INVESTIGATION REPORT (FSI-551)
SUB-SECTION 3035

FIS-551(4/99)

New York State
 Department of Agriculture and Markets
 Division of Food Safety and Inspection

Insp. No. 1 ☐ ☐ ☐ ☐

ILLNESS COMPLAINT INVESTIGATION REPORT Date 2 ☐ ☐ ☐ ☐ ☐ ☐

Consumer Name <u>3</u>		Area Code and Phone No. <u>7</u> ☐ ☐ ☐ ☐ ☐ ☐	
Street <u>4</u>	City and State <u>5</u>	Zip <u>6</u>	

Owner <u>8</u>		Est. No. <u>12</u> ☐ ☐ ☐ ☐ ☐ ☐
Trade Name <u>9</u>		
Street <u>10</u>	City and State <u>11</u>	Zip <u>13</u>
Person Interviewed <u>14</u>	Title <u>15</u>	Time <u>16</u> a.m. ☐ p.m. ☐

Product <u>17</u>		Comm. Code ☐ ☐ ☐
Mfg./Dist. <u>18</u>		
Street <u>19</u>	City and State <u>20</u>	Zip Code <u>21</u>
Date of Purchase <u>22</u>	Container Size and Type <u>23</u>	Container Code <u>24</u>
Complaint Referred By: <u>25</u>		Complaint Referred To: <u>26</u>

#1. Suspected tampering? <u>27</u> ☐ Yes ☐ No	#2. If #1 is "Yes" was Police Department contacted? ☐ Yes ☐ No
#3. If #2 is "Yes" Date <u> </u> Time <u> </u> a.m. ☐ p.m. ☐ Telephone Number <u> </u>	
Police Agency <u> </u>	Contact Person <u> </u> Title <u> </u>
#4. If #2 is "No"; explain in Remarks. <u> </u>	Nature of Complaint: <u>28</u>

Illness History: Date <u> </u> Time <u> </u> a.m. ☐ p.m. ☐	Suspected Food(s) Consumed <u> </u>
<u>29</u> Onset of Illness: Date <u>30</u> Time <u> </u> a.m. ☐ p.m. ☐ Duration <u> </u> (Hours) (Days)	
Signs and Symptoms: ☐ Nausea ☐ Vomiting ☐ Diarrhea ☐ Chills ☐ Fever ☐ Abdominal Cramps ☐ Other	
Explain "Other": <u>31</u>	

Sanitary Inspection ☐ Yes ☐ No <u>32</u>	FOR OFFICE USE ONLY Case Type <u>23</u> Response Letters B. Sample Taken/Satisfactory Results Produced: <u> </u> C. Sample Taken/Unsatisfactory Results Produced: <u> </u> Results: <u> </u> D. Handwritten Responses Reviewed By ☐ ☐ Reviewed Date ☐ ☐ ☐ ☐ ☐ ☐ Hours Spent on Investigation <u>39</u> ☐ Investigation <u>40</u> ☐ Follow-Up <u>41</u>
Limited Inspection ☐ Yes ☐ No <u>33</u>	
Consumer Contacted <u>34</u> ☐ Phone ☐ Personally	
Seizure No., <u>35</u> S- ☐ ☐ ☐ ☐ ☐ ☐	
Sample N(s), If Any <u>36</u> FL- ☐ ☐ ☐ ☐ ☐ ☐	
FL- ☐ ☐ ☐ ☐ ☐ ☐ FL- ☐ ☐ ☐ ☐ ☐ ☐	
Analysis Requested: <u>37</u>	
Inspector's Signature <u>38</u>	

Medical Attention Tendered By: Name 42	
Address	Telephone
Is Consumer on Medication(s)? 43 Yes ☐ No ☐ Does Consumer Have Allergies? 44 Yes ☐ No ☐ (List/Describe Any "Yes" in Remarks)	

PRIOR MEALS (Last 72 Hours)		
Date _____ Time _____ a.m. p.m. Foods 45	Date _____ Time _____ a.m. p.m. Foods	Date _____ Time _____ a.m. p.m. Foods
Date _____ Time _____ a.m. p.m. Foods	Date _____ Time _____ a.m. p.m. Foods	Date _____ Time _____ a.m. p.m. Foods
Date _____ Time _____ a.m. p.m. Foods	Date _____ Time _____ a.m. p.m. Foods	Date _____ Time _____ a.m. p.m. Foods

[illegible]

10/30/03

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**CONSUMER COMPLAINT INVESTIGATIONS
ILLNESS ANALYSIS GUIDELINES CHART
SUB-SECTION 3040**

PROCEDURAL INFORMATION FOR USING THE ILLNESS ANALYSIS GUIDELINES

The Illness Analysis Guidelines chart is designed to assist the Inspector in determining:

1. The most likely type of illness.
2. The most likely food vehicle.
3. Where and how contamination occurred.

The chart lists over 95% of the most commonly reported food poisoning causes. Excluded, because of their relative rarity are: heavy metals, mushroom poisoning, trichinosis, mold and yeast. Requests for analysis for a possible cause of a food poisoning, other than those on the chart, should be avoided unless there is strong supportive evidence. If needed, in-depth foodborne illness information is available through your Supervising Inspector.

USING THE GUIDELINES

The first three columns (#1 - Incubation period, #2 - Signs and Symptoms, and #3 - Foods Included) provide the data needed to determine the possible cause (#4 - Disease). The last two columns (#5 - Cause/Source and #6 - Contributing Factors) provide additional information.

After the complainant has described the time the illness started, the signs and symptoms and all foods eaten in the past 72 hours, the Inspector will use the data to determine the probable disease for which to request an analysis.

If the complainant implicates a specific food and that food corresponds with the Incubation Period and Signs and Symptoms, the Inspector should complete the investigation following that chain of evidence.

If the evaluation logically implicates another food, this should be made clear to the complainant. The Inspector should complete the investigation using this food as the possible cause. If the complainant insists their product be investigated, the Inspector should conduct dual investigations. It is also possible two or more foods may appear to be implicated and will require investigation.

If the Inspector determines none of the foods consumed could cause the illness, this evaluation should be noted in the Remarks section with supportive information. However, the food implicated by the consumer should still be sampled and analyzed and appropriate follow-up action taken.

**CONSUMER COMPLAINT INVESTIGATIONS
ILLNESS ANALYSIS GUIDELINES CHART
SUB-SECTION 3040**

Incubation Period	Signs Symptoms	Foods Included	Disease	Cause/Source	Contributing Factors
Few minutes	Burning of lips, mouth and throat, vomiting, abdominal pain, diarrhea	Bottled beverages	Sodium hydroxide poisoning	Sodium hydroxide in bottle washing compounds, detergents, drain cleaners, or hair straighteners	Inadequate rinsing of bottles cleaned with caustic
Few minutes to 1 hour	Burning sensation in back of neck, forearms, chest, feeling of tightness, tingling, flushing, dizziness, headache, nausea	Chinese food	Chinese restaurant syndrome (MSG poisoning)	Monosodium glutamate (MSG)	Using excessive amounts of MSG as flavor intensifier
Few minutes to 30 minutes	Tingling, burning, numbness around lips and finger tips, giddiness, incoherent speech, respiratory paralysis	Mussels and clams	Shellfish poisoning	Saxitoxin and similar toxins from plankton, which are consumed by shellfish	Harvesting shellfish from waters with high concentration of Gonyaulax or Gymnodinium species
Few minutes to 1 hour	Flushing, sensation of warmth, itching, abdominal pain, puffing of face and knees	Meat or other food in which sodium nicotinate has been added	Nicotinic acid (niacin) poisoning	Sodium nicotinate used as color preservative	Using sodium nicotinate as color preservative
1 to 2 hours	Nausea, vomiting, cyanosis, headache, dizziness, weakness, loss of consciousness, chocolate brown colored blood	Cured meats, any accidentally contaminated food, spinach exposed to excessive nitrification	Nitrite poisoning	Nitrites or nitrates used as meat curing compounds or ground water from shallow wells	Using excessive amounts of nitrites or nitrates in foods for curing or for covering up spoilage, mistaking nitrites for common salt and other condiments, inadequate refrigeration of fresh produce

**CONSUMER COMPLAINT INVESTIGATIONS
ILLNESS ANALYSIS GUIDELINES CHART
SUB-SECTION 3040**

Incubation Period	Signs Symptoms	Foods Included	Disease	Cause/Source	Contributing Factors
1 to 8 hours	Nausea, vomiting, retching, abdominal pain, diarrhea, prostration	Ham, meat and poultry products, cream-filled pastry, food mixtures, leftover foods	Staphylococcal intoxication	Staphylococci from noses, skin, and lesions of infected humans and animals and from udders of cows	Inadequate refrigeration, workers touching cooked food, preparing foods several hours before serving, workers with infections containing pus, holding foods at warm (bacterial incubating) temperatures, fermentation of abnormally low-acid foods
2 hours to 8 days, mean: 18 to 36 hours	Vertigo, double or blurred vision, dryness of mouth, difficulty in swallowing, speaking and breathing, descending muscular weakness, constipation, pupils dilated or fixed, respiratory paralysis. Gastrointestinal symptoms may precede neurological symptoms. Frequently fatal	Home canned low-acid foods, vacuum packed fish; fermented fish eggs, fish, and marine mammals	Botulism	Spores found in soil and animal intestines	Inadequate heat processing of canned foods and smoked fish, uncontrolled fermentations
2 to 48 hours, mean: 12 hours	Abdominal pain, diarrhea, nausea, vomiting, fever, chills, headache	Raw seafood, shellfish	Vibrio parahaemolyticus gastroenteritis	From sea water or seafood	Inadequate cooking, inadequate refrigeration, cross contamination, inadequate cleaning of equipment, using sea water in food preparation
3 to 5 hours, sometimes longer	Tingling and numbness about mouth, metallic taste, dry mouth, gastrointestinal symptoms, watery stools, muscular pain, dizziness, dilated eyes, blurred vision, prostration, paralysis	Numerous varieties of tropical fish	Ciguatera poisoning	Ciguatoxin in intestines, roe, gonads and flesh, of tropical marine fish ¹²	Eating liver, intestines, roe, gonads, or flesh of tropical reef fishes, usually large reef fish are more commonly toxic

**CONSUMER COMPLAINT INVESTIGATIONS
ILLNESS ANALYSIS GUIDELINES CHART
SUB-SECTION 3040**

Incubation Period	Signs Symptoms	Foods Included	Disease	Cause/Source	Contributing Factors
5 to 48 hours, mean: 10 to 24 hours	Abdominal pain, diarrhea, nausea, vomiting, fever, chills, headache, muscular pain	Various foods, water	Pathogenic E. coli gastroenteritis	Enterotoxigenic or invasive strains of E. coli from feces of infected humans and other animals	Infected workers touching foods, inadequate refrigeration, inadequate cooking, inadequate cleaning and disinfecting of equipment
6 to 72 hours, mean: 18 to 36 hours	Abdominal, pain, diarrhea chills, fever, nausea, vomiting, malaise	Poultry and meat and their products, egg products, other foods contaminated by salmonellae	Salmonellosis	Various serotypes of Salmonella from feces of infected humans and other animals	Inadequate refrigeration, holding foods at warm temperatures, inadequate cooking and reheating, preparing foods several hours before serving, cross contamination, inadequate cleaning of equipment, infected workers touching cooked foods, obtaining foods from contaminated sources
8 to 16 hours, mean: 12 hours	Nausea, abdominal pain, watery diarrhea	Cereal products, soups, custards and sauces, meat loaf, sausage, cooked vegetables	Bacillus cereus gastroenteritis	Exo-enterotoxin of B. cereus organism in soil	Inadequate refrigeration, holding foods at warm (bacterial incubating) temperatures, preparing foods several hours before serving, inadequate reheating of leftovers
8 to 22 hours, mean: 10 hours	Abdominal pain, diarrhea	Cooked meat, poultry, gravy, sauces, and soups	Clostridium perfringens gastroenteritis	Endo-enterotoxin formed during sporulation of C. perfringens in intestines, organism in feces of infected humans, other animals, and in soil	Inadequate refrigeration, holding foods at warm (bacterial incubating) temperature, preparing foods several hours before serving, inadequate reheating of leftovers
24 to 36 hours	Severe abdominal pain, fever, headache, malaise, sore throat	Milk, water	Yersiniosis	Yersinia enterocolitica, Y. pseudotuberculosis	Inadequate cooking, contamination of foods by water or rodents

**CONSUMER COMPLAINT INVESTIGATIONS
ILLNESS ANALYSIS GUIDELINES CHART
SUB-SECTION 3040**

Incubation Period	Signs Symptoms	Foods Included	Disease	Cause/Source	Contributing Factors
24 to 72 hours	Abdominal pain, diarrhea, bloody and mucoid stools, fever	Any contaminated foods, frequently salads, water	Shigellosis	Shigella flexneri, S. dysenteriae, S. sonnei, and S. boydii from feces of infected humans	Infected workers touching foods, inadequate re-frigeration, inadequate cooking and reheating
1 to 3 days	Sore throat, fever, nausea, vomiting, rhinorrhea, sometimes a rash	Raw milk, foods containing eggs	Beta-hemolytic streptococcal infections	Streptococcus pyogenes from throat and lesions of infected humans	Workers touching cooked foods, workers with infections containing pus, inadequate refrigeration, inadequate cooking or reheating, preparing foods several hours before serving
1 to 3 days	Profuse, watery diarrhea (rice water stools), vomiting, abdominal pain, dehydration, thirst, collapse, reduced skin turgor, wrinkled fingers, sunken eyes	Raw fish and shellfish, foods washed or prepared with contaminated water, water	Cholera	Enterotoxin of Vibrio cholerae, classical and El Tor biotypes, from feces of infected humans	Obtaining fish and shellfish from sewage contaminated waters, poor personal hygiene, infected workers touching foods, inadequate cooking, using contaminated water to wash foods, inadequate sewage disposal
3 to 5 days	Diarrhea, fever, vomiting, abdominal pain, sometimes respiratory symptoms	Unknown	Viral gastro-enteritis	Enteric viruses (ECHO viruses, Coxsackie viruses, reoviruses, adenoviruses)	Poor personal hygiene, infected workers touching foods, inadequate cooking and reheating
4 to 21 days	Fever, headache, nausea, vomiting, stillbirths, meningitis, encephalitis, sepsis	Coleslaw , cheese, milk, animal products	Listeriosis	Listeria monocytogenes	Inadequate cooking,, failure to properly pasteurize milk, prolonged refrigeration
10 to 50 days, mean: 25 days	Fever, malaise, lassitude, anorexia, nausea, abdominal pain, jaundice	Shellfish, any food contaminated by hepatitis viruses, water	Hepatitis A (Infectious hepatitis)	Hepatitis Virus A from feces, urine, blood of infected humans and other primates	Infected workers touching foods, poor personal hygiene, inadequate cooking, harvesting shellfish from sewage contaminated waters, inadequate sewage disposal

**CONSUMER COMPLAINT INVESTIGATIONS
ILLNESS ANALYSIS GUIDELINES CHART
SUB-SECTION 3040**

Incubation Period	Signs Symptoms	Foods Included	Disease	Cause/Source	Contributing Factors
7 to 28 days, mean: 14 days	Malaise, headache, fever, cough, nausea, vomiting, constipation, abdominal pain, chills, rose spots, bloody stools	Shellfish, foods contaminated by workers, raw milk, cheese, watercress, water	Typhoid fever	Salmonella typhi from feces of infected humans	Infected workers touching foods, poor personal hygiene, inadequate cooking, inadequate refrigeration, inadequate sewage disposal, obtaining foods from unsafe sources, harvesting shellfish from sewage contaminated waters

**NYS Department of Agriculture and Markets
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**CONSUMER COMPLAINT INVESTIGATIONS
SUSPECTED SHELLFISH-RELATED FOODBORNE ILLNESS NOTIFICATION LIST
SUB-SECTION 3045**

PHASE I NOTIFICATION:

New York State Department of Health, Bureau of Community Sanitation and Food Protection

Barbara Gerzonich	518-402-7600	Fax 518-402-7609	bmg02@health.state.ny.us
Ray Woron	518-402-7600	Fax 518-402-7609	r fw01@health.state.ny.us
Darby Greco	518-402-7600	Fax 518-402-7609	djg11@health.state.ny.us
Ed Carloni	518-402-7600	Fax 518-402-7609	erc06@health.state.ny.us

New York State Department of Health, Bureau of Communicable Disease Control

Joel Ackelsberg	518-473-4436	Fax 518-474-7381	jea02@health.state.ny.us
Geraldine Johnson	518-473-4439	Fax 518-474-7381	gsb03@health.state.ny.us

New York City Department of Health, Bureau of Communicable Disease Control

Marcelle Layton	212-788-4193	Fax 518-788-4268	my14@cdc.gov
Farzad Mostashari	212-788-4193	Fax 518-788-4268	fdm6a@ibm.net

New York State Department of Environmental Conservation

Gordon Colvin	631-444-0430	Fax 631-444-0434	gccolvin@gw.dec.state.ny.us
Bill Hastback	631-444-0472	Fax 631-444-0472	wghastba@gw.dec.state.ny.us
Tom Drumm	631-444-0494	Fax 631-444-0484	tedrumm@gw.dec.state.ny.us
Ken Koetzner	631-444-0475	Fax 631-444-0484	klkoetzn@gw.dec.state.ny.us

New York State Department of Agriculture and Markets

Joe Corby	518-457-4492	Fax 518-485-8986	Joe.Corby@agmkt.state.ny.us
Al Bugenhagen	518-457-5382	Fax 518-485-8986	Alfred.Bugenhagen@agmkt. state.ny.us
Curt Vincent	518-457-5380	Fax 518-485-8986	Curtis.Vincent@agmkt.state. ny.us

New York State Department of Health, Axelrod Institute Laboratory

Nellie Dumas	518-473-2798	Fax 518-486-7971	nbd01@health.state.ny.us

**CONSUMER COMPLAINT INVESTIGATIONS
SUSPECTED SHELLFISH-RELATED FOODBORNE ILLNESS NOTIFICATION LIST
SUB-SECTION 3045**

Dianna Bopp	518-474-5822	Fax 518-486-7971	djs03@health.state.ny.us
Tim Root	518-474-2191	Fax 518-486-7971	tpr02@health.state.ny.us
<u>PHASE II NOTIFICATION:</u>			
Food and Drug Administration			
Jerry Mulnick	718-340-7000	Fax 718-340-5071	Jmulnick@ora.fda.gov
Centers for Disease Control and Prevention			
Nick Daniels	404-639-2839		nbd5@cdc.gov
Ellen Steinberg	404-639-2206	Fax 404-638-2205	eis8@cdc.gov
Mary Evans	404-639-4020	Fax 404-639-2205	mde0@cdc.gov

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SAMPLING
SAMPLING - AN OVERVIEW
SUB-SECTION 3080**

OVERVIEW

The collection of an official sample is an important part of the Inspector's work. The sample may become the basis on which legal action is taken, penalties assessed, products seized and/or destroyed and administrative actions founded. The importance of using correct sample collection procedures and practices, as well as a sample of sufficient size, cannot be overly emphasized. Errors in the collection of samples will result in incorrect conclusions, wasted time, money and effort.

The Inspector is responsible not only for submitting a sample that will reflect any contamination or misbranding present, but is also responsible for selecting samples that are truly representative of the lot so that the laboratory does not arrive at a false evaluation of the lot being sampled.

PAYMENT FOR SAMPLES

Although current law does not require it, it is the policy of the Department to pay for all samples with the exception of Seizure samples. In those instances where payment is not accepted by management of the firm where the sample is obtained the statement "Payment Refused By Management" will be noted in the label section of sample FL Report.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SAMPLING
REPORT OF SAMPLING AND ANALYSIS (FL-1)
SUB-SECTION 3085**

OVERVIEW

A separate Report of Sampling and Analysis (FL-1) must be completed for each commodity sampled and for each type of examination requested (Bacteria or Chemistry); e.g., sampling of ground beef and ground chuck to be examined for fat content and bacteria.

This would require four FL reports as follows: FL-1- ground beef examined for fat content; FL-2- ground beef examined for bacteria; FL-3- ground chuck examined for fat content; FL-4- ground chuck examined for bacteria. This is necessary because different types of analysis; e.g., chemical, bacteria and standards are done in different sections of the laboratory. (See Sub-Section 4010, Laboratory Testing Area Assignments, for additional information on completing the FL Report of Sampling and Analysis).

The sample report is used for all types of samples obtained by an inspector-surveillance, scheduled, suspect, complaint, seizure, requested, or reinspection. The sample report is to be completed up to the center solid black line. The completed FL report is placed in a plastic bag and put between the Styrofoam insulation and the top cardboard cover of the sample case.

Write the FL number (which appears in red at the top of the form) using a heavy-duty permanent marker (broad tip) on the plastic bag in which the individual sample is placed and sealed. This is of utmost importance so that the laboratory can match the sample with the report.

Except for scheduled samples, the original copy of a Report of Investigation is to accompany the FL report and sample, with the copy of the investigation report going to the Supervising Inspector for his retention. On all food samples taken in conjunction with an FDA Contract Inspection the FL report must be marked on the top of the statement "FDA Contract".

REPORT COMPLETION

Use the following as a guide in completing the Report of Sampling and Analysis form. The numbers correspond to the numbered spaces on Page 7 of this section.

1. Check the appropriate box. For initial samples mark the "Inspection" box. When a repeat sample of a previously sampled commodity is requested, the reinspection box is marked and the previous FL number placed in the space after the reinspection line. Also, on reinspections the previous lab number (Item 33) must be placed in the space provided.
2. Enter your inspector's number.
3. Check the FSI box for all samples collected. This is a combined form and other boxes are used by other Divisions.

**SAMPLING
REPORT OF SAMPLING AND ANALYSIS (FL-1)
SUB-SECTION 3085**

4. Print the section pertaining to Owner, Street, City, County, ZIP code, County Code, and Establishment Number from which the sample was obtained. This information should properly reflect the business entity responsible for operation of the regulated establishment. This would be an individual, a partnership (which may be composed of two or more persons), or a corporation.
5. List establishment type by code letter (A-Store, B-Bakery, etc.). Do not use the letter-prefix "J" (multiple operations). Indicate the separate operations; e.g., D, C, or A, B, C, etc.
6. Enter the region and zone in which the sample was taken.
7. Product: Identify the sample by common name and whether it was obtained from bulk or is an individual package.
8. Where Stored: Note the storage location using descriptions such as refrigerated display case, basement, warehouse, sales area.
9. Temperature: For frozen or refrigerated sample use your thermometer and check the temperature of the product. Do not contaminate the sample in doing so. The thermometer may be used between layers of containers to obtain the temperature.
10. Commodity Code: Refer to commodity code listings and enter the correct code for the commodity sampled. Use the first two boxes for the code, leaving the third box blank.
11. Stock on Hand: Take a physical count or obtain the exact weights, whichever is appropriate. Estimate count or weight only when exact figures cannot be obtained. Indicate on the form if count or weight are estimates.
12. Time of Sampling: Insert hour you started taking the sample and circle A.M. or P.M. This entry is used by laboratory to establish hours between sampling and receipt at laboratory.
13. Month, Day, Year: Fill all boxes; e.g., (10-01-95).
14. Description of container: Simply describe the container sampled, including Container Code, Type, and Size.
15. Circle Manufacturing Process.
16. Original container sealed or transferred and sealed: When an original container is sampled and placed in a plastic bag and sealed, so indicate. When the product is removed from its original container, as in the case of bulk salads, and transferred and sealed, so state; e.g., "Removed product from bulk tray, packed in whirl pack with sterile spoon, placed in a plastic bag and sealed".

**SAMPLING
REPORT OF SAMPLING AND ANALYSIS (FL-1)
SUB-SECTION 3085**

17. Self-Service or Served: Indicate which.
18. Full name and title of responsible person before whom these two functions were conducted. (Repeat title in last two boxes.)
19. Product Sampled: Check appropriate box.
20. When not produced by the establishment where sampled, copy name of manufacturer or packer as shown on label and enter this information in the "Manufacturer or Packer" box.

The Inspector should ask the establishment operator for the name and address of the firm which actually supplied his company with the product being sampled and enter this information in the "Distributor" box. On occasion, this may be the same firm listed on the product label, however, in many instances, it will not. This information is, of course, critical in product recall situations.

In those situations where the actual distributor is different from the distributor listed on the product label, the information on the product label will still appear on the report in the "Copy of Statement Upon Container Purchased by Inspector" area.

21. Check source of product.
22. Address: Copy address from label, giving manufacturer's or packer's and/or distributor's address. Specify which it is.
23. If known, enter establishment number of manufacturer, packer or distributor. If you do not know the number, leave the space blank.
24. Check which laboratory the sample is sent to. Include name of private lab, if known.
25. Enter method by which sample was sent to the lab (UPS, US Mail, inspector). Enter date and time of day shipped (AM or PM).
26. Copy of statement upon container purchased by inspector. All pertinent information which appears on the label is to be copied and inserted here or, the entire label from another, like container may be attached.
27. Circle type of sample: F - if seizure is made, enter seizure number so the reports can be matched; H - Consumer Complaint; I - Scheduled Sample; J - Compliance or Resampling.
28. If the sample was requested by an individual from the Central Office in Albany or your Supervising Inspector, enter that person's name in this space.

**SAMPLING
REPORT OF SAMPLING AND ANALYSIS (FL-1)
SUB-SECTION 3085**

Enter K - Inspection, when part of a Sanitary Inspection, not a Scheduled sample or a Consumer Complaint.

29. Sub-units: When sub samples are taken, show the number of individual units taken (4 cans of one brand and code of product to be analyzed for the same thing would be 4 sub-units).
30. Examine For: Name of test requested.
31. Full signature of Specialist/Inspector.
32. The lab number will be entered in this space and if a reinspection is requested, this number must be recorded in space 1-b of the reinspection sample report.

Note: When the analysis is complete, the laboratory prints out a computer-generated copy with the results. The action codes at the bottom of the page reflect the following:

- A. Satisfactory in all areas
- B. Violation
- C. Non-actionable (or action to be taken at the discretion of the Division)
- D. Unable to analyze

The original copy and the computer generated copy are keypunched as statistical information and then returned for filing in the establishment folder. The second copy will be returned to the field. It is suggested that each inspector keep a small notebook or ledger of personal choice to record the FL-number, date, place where sample was taken, and what the sample was, and analysis requested. This will point out reports that are not returned or when to expect the returns of the report.

SAMPLING
REPORT OF SAMPLING AND ANALYSIS (FL-1)
SUB-SECTION 3085

The following charts (1 - Commodity Codes for Sampling Reports, 2 - Establishment Codes and Establishment Types and, 3 - Test Codes), represent the Food Laboratory Microbiological Guidelines used in arriving at the A, B, C, D action codes.

1 - COMMODITY CODES FOR SAMPLING REPORTS	
01 - Soft Drinks and Waters	31 - Jams, Jellies, Preserves, Butters
02 - Beverage Bases	32 - Fruit Products
03 - Coffee, Tea	33 - Animal Feeds
04 - Alcoholic Beverages	34 - By-products for Animal Feeds
05 - Bread, Rolls, Buns, Sweet Goods	35 - Meat, Meat Products
06 - Custard, Cream-filled Sweet Goods	36 - Nuts, Nut Products
07 - Macaroni, Noodle Products	37 - Vegetable Oil Seed, Oil Stock, Crude Oil
08 - Breakfast Cereals Ready-to-Eat	38 - Refined Vegetable Oil, Shortening, Oleomargarine
09 - Whole Grains, Beans - Bulk	39 - Fresh Vegetables
10 - Pretzels, Chips, Specialty Items	40 - Frozen Vegetables, Vegetable Juices
11 - Processed Grain, Starch Products-Human	41 - Canned Vegetables, Vegetable Juices
12 - Prepared Mixes, Dry-Flour/M Meal Base	42 - Dried, Dehydrated Vegetables
13 - Candy, Gum, Chocolate, Cocoa Products	43 - Cured, Processed Vegetable Products
14 - Syrup, Sugar, Maple Syrup, Honey	44 - Dry Dessert, Pudding Mixes
15 - Butter, Butter Products	45 - Prepared Multiple Foods
16 - Cheese, Cheese Products	46 - Misc. Food Use Items
17 - Milk, Milk Products	47 - Food Storage
18 - Dried Milk, Dried Milk Products	48 - Food Chemicals
19 - Ice Cream, Related Products	49 - Infant, Jr., Geriatric Foods
20 - Eggs, Egg Products	50 - Dietary Specialties, Artificial Sweeteners
21 - Fish, Fish Products (not smoked)	51 - Other
22 - Shellfish, Crustaceans, Etc.	52 - Tofu, Soy-Based Products
23 - Smoked Fish	54 - Honey
24 - Spices, Salt	91 - Medicated Feed
25 - Extracts, Flavors	
26 - Dressings, Condiments	
27 - Fresh Fruits, Juices, Apple Cider	
28 - Frozen Fruits, Juices	
29 - Canned Fruits, Concentrates, Nectars	
30 - Dried Fruits	

**SAMPLING
REPORT OF SAMPLING AND ANALYSIS (FL-1)
SUB-SECTION 3085**

2 - ESTABLISHMENT CODES & ESTABLISHMENT TYPES

A - Store	J - Multiple Operations	Q - Feed Mill - Medicated
B - Bakery	K - Vehicle	R - Pet Food Manufacturer
C - Food Manufacturer	L - Produce Refrigerated Warehouse	S - Feed Warehouse and/or Distributor
D - Food Warehouse	M - Salvage Dealer	T - Disposal Plant
E - Beverage Plant	N - Wholesale Produce Packer	U - Disposal Plant Transportation Service
F - Feed Mill/Non-Medicated	O - Produce Grower/Packer/ Broker, Storage	V - Slaughterhouse - Art. 5-A
G - Processing Plant	P - C.A. Room	W - Farm Winery
H - Home Processor		Z - Farm Product Est. with #
I - Refrigerated Warehouse		

3 - TEST CODES

01 - Added Color	11 - Rodent Contamination
02 - Added Preservatives	12 - Bacteriological - Standard of Quality
03 - Excessive Fat	13 - Bacteriological - Other
04 - Excessive Moisture or Added Water	14 - Dietary Claim
05 - Added Extenders	15 - Misleading Statements
06 - Undeclared Tenderizer	16 - Free Liquor
07 - Standard of Identity-enrichment, fill, drained weight, etc.	17 - Filth/foreign objects
08 - Heavy Metals	18 - Artificial Sweeteners
09 - Pesticide Residue	19 - Misbranding/product identity
10 - Insect Contamination	20 - Spoilage
	21 - Undeclared Ingredients

FL-1 (Rev. 8-05)		STATE OF NEW YORK DEPARTMENT OF AGRICULTURE AND MARKETS REPORT OF SAMPLING		Specialist / Inspector No.	
1 ☐ Inspection ☐ Reinspection Prev. FL No. _____ ☐ Investigation Report attached _____ of _____ samples				2 	
FL-306400		3		☐ FSI ☐ MC/DS ☐ OTHER	
Owner (dealer) 4		Type Est. 5	County Code 4	Establishment No. 4	
Street		City	County	Zip Code	Zone/Area 6
Brand Name 7		☐ Orig. Pkg. ☐ Bulk	Where Stored 8	Temp. 9	Com. Code 10
Product		Stock on Hand 11	Time of Sampling 12	AM PM	Month Day Year 13
Description of Original container 14			Manufacturing process; Raw Canned Aseptic Pasteurized Dried Cultured Cured Irradiated 15 Not commercially sterile		
Container Code	Container Type	Size Code	Size Description		
Original ☐ Sealed		Describe 16		☐ Self Service ☐ Served 17	
Container ☐ Transferred and sealed					
Sealed & labeled in the presence of 18		Title	Inspector's Identity Revealed To		Title
19 PRODUCT SAMPLED: ☐ Own Production ☐ Purchased by Dealer (if purchased fill in below)					
Manufacturer or Packer 20			Establishment Number 23		
Distributor			Address 22		
Source: Domestic ☐ Imported ☐ Unknown ☐					
Country: 21					
SAMPLE DESTINED FOR:			Via	Date	Time
☐ State Food Laboratory ☐ Private Laboratory 24			25		
(Name)					
F Seizure No.		Copy of statement on container (attach label if possible)			
H Type of Sample		Label Attached ☐ 26			
I Consumer Complaint					
J Scheduled					
K Compliance					
L Inspection					
M Quality Assurance					
N Import Food Initiative					
O Milk Import					
Sample requested by: 28					
Units 29	Examine for 30		Specialist / Inspector 31		

Rec By: _____ Sealed and Trans. To: _____ State Sealed: Y___ N___ Temp: _____
Orig. Container _____ Mfg. Process: _____ Source: Dom___ Imp___ Unk___ Country: _____
Notes: _____

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**SAMPLING
BACTERIAL SAMPLING
SUB-SECTION 3090**

SAMPLING/PACKAGING PROCEDURES FOR BACTERIOLOGICAL ANALYSIS

Bulk Products

1. When sampling from a bulk product such as ground meat and deli salads, the sterile Whirl Pak plastic bags are to be used to contain the sample. Sterile plastic spoons are to be used to put the product into the Whirl Pak.
2. Samples should be shipped to the lab under temperature conditions which are the same as those at which they are ordinarily displayed or stored. Refrigerated samples should not be frozen during shipment to the lab nor should frozen samples be shipped under conditions where they may thaw.

Note: Freezing of refrigerated samples can cause the destruction of certain micro-organisms, thereby giving misleading bacteriological results. Freezing of such products can also alter physical appearances. The only exception to the prohibition against freezing products which should be refrigerated would occur when circumstances do not allow overnight delivery of perishable samples to the laboratory. For example, if it is necessary to pick up a consumer sample on a Friday and hold it over the weekend prior to shipping it to the laboratory, it is preferable to freeze such samples if continued storage at refrigeration temperatures would likely result in the decomposition or spoilage of the sample.

3. Refrigerated samples must be cooled with wet ice to 0⁰- 7.2⁰C (32⁰- 45⁰F) and packed so as to maintain the samples at 0⁰- 7.2⁰C (32⁰- 45⁰F) until arrival at the laboratory.
4. Wet ice must be placed in a separate plastic bag and properly sealed to prevent leakage into, or adjacent to, the sample. The use of Scotch ice or similar cooling material is acceptable in lieu of wet ice. Scotch ice packs will be returned with shipping case by laboratory.
5. A temperature control consisting of a container of water or a duplicate package of the product being sampled shall be included. One temperature control per sample case is sufficient. Identify the temperature control as "TC". If no TC is included, when required, then the first sample collected will be sacrificed and used as a TC.
6. A refrigerated sample that has been received by the bacteriology laboratory in a frozen condition, is no longer in its original state and will not be analyzed (except as described in the "Note:" under item 2, above).

**SAMPLING
BACTERIAL SAMPLING
SUB-SECTION 3090**

7. Secure dry ice or wet ice and place in sample case before taking samples. Wrap dry ice in paper to prolong its life.
8. Write the FL number on the outside of the Whirl Pak that is to be filled.
9. Secure a sterile plastic spoon and remove it from its wrapper. Do not place it on a contaminated surface.
10. Mix the product with the spoon to produce an homogeneous sample. (Leave the spoon in the product at this time).
11. Tear the top from the sterile bag; open by pulling the tabs. Support the bag by grasping it in the left hand with the end of the coated wire resting on the thumb and index finger.
12. Fill bag approximately one-half full using the sterile spoon. Place the spoon back in the bulk container if other sub samples are needed. If not, discard the spoon.
13. Close the bag by pulling both ends of the coated wire. Expel the excess air from the bag by gently pressing its sides. Then whirl the bag 4 or 5 times for proper sealing. Bend each end of the coated wire against the bag to prevent reopening.
14. Place the sample and each sub in a regular plastic bag on which the FL number has been written. Seal the bag with wire and clamp.
15. Place the sample in the sample case containing the wet or dry ice.
16. When additional samples are required, repeat the above procedures. However, it is absolutely necessary to use a new sterile spoon.
17. Before shipping refrigerated or frozen samples, wrap them sufficiently to prevent damage during transit. Be sure to include sufficient dry or wet ice to insure that the samples will arrive at the laboratory at the proper temperature.
18. Complete the FL report; insert it in plastic bag and place the bag between the top of the insulated cover and the cardboard outer shell of the sample case.
19. *Routine refrigerated and perishable samples for bacterial and specie analysis must be shipped to arrive at the Food Laboratory within 48 hours after collection on a regular workday, and no later than Noon on Friday. Samples received later than 48 hours after collection will not be analyzed.

**SAMPLING
BACTERIAL SAMPLING
SUB-SECTION 3090**

20. Samples for bacterial analysis that do not require refrigeration must be shipped to arrive at the Food Laboratory on any regular workday and no later than Noon on Friday.
21. Courier service does not pick up or deliver sample boxes on State holidays. UPS does not make deliveries to the laboratory on State holidays.
22. Samples that are not shipped to the food laboratory the same day they are selected, shall be accompanied by an investigation report outlining the circumstances involved in the delayed shipment.

*(It is not always possible to observe the 48 hour rules when consumer samples are involved and these should be delivered, under refrigeration, to the lab as soon as possible.)

SAMPLING/PACKAGING PROCEDURES FOR BACTERIOLOGICAL ANALYSIS

Consumer Pack/Closed Containers

1. When sampling products in a consumer pack or other closed container, care must be taken to prevent decomposition and spoilage, and to prevent frozen products from thawing. The following procedures should be used when sampling food in consumer size packages for bacteria.
 - A. Determine if the product should be shipped with or without refrigeration.
 - B. Select a sample of recommended size and one which is representative of the lot being considered. When sample requires more than one package to meet the minimum sample size, every attempt shall be made to obtain the same code.
 - C. Write the FL number on the plastic bag.
 - D. Place the sample in the plastic bag, close the bag by spinning it, make a loop in the twisted section; place the wire tie through the loop and wrap it around the top of the bag to seal it. Place the state clamp on the end of the twist tie so that the bag cannot be opened without breaking the bag or seal.
 - E. Place the sample into the shipping case with the proper refrigerant and temperature control, if refrigeration is needed.
 - F. Complete the FL report and insert it in a plastic bag and place the bag between the top of the insulated cover and the cardboard cover of the outer shell of the sample case and ship to the Food Lab.

**SAMPLING
BACTERIAL SAMPLING
SUB-SECTION 3090**

2. *Samples that are not shipped to the food laboratory the same day they are selected, shall be accompanied by an investigation report outlining the circumstances involved in the delayed shipment.

*(It is not always possible to observe the 48 hour rules when consumer samples are involved and these should be delivered, under refrigeration, to the lab as soon as possible.)

BACTERIAL SAMPLE COMMODITIES

1. Salads: macaroni, potato, shrimp, ham, bean, fruit, etc.
2. Hot, Ready-to-Eat: deli items, chickens, short ribs, meatballs, stuffed peppers, breaded fish, pies, etc.
3. Heat and Serve: all frozen dinners, meat pies, breaded fish, pastries, deli items, canned dinners
4. Pastries: custard-type pies, cream-filled baked goods, pumpkin pies, etc.
5. Hard Fabricated Meats: hard salami, jerky, thuringer, pepperoni, etc.
6. Candies: milk chocolate, candy bars, seasonal candies
7. Mixes: custard mix, puddings, dry beverage mix, frosting mix, etc.
8. Frozen Desserts: frozen pies, cakes, pastries, and toppings
9. Vegetable Oil: olive oil, soya, coconut oil, corn, etc.
10. Ground Meats: beef, pork, veal, lamb, meatloaf mixes
11. Dry Noodles: various egg noodle products
12. Coconut: ground or grated

**SAMPLING
BACTERIAL SAMPLING
SUB-SECTION 3090**

13. Shelled Nuts: peanuts, cashews, walnuts in bags, cans or jars
14. Shellfish: clams, lobster, crab, mussels, etc.
15. Cheeses (for pathogens): soft and semi-soft

MINIMUM SAMPLE SIZES FOR BACTERIOLOGICAL EXAMINATION

1. Salads - 1 pound
2. Hot Ready-to-Eat - 1 pound
3. Heat and Serve - 1 consumer size package or 1 pound on bulk items
4. Pastries - 1 unit; on small pastries - 3 units
5. Hard Fabricated Meats - 1 pound
6. Candies - 1/2 pound or equivalent in individual bars
7. Mixes - 2 consumer size packages
8. Frozen Desserts - 2 consumer size packages
9. Ground Meats - 1 pound
10. Dry Noodles - 1 pound or 1 consumer unit
11. Coconut - 8 ounces
12. Shelled Nuts - 1/2 pound
13. Shellfish - 1 pound
14. Soft Cheeses and Semi-soft Cheeses - a single 1-pound unit or 2, 8-ounce units
15. Other Products - 1 consumer size package of approximately 1 pound

**SAMPLING
BACTERIAL SAMPLING
SUB-SECTION 3090**

MICROBIOLOGICAL GUIDELINES

The data listed below are the guidelines used by NYS Food Laboratory personnel when evaluating sample analysis results. This information will assist you in better understanding and evaluating completed sample reports returned to you.

1. Raw meat, hamburger, fresh sausage, fresh pork, fresh beef, fresh poultry, etc.:

Aerobic Plate Count (APC)	Not to exceed 5 million/g
E. coli	Not to exceed 50/g
Salmonella (excludes fresh poultry)	None found in 25/g
Staphylococcus aureus	If positive test for staph enterotoxins
E. coli (0157:H7)	< 1/g
Listeria monocytogenes	None found in 25/g

2. Cooked meat products; i.e., hot dogs, bologna, cooked ham, etc.; cooked ready-to-eat foods, i.e., frozen TV dinners, macaroni salad, barbecued chicken and other delicatessen foods, and cold smoked/hot smoked fish:

Aerobic Plate Count(APC)*	Not to exceed 1 million/g
E. coli (with or without raw ingredients)	Less than 1/g
Salmonella	None found in 25/g
Staphylococcus aureus	If positive test for staph enterotoxins
Listeria monocytogenes	None found in 25/g
Coliforms	Addressed on an individual basis

*Exempt if product contains cultured ingredients or is a fermented product.

Note:

Alfalfa and Bean Sprouts: APC not to exceed 100,000,000/g

Fresh Cut Salads: E. coli not to exceed 100/g mpn

APC of 1 million or more/g in cooked ready-to-eat foods is an indication of spoilage

Staphylococcus aureus of more than 1,000/g may indicate faulty handling procedures

E. coli greater than 1/g in ready-to-eat foods indicates faulty handling procedures

**SAMPLING
BACTERIAL SAMPLING
SUB-SECTION 3090**

Salmonella present in ready-to-eat food indicates insanitary conditions and the product is considered adulterated

$a_w < 0.86$ will inhibit the growth of all foodborne pathogens. The minimum a_w for growth of:

<u>C. botulinum</u> :	Type A - 0.95	<u>Staphylococcus aureus</u> :	0.86
	Type B - 0.94		
	Type E - 0.97		

REFRIGERATION REQUIREMENT FOR SAUSAGE

Dry Sausage:	Moisture protein ratio
(pH 4.4-8.6)	1.9 to 1.0 or less or $a_w \leq 0.85$ and $pH \leq 5.3$ – Refrigeration not required.
(Water Content 25-35%)	
(Water Activity .85-.91)	

Semi-dry Sausage:	Moisture protein ratio
{pH 4.2-5.0}	3.1 - 1.9 to 1.0 or $a_w \leq 0.85$ and $pH \leq 5.3$ – Refrigeration not required
{Water Content $\approx 50\%$ }	
{Water Activity .90-.94}	

Sausage not within the above parameters requires refrigeration.

TIME TO BE ALLOWED FOR SAMPLE ANALYSIS

The following are the working days required for bacteriological analysis of food products according to each test:

	<u>Min.</u>	<u>Max.</u>
1. APC (AEROBIC PLATE COUNT)	2 days	2 days
2. E. coli	2 days	10 days
3. Staph Aureus	2 days	3 days
4. Coliforms	2 days	4 days
5. Salmonellae	4 days	11 days
6. Commercial sterility of canned foods	10 days	14 days
7. Listeria Monocytogenes	3 days	8 days
8. E. coli 0157:H7	1 day	2 days

Please be aware of these time frames before contacting the Central office to seek results. Also, add 24 hours to the above time to allow for shipment to the laboratory.

REASON FOR REJECTING SAMPLES RECEIVED IN THE BACTERIOLOGY

**SAMPLING
BACTERIAL SAMPLING
SUB-SECTION 3090**

LABORATORY

1. Sample received too warm for analysis.
2. Frozen samples that have thawed between collection and arrival in the laboratory.
3. Decomposed samples.
4. Samples that were in a refrigerated condition at time of collection but were frozen subsequent to shipment to the lab.
5. Leaking or damaged samples.
6. When a temperature control is not included with refrigerated samples, an official sample will be sacrificed as a control.
7. Insufficient sample.
8. Failure to use sterile containers when required.
9. Missing, illegible or incorrect FL# on sample.

**REASONS FOR DELAYS IN OBTAINING RESULTS FROM THE BACTERIOLOGY
LABORATORY**

1. Failure to include an investigation report with a consumer complaint or seizure samples:

When an investigation report is not submitted with the sample, it is necessary for the Lab to contact the Division of Food Safety and Inspection and ask for the information. Occasionally, an FL-1 is marked for bacteriological analysis and the investigation report indicates a chemistry analysis would be more appropriate.

2. Failure to include previous FL# and laboratory number on FL-1 report:

When a previous Lab number is recorded, the Laboratory is able to check their records and determine what the original analysis results were.

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Field Operations Manual**

**SAMPLING
WATER SAMPLING
SUB-SECTION 3095**

SAMPLING WATER (H₂O) FOR BACTERIOLOGICAL ANALYSIS

All water sample vials supplied by the Division will contain a sodium thiosulfate tablet to neutralize any residual chlorine. A 4 oz. plastic sample vial with security seal will be utilized.

The first phase of water analysis for coliforms requires 48 hours; therefore, the Laboratory cannot accept water samples that arrive on Thursday or Friday.

Samples must arrive at the Laboratory so that the time between collection and examination does not exceed 30 hours. Samples received more than 30 hours after collection cannot be analyzed.

Ship water samples under refrigeration (wet ice or Scotch packs). Frozen samples cannot be analyzed.

PROCEDURE

1. The tap chosen should supply water from a service pipe directly connected with the main supply.
2. Do not select leaking taps.
3. Open tap fully and allow to run to waste for two to three minutes or for a sufficient time to clean the service line.
4. Restrict the flow enough to allow the bottle to be filled without splashing.
5. Keep the sample bottle closed until just before sampling.
6. Remove cap and protect from contamination. Do not rinse the bottle.
7. Hold bottle near the base.
8. Fill, without rinsing, to the E.P.A. 100 ml fill line.
9. Replace cover tightly and affix the security seal strip over top of lid and two sides of vial.
10. Write sample number and date on sample container label.
11. Ship promptly using the packing and shipping procedures outlined in Sub-Section 3090.

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**SAMPLING
PESTICIDE RESIDUE SAMPLING
SUB-SECTION 4000**

Do not procure any routine, non-scheduled pesticide residue samples without the prior knowledge and consent of your Supervisor.

LOT SAMPLING FOR PESTICIDE RESIDUES

Food samples for pesticide residue testing should be collected at the wholesale or farm level so that follow-up sampling can be completed, if necessary. When the results of an analysis are used to draw conclusions about large lots of product, the sample must be representative of the lot. A pesticide spraying of a crop does not result in every plant in a field receiving an equal dose.

The method of collection and the sample size will depend on a number of factors, which include whether the produce is still growing or if it has been harvested, and whether a selective or objective sample is desired.

SAMPLING PROCEDURES

1. Samples of berries, fruits, and vegetables, composed of several sub-units from the same lot should be combined into one portion and submitted as one sample.
2. Place the sample in a plastic bag and secure with a twist tie and state seal.
3. Record the FL number on the exterior of the plastic bag with a felt tip-marking pen.
4. Enclose report of sampling and analysis form(s) in a separate plastic bag and place between the top of the insulated cover and the outer shell.
5. Provide sufficient dry ice for frozen samples to insure they arrive at the lab in a frozen state. A sufficient number of pre-cooled scotch ice packs must be provided to maintain products, which require refrigeration below 40 degrees Fahrenheit. Samples such as macaroni, noodle products, honey, syrups, oils and other products which are kept at room temperature do not require refrigeration.
6. No other analysis requests can be made on samples submitted for pesticide residue analysis.

PESTICIDE SAMPLE QUANTITIES

1. Berries, fresh - 5 or more portions or packages from a uniform lot for a five-pound minimum sample.
2. Butter, Oleo, Lard - 2 or more packages from a uniform lot for a two-pound minimum sample.
3. Canned products including baby foods - 5 cans or bottles from a uniform lot.
4. Cereal, dry - 5 or more packages from a uniform lot.

SAMPLING
PESTICIDE RESIDUE SAMPLING
SUB-SECTION 4000

5. Cheese - 2 or more packages from a uniform lot for a two-pound minimum sample.
6. Cream - 2 packages from a production lot or 8-ounce packages from the producers.
7. Dry products (grain, feed, silage, hay, etc.) - 5 or more packages or portions from a uniform lot for a five-pound minimum sample.
8. Flour - 2 or more packages from a uniform lot.
9. Frozen Desserts - 2 or more packages from a uniform lot for a one-half gallon minimum sample.
10. Eggs - 3 dozen from one lot.
11. Fish and Shellfish - Composite of 5 pounds from one uniform lot or five or more portions or packages from a uniform lot.
12. Fruit, fresh - 5 or more portions or packages taken from a uniform lot for a five-pound minimum sample.
13. Fruit juices and beverages - 2 consumer-size containers from a uniform lot.
14. Honey, syrup, etc... - Consumer-size container of at least one pint.
15. Macaroni and noodle products - 5 or more packages from a uniform lot.
16. Meat Products - 5 or more packages from a uniform lot.
17. Milk - 2 packages from a production lot or an 8-ounce jar from a producer.
18. Oils - 2 consumer-size containers (at least 1 pt. each) from a uniform lot.
19. Poultry - 5 birds from a uniform lot.
20. Turkey, goose, duck - 1 bird.
21. Vegetables - 5 or more portions or packages from one uniform lot for a five-pound minimum sample.
22. Liquid products - one pint.
23. Packaged food other than above - 5 or more packages.

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**SAMPLING
CHEMISTRY SAMPLING
SUB-SECTION 4005**

OVERVIEW

This category includes analysis for filth, extraneous matter, insect and insect fragments, rodent excreta, hair, deviation from standards for standardized foods, undeclared or prohibited colors, preservatives, excessive water, extenders, heavy metals, artificial sweeteners and undeclared ingredients.

Samples are to be packed and shipped as explained in Sub-Section 4000, Pesticide Residue Samples, Sampling Procedures.

Size of samples should be one pound or one or more consumer size packages totaling at least one pound. When sample requires more than one package to meet the minimum sample size every attempt shall be made to obtain the same code.

Foods suspected of being adulterated should be sampled and the requested analysis should reflect the form of adulteration suspected.

ANALYSIS CATEGORIES

1. Dietetic foods: claims of “low sodium,” “sugar free,” “low calorie,” etc.
2. Processed vegetables (canned, frozen): insects, filth
3. Spices: insects, rodent excreta, filth
4. Fresh fish: parasitic worms, decomposition, heavy metals
5. Canned fish: decomposition, spoilage, mercury
6. Tomato products: mold, fly eggs, maggots
7. Chopped salad mix: dirt, insect filth
8. Nuts: label statements, aflatoxins
9. Ground meats: fat content, sulfites, extenders, other additives or preservatives
10. Blended oils labeled as containing 25% or more olive oil: check for olive oil content

**SAMPLING
CHEMISTRY SAMPLING
SUB-SECTION 4005**

11. Noodles: egg solids, enrichment
12. Breads, rolls, rice, macaroni: enrichment, added color
13. Jams and Jellies: for standard, added color, preservatives
14. Juice: fruit content, added sugar
15. Raisin Bread: raisin content, added color
16. Breaded shrimp: standard
17. Dried foods and packaged foods: insects, rodent filth, foreign material
18. Grated cheese: for standard, labeling
19. Roast beef or ham for maximum internal temperature: sample size, 2 inch center slice
20. Cooked or smoked poultry for maximum internal temperature: sample size - entire bird or breast

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**LABORATORY TESTING AREA
ASSIGNMENTS
SUB-SECTION 4010**

MICROBIOLOGY								
	These seven analyses can be run on the same sample and FL							
	1	AEROBIC PLATE COUNT						
	2	COLIFORM AND E. COLI						
	3	E. COLI AND 0157:H7						
	4	LISTERIA						
	5	SALMONELLA						
	6	STAPHYLOCOCCUS						
	7	YEAST AND MOLD						
	These two analyses can be run on the same sample and FL							
	1	pH						
	2	WATER ACTIVITY						
	This one analysis requires its own sample and FL							
	1	PEANUT PRESENCE						
	This one analysis requires its own sample and FL							
	1	EGG PRESENCE						
	This one analysis requires its own sample and FL							
	1	CAN SEAM EVALUATION						
Samples sent to the Microbiology Laboratory and also needing tests which are done in the Chemistry Laboratory, require a separate FL and sample for Chemistry.								

**LABORATORY TESTING AREA
ASSIGNMENTS
SUB-SECTION 4010**

CHEMISTRY							
		Each analysis numbered 1 thru 9 requires a separate sample and FL					
	1	ALCOHOL					
	2	CARBON SIRA (HONEY OR MAPLE SYRUP)					
	3	FILTH, EXTRANEIOUS MATERIAL AND EVISCERATION					
	4	HEAD SPACE ANALYSIS					
	5	INTERNAL TEMPERATURE					
	6	RAISIN BREAD					
	7	HISTAMINES					
	8	ALFATOXINS					
	9	MEAT SPECIES					
		Any combination of the analysis numbered 10 thru 28 can be run using the same sample and FL.					
	10	BLOOD					
	11	CAFFEINE					
	12	COLORS					
	13	ENRICHMENT					
	14	FAT					
	15	FATTY ACID PROFILE (VEGETABLE OILS)					
	16	HEAVY METALS					
	17	JUICE ANALYSIS					
	18	MOISTURE PROTEIN RATIO					

**LABORATORY TESTING AREA
ASSIGNMENTS
SUB-SECTION 4010**

CHEMISTRY		(Continued)					
	19	NIRITES					
	20	PRESERVATIVES					
	21	SALT					
	22	SODIUM					
	23	SOLUBLE SOLIDS					
	24	STANDARD OF IDENTITY					
	25	STEROL					
	26	SUGARS					
	27	VANILLA/COUMARIN					
	28	WATER PHASE SALT					
Samples sent to the Chemistry Laboratory and also needing tests which are done in the Microbiology Laboratory, require a separate FL and sample for Microbiology.							

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**ADVERTISING AND LABELING INSPECTIONS
UNIT PRICING
SUB-SECTION 4020**

OVERVIEW

Each person who sells, offers or exposes for sale in a retail store a consumer commodity shall disclose to the consumer the unit price and the total price of the commodity as provided in Section 214-h, Article 17 of the Agriculture and Markets Law. The following pages contain the exact procedure to be used in the performance of a unit pricing survey.

REQUIREMENT TO PROVIDE UNIT PRICING INFORMATION

Any retail store, which sells consumer commodities at retail, shall have the unit price and total price disclosed to the consumer in the manner prescribed by Section 214-h, Article 17 and Part 345, 1 NYCRR. The provisions of this section shall not apply to any retail store having had annual gross sales of consumer commodities in the previous calendar year of less than two and one-half million dollars.

DEFINITION OF CONSUMER COMMODITIES

“Consumer commodities” shall mean the following, however packaged or contained:

1. Food, including all material, solid, liquid or mixed, whether simple or compound, used or intended for consumption by human beings or domestic animals normally kept as household pets and all substances or ingredients to be added thereto for any purpose; and
2. Napkins, facial tissues, toilet tissues, foil wrapping, plastic wrapping, paper toweling, disposable plates; and
3. Detergents, soaps and other cleansing agents; and
4. Non-prescription drugs, female hygiene products and toiletries.

Note: “Toiletries” are defined as articles used in bathing, dressing and grooming.

GUIDELINES FOR PERFORMING A UNIT PRICING SURVEY

The following procedures will be followed in the performance of all assigned unit pricing surveys and reporting of violations. Strict adherence to these guidelines is required to ensure uniformity throughout the State in our enforcement of the Law.

Note: Unit pricing surveys are performed only by direction of the Albany Office.

ADVERTISING AND LABELING INSPECTIONS
UNIT PRICING
SUB-SECTION 4020

1. Inspector(s) performing the survey will ensure they have a copy of the current Unit Pricing Law (Section 214-h) and the Rules and Regulations (Part 345) promulgated thereunder. They must also be equipped with a working calculator, measuring device, paper and writing instrument.
2. On entry into the establishment, the inspector(s) will identify themselves to the most responsible establishment representative present and explain the reason for the visit. The inspector(s) will verify that the establishment had sales of two and one-half million dollars of consumer commodities for the previous calendar year.

Note: Establishments who have not been in business for one full year **do not** qualify. If the ownership has changed, it is a new business, the sales of the previous owner **do not** apply. The survey **will not** be performed at these locations.

3. To determine the number of consumer commodity tags to be examined, it is first necessary to estimate the number of consumer commodities being sold within the establishment. When the number of consumer commodities is determined, the following formula will be used to determine the sample size:

NUMBER OF COMMODITIES	SAMPLE SIZE
3,000 - 7,499	150
7,500 - 9,999	200
10,000 - Plus	250

Note: At no time shall the number of consumer commodities examined be less than 150 or more than 250.

4. The method for choosing the exact consumer commodities to be examined is as follows:
 - A. Divide the total number of consumer commodities to be examined by the total number of aisles in the sales area. This determines the number of consumer commodities in each aisle that shall be examined. (Example: 150 consumer commodities divided by 15 sales aisles equals 10 consumer commodities per aisle).
 - B. The beginning point for the aisle shall be determined by the inspector, the same point will be used in each subsequent aisle. Selection will continue down the aisle until the required number of consumer commodity tags for that aisle have been examined. Only consumer commodities shall be examined. If there are insufficient consumer commodities available in an aisle, the remaining samples shall be taken from the next aisle. The total number of samples to be examined shall be accomplished, even if it is necessary to return to the first aisle.

ADVERTISING AND LABELING INSPECTIONS
UNIT PRICING
SUB-SECTION 4020

5. When a unit pricing stamp, tag or label is found to be missing or violative, the exact violative condition shall be adequately documented on a Report of Investigation (FSI-30) using one of the descriptive statements shown on Attachment #1. Any stamp, tag or label that contains a violation of the statutes shall be documented by copying the label information exactly as it appeared on to one of the blank tags on Attachment #2.

Note: Handwritten tags will not be considered violative as long as they are clear, conspicuous, in the proper format, meet the size requirements and contain all the required information. If ruled violative, the report must indicate the exact reason the tag was ruled violative.

6. Absolute care must be taken to ensure that only consumer commodities are examined and that statutory exempt items are not part of the survey (See Attachment #3 for exempt items).
7. Results of the survey will be discussed with the establishment representative upon completion of the report. Any discrepancies or questionable items shall be discussed and resolved, if possible, prior to departing the establishment. If they request a copy of the report, you may photocopy it for them. If no photocopier is available at the establishment, inform them that a copy will be forwarded to them from the Regional Office (Attach a note to the report advising your supervisor of this requirement). Inform them that any questions on unit pricing should be addressed to the Economic Unit at (518) 457-1762.
8. Submit the completed report through your Supervisor per normal procedures.

**ADVERTISING AND LABELING INSPECTIONS
UNIT PRICING
SUB-SECTION 4020**

ATTACHMENT # 1

UNIT PRICING VIOLATIONS

Unit price stamp, tag or label not present.

Unit price stamp, tag or label fails to display unit price.

Unit price stamp, tag or label fails to display item price.

Unit price stamp, tag or label does not meet the requirements of Section 345.3 (c) in that it fails to ...

Unit price calculation was not rounded off and stated to the nearest full cent.

Identical consumer commodities being offered or exposed for sale at two or more prices within a store did not have the unit pricing information calculated and displayed based upon either (a) each price at which the item was offered or exposed for sale or (b) the highest price at which the item is offered or exposed for sale. When unit priced at its highest price only, a statement was not present clearly indicating that identical consumer commodities are available at more than one price and that the unit pricing information shown is based upon the highest selling price.

Unit price calculation was incorrect (show exact information on Attachment #2).

Unit price stamp, tag or label information was incorrect, e.g., incorrect unit of measure used for calculation.

Multiple product signs are not located near the point of sale and/or not listing the products in alphabetical order according to brand name.

**ADVERTISING AND LABELING INSPECTIONS
UNIT PRICING
SUB-SECTION 4020**

ATTACHMENT # 2

VIOLATION # _____

VIOLATION # _____

**ADVERTISING AND LABELING INSPECTIONS
UNIT PRICING
SUB-SECTION 4020**

ATTACHMENT #3

ITEMS EXEMPT FROM UNIT PRICING

Spices, flavor extracts and imitation flavorings, and bouillon cubes, where the total content of the package or container weighs three ounces or less;

Snack foods such as cakes, candies, chips, nuts offered for sale in single packages and weighing 5 ounces or less;

Any food item displayed for sale in bulk which is packaged for and served directly to the consumer by a store employee, provided that such food item is segregated and displayed as a specialty food;

Any food item for which there is no like or similar product to which it may be compared within the store, provided that such food item is segregated and displayed as a gourmet specialty food;

Any commodity whose net quantity as offered for sale in one dozen, or 100 square feet, provided that it has the retail selling price marked plainly thereon;

Any fluid milk, or cream, or mellorecream product for which the capacity of the container used for the sale of such product where the net quantity as offered for provided the retail price is marked plainly thereon or displayed on a sign or list at or near the point at which the item is offered or exposed for sale;

Any frozen dessert for which the capacity of the containers used for the sale of such product where the net quantity as offered for sale is one-half pint, one pint, one-half pint, one-half quart, one quart, one-half gallon or one gallon, provided that the retail price is marked plainly there on or displayed on a sign or list at or near the point at which the item is offered or exposed for sale;

Any milk product or product in semblance thereof which is required to be sold by net weight and in prescribed units of weight, where the net quantity as offered for sale is one-half pound, one pound or two pounds, provided that it has the retail price marked plainly thereon or displayed on a sign or list at or near the point at which the item is offered or exposed for sale, e.g., butter, oleomargarine, margarine, sour cream and yogurt are required by law or regulation to be sold by net weight;

Fresh food produce.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**ADVERTISING AND LABELING INSPECTIONS
ADVERTISING AND LABELING REPORT (FSI-500)
SUB-SECTION 4025**

ADVERTISING/LABELING REPORT (FSI-500)

The FSI-500 is used for Misbranding, Adulteration, False or Misleading Advertisements, Price Checks and Product Availability Reports.

Article 17 of the Agriculture and Markets Law, Sections 200 and 201 state the definitions under which food and food products may be deemed adulterated and/or misbranded. (Labeling of commercial feed is outlined in Article 8, Section 130).

A single original copy of the report (paper or electronic) is all that is submitted, whether it is to report a violation or a satisfactory follow-up.

Note: The following numbered explanations pertain to the numbered spaces on the Exhibit:

1. Check the “investigation” box for all initial reports. The “re-investigation” box is checked for all subsequent reports on the same violation.
2. Date the investigation/re-investigation is performed.
3. Enter the establishment owner’s name, trade name, street address, city, state and ZIP code.
4. Enter the establishment number if known. If unknown, enter the two digit county code in the first two boxes. LEAVE THE REMAINING FOUR BOXES BLANK.
5. Indicate the name and title of the individual with whom the violation was discussed.
6. Indicate the time the investigation/re-investigation began.
7. Check the appropriate box to indicate the type of violation being reported.
8. Check the method of media being used to represent the product. If a copy of the media used to represent the product is attached to the report, check “yes”, if not, check “no”.
9. Establishment type - Enter the single letter code for the type of establishment for which the report is submitted.

**SECTION 4025-A
ADVERTISING AND LABELING
(ECONOMIC INSPECTIONS)**

10. Enter the two-digit commodity code for the violative commodity. Only one commodity code shall be reported per report. A separate report is required for different commodity codes.
11. If official samples of the commodity are submitted to the food laboratory, enter the appropriate FL number(s).
12. Briefly describe how the product is being represented to consumers; e.g., crabmeat.
13. Identify by the actual name, the product used as a substitute for the represented product; e.g., imitation crabmeat.
14. Identify the exact location of the product being offered for sale to the consumer; e.g., self-service meat display case.
15. Describe in detail the violation being reported. All pertinent information relating to the product should be included.
16. Name of inspector(s) submitting report.
17. Name of Reviewer.

Note: Following review of the electronic form by the Food Inspector II, the report is to be e-mailed as an attachment to the Mail & Supply Clerk (Laverne Edwards) and the back-up (Tammy Davis) with the Food Inspector III copied.

SECTION 4025-B
ADVERTISING AND LABELING
(ECONOMIC INSPECTIONS)

FSI-500 (Rev. 3/06)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
10B AIRLINE DRIVE, ALBANY, NEW YORK 12235

ADVERTISING/LABELING REPORT

☐ Investigation

☐ Re-Investigation

DATE: 2

OWNER: 3		EST. NO.: 4						
TRADE NAME:								
STREET:			CITY:				ZIP	
PERSON INTERVIEWED: 5			TITLE:			TIME: 6 ☐ AM ☐ PM		
7 ☐ SATISFACTORY ☐ MISBRANDING ☐ ADVERTISEMENT ☐ ADULTERATION ☐ PRICE CHECK ☐ DIETARY ☐ PRODUCT AVAILABILITY			PRODUCT REPRESENTED BY ☐ MENU ☐ LABEL 8 ☐ WALL SIGN ☐ ADVERTISEMENT ☐ PLACARD ☐ VERBAL IS ABOVE ATTACHED? ☐ YES ☐ NO			EST. TYPE 9 COMMODITY CODE 10 FL NO. 11 FL NO.		
PRODUCT REPRESENTED AS: 12								
SUBSTITUTE USED: 13								
WHERE DISPLAYED: 14								
DESCRIBE DETAILS OF VIOLATION BELOW. ATTACH AN APPLICABLE LABEL, DIGITAL PHOTOGRAPH OR ADVERTISEMENT. 15								
INSPECTOR: 16					REVIEWED BY: 17			

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**ADVERTISING AND LABELING INSPECTIONS
PRICE CHECKS AND PRODUCT AVAILABILITY INSPECTIONS
SUB-SECTION 4030**

STATUTORY AUTHORITY

Agriculture and Markets Law, § § 3, 16 (1); (23); 18 (2); 202-a.

Title 1, State of New York Official Compilation of Codes, Rules and Regulations, Subpart 272-2, Advertising and Marketing of Food for Sale at Retail.

PROCEDURE

1. Assignment of Price Checks and/or Product Availability Inspections will be by the Central Office or the Region Supervisor.
2. The inspector assigned to perform the inspection shall secure a copy of the current sale circular for the establishment to be inspected.
3. Posing as a regular customer, and using the copy of the current sale circular the inspector shall conduct a price check and/or a product availability inspection.

PRICE CHECK INSPECTION

1. Randomly, select at least ten (10) sale items from the sale circular; if less than ten (10) items are on sale, check all sale items.
2. Inspect the sale items to ensure they are conspicuously available and are available at, or below, the stated sale price.
3. When the items are not available at, or below, the stated sale price, the inspector shall purchase the items. If the price charged is higher than the stated sale price the inspector shall report this as a violation in the manner outlined in Sub-Section 4020 and Sub-Section 4025.

PRODUCT AVAILABILITY

1. When performed in conjunction with a price check, the same items will be inspected. If performed separately, select at least ten (10) sale items from the sale circular.
2. Check for availability of the items. Items found not available shall be reported using the format outlined in Sub-Section 4020 and Sub-Section 4025.
3. After purchase of the items, the inspector should present his credentials to management and state the nature of the inspection(s).

ADVERTISING AND LABELING INSPECTIONS
PRICE CHECKS AND PRODUCT AVAILABILITY INSPECTIONS
SUB-SECTION 4030

4. Discuss the results of your inspection(s) with management. Include in the report any statements made by management that are pertinent. Pricing violations should be corrected prior to the inspector departing the establishment.
5. Discuss with management the items that were not available. Examine invoices to determine the normal amount ordered, the quantity ordered for the sale period and quantity received. Provide any other pertinent information provided by management relative to unavailability of the sale items.
6. Include a statement about the store's raincheck policy.
7. Request management refund the money for the items purchased and return the items to the establishment.

REPORTING

An original and one copy of the Advertising and Labeling Report form (FSI-500), shall be prepared at the establishment to reflect the finding for each type inspection performed. The original, with sale circular attached, is forwarded to the Albany office through normal channels. The second copy is given to management of the establishment.

See Sub-Section 4025, Advertising and Labeling Report (FSI-500) for form completion instructions.

Note: Commodity code 51 is used on the FSI-500.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**LEGAL ACTIVITIES
LEGAL DOCUMENTS AND AFFIDAVITS OF SERVICE
SUB-SECTION 4040**

OVERVIEW

During your normal inspection activities you will have to serve various legal papers on establishment operators under our jurisdiction. These legal papers could include:

1. Notice of Hearing:

Notifies the establishment operator that a hearing has been scheduled to consider revocation or denial of a license application or to consider destruction of food products held under Department seizure.

2. Commissioner's Final Determination:

Notifies the establishment operator of the results of the hearing and the action(s) the establishment must follow to comply with the Commissioner's determination.

3. Notice of Motion for Preliminary Injunction:

Notifies the establishment operator that the Department is seeking injunctive relief to enjoin the establishment from operating under insanitary conditions, without a license and/or offering for sale adulterated food products.

4. Order of Preliminary Injunction:

Notifies the establishment operator of the decision of the Court and the action(s) the establishment must take to comply with the Order.

5. Notice of Motion for Contempt:

Notifies the establishment operator that the Department is advising the Court that the establishment has not complied with the Court Order and is requesting penalties or other appropriate action.

6. Order of Contempt:

Notifies the establishment operator of the penalties incurred and action to be taken for violation of the Court Order. In severe cases, the Contempt Order is followed by the issuance of an Arrest Warrant.

LEGAL ACTIVITIES
LEGAL DOCUMENTS AND AFFIDAVITS OF SERVICE
SUB-SECTION 4040

7. Inspection Warrant: Advises the establishment operator of the right of representatives of the Commissioner to inspect the food establishment without interference from establishment representatives or employees. The Warrant usually provides for the taking of photographs and samples.
8. Temporary Restraining Order: Notifies the establishment operator that the court has ordered the establishment to immediately cease violative operating and/or practices mentioned in the order. The order can be lifted by the court after the establishment has corrected the violative conditions.
9. Summary Suspension: Notifies the establishment operator that the Commissioner has ordered the establishment to immediately cease operations requiring a license and that a hearing is scheduled.

SERVICE OF LEGAL PAPERS

The following guidelines shall be used in the Service of Legal Papers. If there are any questions, contact the Food Safety and Compliance Unit.

1. Upon receipt, carefully read and review the packet of papers including the accompanying memorandum. The packet should include the original and one copy of the papers to be served (original to be served upon the establishment, copy for your files), an Affidavit of Service and a cover memorandum.
2. The papers must be served by the date indicated in the accompanying memorandum and upon the individual(s) listed in the papers. In the case of a corporation, the papers may be served upon a corporate officer or manager. Allow enough time for service in case individuals to be served are not available on the first attempt. The Inspector making service shall explain the content of the legal papers to the person being served.

Note: See “Alternate Service” on page 4 of this Sub-Section for instructions for completing an “Affidavit of Service by Mail.”

3. At least two attempts must be made to make service on the owner(s).
4. If directed in the memorandum, a sanitary inspection shall be conducted. This inspection should include the taking of photographs and, if appropriate, food samples.
5. After service, the serving Inspector shall immediately complete the Affidavit of Service and sign it before a Notary Public. The Affidavit must then be immediately mailed to the Food Safety and Compliance Unit.

LEGAL ACTIVITIES
LEGAL DOCUMENTS AND AFFIDAVITS OF SERVICE
SUB-SECTION 4040

6. All reports, including Affidavits, Investigations, and Sanitary Inspections are to be mailed by the Inspector directly to the Food Safety and Compliance Unit, the same day that the action occurs, with a red tag attached (See “**EXCEPTION**,” page 5). Electronic reports are to be uploaded the day of the inspection.
7. A telephone report of the service and/or inspection is to be made by the Inspector directly to the Food Safety and Compliance Unit (518-457-2840) after completion.

AFFIDAVITS OF SERVICE

Following service of legal papers, an Affidavit of Service must be promptly completed. Listed below are the instructions for completion of the **Affidavit of Personal Service** (page 7) and **Affidavit of Service by Mail** (page 8). All information is to be printed unless otherwise specified.

Note: The Affidavit you may serve may differ slightly in appearance from the attached exhibits, however, the information contained within each affidavit will remain, essentially, the same.

Affidavit of Personal Service

1. Est. No. - Enter the establishment number.
2. Caption - This section is filled in with the statement:

Plaintiff: (Commissioner’s Name), Commissioner of Agriculture and Markets of the State of New York,

“against”

Defendant/Respondent - Circle “Respondent” for “Notices of Hearing” and “Commissioner’s Determinations.” Circle “Defendant” for all other services.

D/B/A

Address

(These sections should be filled in by the central office)

3. County - fill in the name of county where service is made (this section may have been filled in by the Central Office).
4. Inspector’s Name - Print your first name, then your last.
5. He/She - Draw a circle around the appropriate word; e.g., He /She
6. Day, Month, Year - Fill in the day, month, and year of service; e.g., 16 day of July, 2006.

LEGAL ACTIVITIES
LEGAL DOCUMENTS AND AFFIDAVITS OF SERVICE
SUB-SECTION 4040

7. Complete Address - Print the name of the street and the city where service was made.
8. Papers to be Served - This section will filled in by the Central Office.
9. Defendant/Respondent - Place an "X" in the appropriate blank. The term "Respondent" should be used for "Notices of Hearing" and "Commissioner's Final Determinations." Use "Defendant" for all other services.
10. Name - Print the name of the person served. Make certain that it is spelled correctly.
11. Title - Print the title of the person served; e.g., Manager.
12. Establishment Name - Print the owner(s) name(s) and the establishment's trade name.
13. Description - Fill in a complete description of the person served. This description is to include sex, color of skin, color of hair, approximate age, approximate weight, approximate height, and any other distinguishing features.
14. Notary Public & Deponent's Signature - The Department employee making the service is the Deponent. Sign your full name in front of a Notary Public.

ALTERNATE SERVICE:

IF THE PAPERS CANNOT BE HAND DELIVERED AND SERVED UPON THE SOLE OWNER OR THE PARTNERS OF AN ESTABLISHMENT ACCORDING TO THE INSTRUCTIONS LISTED ABOVE, AN ALTERNATE SERVICE, USING AN "AFFIDAVIT OF SERVICE BY MAIL" SHALL BE USED IN THE FOLLOWING MANNER:

1. At least two attempts must be made to make personal service on the owner(s).
2. If unable to serve the owner(s), the papers are to be served upon the most responsible person in the establishment.
3. After making service, mail a copy of the papers by **first class mail**, in a **Department** envelope, to the owner's last known residence. If the last known residence is unable to be determined, the papers may be mailed in the aforementioned manner to the actual place of business. In either case, the mailing is to take place on the same day as the service.

LEGAL ACTIVITIES
LEGAL DOCUMENTS AND AFFIDAVITS OF SERVICE
SUB-SECTION 4040

4. The Inspector is then to complete an "Affidavit of Service by Mail." This affidavit will indicate that a copy of the legal papers were served to the owner by mail and a copy of the legal papers also were served upon the most responsible person in the establishment.

Note: Copies of "Affidavit of Service by Mail" may be obtained from your Zone Supervisor.

5. All reports, including Affidavits, Investigations, and Sanitary Inspections are to be mailed by the Inspector directly to the Food Safety and Compliance Unit the same day that the action occurs, with a Red Tag attached.

EXCEPTION: In the case of a Pre-Hearing Inspection, the Inspector shall retain the Inspection Reports and hand carry them to the Hearing. However, a copy of the Pre-Hearing inspection report and all investigation reports, including seizures, **must** be sent, by FAX, to the Food Safety and Compliance Unit immediately upon completion of the inspection. It is not necessary to send copies of other related reports. The FAX number is: (518) 485-8986.

Affidavit of Service by Mail

1. Est. No. - Enter the establishment number.
2. Caption - Fill in this section with the Commissioner's name, and the statement:

Plaintiff: (Commissioner's Name), Commissioner of Agriculture and Markets of the State of New York,

"against"
3. Defendant/Respondent - Circle "Respondent" for "Notices of Hearing" and "Commissioner's Final Determinations." Circle "Defendant" for all other services.
4. Enter the name of the owner, the d/b/a and the complete address
5. Deponent's Name - (The person making the service) Print your first name, then your last.
6. He/She - Draw a circle around the appropriate word; e.g., He /(She)
7. Day, Month, Year - Fill in the day, month, and year of service; e.g., 16 day of July, 2006.
8. Full address - Enter the address where the establishment representative was served a true copy of the service.
9. Papers to be Served - Check the space before the name of the papers to be served.
10. Other - If "Other," check the space and enter the name of the document being served, e.g.; Commissioner's Final Determination, etc.

LEGAL ACTIVITIES
LEGAL DOCUMENTS AND AFFIDAVITS OF SERVICE
SUB-SECTION 4040

11. Place of Mailing - Enter the location of the letter box, including the name of the county, where the document was mailed.
12. Full Address - Enter the complete address of the Home / Place of Business where a copy of the document was mailed.
13. Home / Place of Business - Circle the place where the alternate service was mailed.
14. Person Being Served - Enter the name of the establishment representative receiving a copy of the document being served.
15. Title - Enter the title of the establishment representative being served.
16. Description - Enter a concise description of the establishment representative served.
17. Notary Public & Deponent's Signature - The Department employee making the service is the Deponent. Sign your full name in front of a Notary Public.

LEGAL ACTIVITIES
LEGAL DOCUMENTS AND AFFIDAVITS OF SERVICE
SUB-SECTION 4040

a:\affidav\affmastr2.dot (1/96) msw

STATE OF NEW YORK
DEPARTMENT OF AGRICULTURE AND MARKETS
COUNSEL' S OFFICE

EST.NO. **1**

Plaintiff: Commissioner of Agriculture and Markets of the State of New York,

2
Defendant/Respondent: -against-

AFFIDAVIT OF
PERSONAL SERVICE

STATE OF NEW YORK)
:SS.:
COUNTY OF _____ **3**

_____, Being duly sworn, deposes and says:

5
1. That he / she is over the age of eighteen years and not a party to this action and is an employee of the

New York State Department of Agriculture and Markets

2. That on the **6** day of _____, _____, at **7**

New York, he / she served a true copy of the :

8

Notice of Motion,
Affidavit in Support, Summons & Verified Complaint

Personally upon the above named: _____ **9** Defendant Herein, _____ Respondent Herein, by delivering a copy thereof to: _____ **10** _____ personally leaving the same with him / her. He/ she knew _____ **10** to be at that time the _____ **11** of said _____ **12** described in said papers as the _____ Respondent **2** _____ Defendant in this matter

3. The description of the person so served is, to the best of the deponents knowledge and observation, as follows:

13 Sex: _____ Color of skin: _____ Color of hair: _____
Approximate age: _____ Approximate weight: _____ Approximate height: _____

Other distinguishing features _____

The foregoing is based on the deponents personal observation and represents his best judgement and nearest approximation of the descriptive features listed.

Sworn to before me this _____ day of _____, _____ **14**

Notary Public

Deponents Signature

LEGAL ACTIVITIES
LEGAL DOCUMENTS AND AFFIDAVITS OF SERVICE
SUB-SECTION 4040

STATE OF NEW YORK
DEPARTMENT OF AGRICULTURE AND MARKETS
COUNSEL'S OFFICE
AFFIDAVIT OF SERVICE BY MAIL

a:\affidav\mailarvc (9/95) pm5

Est. No:

1					

Plaintiff: 2 Commissioner of Agriculture and Markets of the State of New York
-against-

Defendant / Respondent: 3

D/B/A: 4

Address:

Enter the owner(s) name(s)
and Establishment Name
(DBA) and Address

CIRCLE "RESPONDENT" FOR
"NOTICES OF HEARING" AND
"COMMISSIONER'S FINAL DETER-
MINATIONS".

CIRCLE "DEFENDANT"
FOR ALL OTHER SERVICES.

STATE OF NEW YORK)
COUNTY OF 5)
6)
ENTER THE NAME OF THE COUNTY WHERE SERVED.
:ss.:

7 (Deponent's name), Being duly sworn, deposes and says:

1. That he / she is over the age of eighteen years, and not a party to this action and is an employee of the New York State Department of Agriculture and Markets.
Circle the correct gender term in all underlined sections. Put an X or checkmark on the line in front of the applicable terms.

2. That on the 8 day of _____, 1999, at _____,
(Day) (Month) (Year) (Full Address)
New York, he / she served a true copy of the:

10
____ Order of Preliminary Injunction ____ Order of Civil and Criminal Contempt
____ Notice of Motion, Affidavit in Support, ____ Notice of Motion and Affidavit in Support,
____ Commissioner's Final Determination ____ Summons and Verified Complaint
____ Notice of Hearing, Exhibits and Summary of
____ INYCRR PART 367

11 (Other) _____ personally upon the above named Defendant /
(Describe "other")

Respondent Herein, by depositing said papers, securely enclosed in a postpaid wrapper in the Post Office regularly maintained by the United States Government at 12, in said County of 5, directed to said Defendant / Respondent at 13, that being the actual home / place of business of the Defendant / Respondent and by leaving copies of said papers at the actual place of business of Defendant / Respondent with one 15, who was present at the above address and identified himself / herself as the 16, and at the same time, informing 15, that they were for the Defendant / Respondent.
(Name of person served) (Full address of place of mailing) (True)

3. The description of the person so served is, to the best of deponent's knowledge and observation, as follows:

17 Sex; _____ Color of skin; _____ Color of hair; _____
Approximate age; _____ Approximate weight; _____ Approximate height; _____
Other distinguishing features; _____

The foregoing description is based on the deponents personal observation and represents his best judgement and nearest approximation of the descriptive features listed.

Sworn to before me this _____ day of _____, 1999

Notary Public

Deponent's Signature

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**LEGAL ACTIVITIES
LEGAL PROCEDURES, HEARING AND
COURTROOM DEPARTMENT
SUB-SECTION 4045**

OVERVIEW

As a Department Food Inspector, you may be required to appear as a witness at an administrative hearing or court proceeding. Normally, you will be required to testify on matters related to your observations during sanitary inspections. This would include insanitary conditions, the taking of photographs and samples, and examination of food products.

HEARING AND COURTROOM DEPARTMENT

For a witness to be effective, their statements must be understandable and accepted as truth by a hearing officer or judge. The effectiveness of your testimony is not by the statements that you make, but by those that the hearing officer or judge understands.

Their appearance and general demeanor often determine the credibility of a witness. This would include: Attire, how you walk, posture, how you answer questions, clarity of voice, facial expressions and gestures.

Besides being truthful and honest, making a favorable impression upon the hearing officer or judge should be your first aim as a witness. The following principles listed as do's and don'ts should help you in making that favorable impression.

1. Be as inconspicuous as possible. Facial grimaces during testimony, or nods of approval or disapproval at the testimony of others shall be avoided. Talking in the hearing room, reading reports or newspapers, passing notes, or making audible comments shall also be avoided.
2. Dress neatly and conservatively. Your appearance is important. It enhances your image. The cliché "clothes make the person" was never more applicable than for a witness in the hearing room.
3. Answer each question by spoken words. Don't nod, assent, or shake your head in dissent. The hearing reporter cannot read your mind.
4. Speak clearly and distinctly. Use simple language the layman can understand. Minimize your use of technical jargon. Keep your voice at a level that can be heard and understood by everyone in the room.

**LEGAL ACTIVITIES
LEGAL PROCEDURES, HEARING AND
COURTROOM DEPARTMENT
SUB-SECTION 4045**

5. Wait until you are asked to contribute to the hearing by acting as a witness. Don't be an "impetuous prompter". Don't clarify another person's testimony from the floor.
6. Keep to yourself. Avoid conversations with the principals or witnesses from the opposing side during the hearing.
7. During periods of recess don't engage in horseplay, wisecracking or loud conversations, especially about the case. Also, do not hold loud conversations in the corridor outside of the hearing room while the hearing is in session.

TESTIMONY

1. Testimony should be clear, calm and truthful. Don't lose your patience or temper while testifying. Don't verbally spar or try to match wits with the questioning attorney. Keep your temper at all times.
2. Wait for the question to be asked in its entirety before you reply. Make certain that you understand it, and never attempt to answer a question that you do not fully understand.
3. If you don't know the answer to a question, say so. Don't try to cover up ignorance of some fact.
4. Don't be over anxious to get something into evidence that the attorney has not asked for.
5. If asked if you have discussed the case with Department representatives, state the truth. There is nothing improper in a discussion of your testimony with our attorneys.
6. Avoid legal arguments with attorneys during the hearing. Save your questions on legal points until you can discuss them informally with the Department's Attorney.
7. Don't answer any question, which has been objected to by either side, until the hearing officer has ruled on the objection.
8. Come into the hearing prepared. Know your facts, pertinent dates and times. Be organized. Arrange your notes in good working order. Don't hesitate to ask permission to refer to your notes to refresh your memory. But do not bring your notes with you when testifying unless you are willing to let the other side see them.
9. Answer only questions asked, and answer them fully and to the point. Don't volunteer unnecessary information. Don't exaggerate.

**LEGAL ACTIVITIES
LEGAL PROCEDURES, HEARING AND
COURTROOM DEPARTMENT
SUB-SECTION 4045**

10. State only the facts. Don't express opinions or conclusions unless authorized to do so. Don't presume expert knowledge in a field unless you are, in fact, an expert by reason of your training and experience.
11. To err is human. Don't pretend you are perfect. If you've made an error, admit it.
12. Finally, the hearing procedure is to present the facts. It is up to the Commissioner to make the final determination. Remember, the hearing officer should be treated with respect and deference. Any questions should be answered and instructions followed.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**LEGAL ACTIVITIES
DELEGATION OF AUTHORITY
SUB-SECTION 4050**

OVERVIEW

Pursuant to provisions of section 17 and 22 of the Agriculture and Markets Law, the Commissioner of Agriculture and Markets has delegated to specified employees of the Department, the authority and power to administer oaths and take affidavits in relation to matters or proceedings within the jurisdiction of the Department pursuant to the Agriculture and Markets Law, or of any rule or regulation duly promulgated pursuant to such Law, and falling within an area of responsibility assigned to the Division of Food Safety and Inspection. Any exercise of such authority shall be in accordance with the direction and approval of the Director of the Division of Food Safety and Inspection.

This Delegation will remain in effect for each specified individual so long as he or she is employed by the Department unless such delegation is sooner modified or revoked by the Commissioner.

This authorization does not extend to misconduct investigations involving Department personnel or other matters which fall outside the authority provided in those Agriculture and Markets statutes and regulations assigned to the Division of Food Safety and Inspection.

**LEGAL ACTIVITIES
DELEGATION OF AUTHORITY
SUB-SECTION 4050**

PROCEDURE FOR AND COMPLETION OF AFFIDAVITS

1. This form for an affidavit must be sworn to by the witness before a Department of Agriculture and Markets representative specifically authorized to administer oaths and take affidavits pursuant to Section 22 of the Agriculture and Markets Law.
2. The statement may be typewritten, or printed by either the witness or the investigator.
3. Record the witness's statements exactly as he or she makes them. Do not correct the witness's grammar.
4. Have the witness read the entire statement in your presence. If there are any mistakes that the witness desires to correct, the witness should be encouraged to make the corrections and place his or her initials next to each correction.
5. Paragraphs should be numbered and closely spaced so that there are no blank spaces in the body of the affidavit.
6. Do not end a page with a complete sentence. Continue the last sentence of a page on the first line of the next page.
7. Each page should be numbered at the bottom indicating what portion of the entire statement it represents - "Page 2 of 5," etc., and should be initialed by the witness.
8. All of the pages of the statement should be securely stapled together.
9. The witness must personally appear before a Department representative authorized to administer oaths and take affidavits and swear to the contents of the statement. No changes can be made in the affidavit after it is signed and sworn to.
10. The original of the affidavit must be kept by the investigator. A photocopy can be furnished to the witness at a later date.
11. A sample affidavit follows on Pages 3 and 4.

**LEGAL ACTIVITIES
DELEGATION OF AUTHORITY
SUB-SECTION 4050**

State of New York
Department of Agriculture and Markets
Division of Food Safety and Inspection
10B Airline Drive
Albany, New York 12235

STATE OF NEW YORK)
 : ss.:
COUNTY OF _____

_____ being duly sworn, deposes and says:

(Signature)

(Print Name)

Sworn to before me
this _____ day of _____, 20____

(Signature)

(Print Name)

Authorized to Administer Oaths and Take
Affidavits Pursuant to Section 22 of the
Agriculture and Markets Law.

Page _____ of _____

(Witness's Initials)

State of New York

**LEGAL ACTIVITIES
DELEGATION OF AUTHORITY
SUB-SECTION 4050**

Department of Agriculture and Markets
Division of Food Safety and Inspection
10B Airline Drive
Albany, New York 12235

STATE OF NEW YORK)

: ss.:

COUNTY OF (Enter county where statement is sworn to)

(Name of Witness), being duly sworn, deposes and says:

1. The first paragraph should include a complete background identification of the witness such as his or her date and place of birth, marital status, number of children, home address, home telephone number, job title, employer and employer's address. This information is necessary both to identify the witness and to enable you to locate him or her in the future.
2. The second paragraph should describe, in logical or chronical sequence, the information (observations, admissions, statements, etc.), that the witness is swearing to.
3. The last paragraph should be printed by the witness as follows: "I have read the foregoing statement, consisting of one typewritten page and have been given an opportunity to make additions or corrections. This statement is true and correct to the best of my knowledge and I am giving it freely and of my own accord."
4. The affidavit closes with the signature of the witness and the dated signature and notary stamp of the notary public before whom the witness swore to his or her statement.

(Signature of Witness)
(Printed Name of Witness)

Sworn to before me
this _____ day of _____, 20____

(Signature)

(Print Name)

Authorized to Administer Oaths and Take
Affidavits Pursuant to Section 22 of the
Agriculture and Markets Law.

Page _____ of _____

(Witness's
Initials)

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**LICENSING
LICENSES AND PERMITS
SUB-SECTION 4065**

GENERAL INFORMATION

The Division of Food Safety and Inspection is responsible for the licensing and inspection of food establishments operating in the following capacities:

1. Slaughterhouses *(V): (slaughterhouses not under the Federal USDA Meat and Poultry Inspection Program) licensed and regulated under Articles 5-A. Refer to Circular 925.
2. Food Salvager *(M): as defined and licensed by Article 17-B. Refer to Circular 855.
3. Refrigerated Warehouse/Locker Plant *(I) or Produce Refrigerated Warehouse *(L): as licensed and regulated by Article 19. Refer to Circular 831.
4. Food Processing Plant *(G): establishments that purchase fruits and/or vegetables for processing directly from New York State growers and are required to be bonded and licensed by this Department under Article 20 of the Agriculture and Markets Law and licensed under Article 20-C as a Food Manufacturer *(C).
5. Food Processing Establishments: such as Bakeries *(B), Beverage Plants *(E) or Food Manufacturers *(C) licensed and regulated by Article 20-C as defined by Circulars 951, 938 and 1029.
6. Retail Food Stores (A3): Stores that sell potentially hazardous foods (eggs, fluid milk, and refrigerated meats) are required to have an Article 28 Retail Food Store License.
7. Food Warehouse (D): Firms that hold food for commercial distribution are required to be licensed under Article 28 Food Warehouse License.
8. Disposal Plant *(T) and Disposal Plant Transportation Service *(U): regulated and licensed under Article 5-C.

Inspectors should familiarize themselves with each of the specific areas of Agriculture and Markets Law and Regulations which relate to the various establishments within their assigned areas.

INSPECTOR'S PROCEDURES

During each inspection, reinspection, or limited inspection, the inspector shall determine if licensable activities are being conducted by the establishment, or if potentially hazardous foods are sold. If so, request to see the establishment's license to determine if the information on the license

**LICENSING
LICENSES AND PERMITS
SUB-SECTION 4065**

is accurate and current; i.e., type of license, expiration date, owner's name, and the address of the establishment.

When the information on the license or establishment printout differs from the actual conditions in the establishment, the inspector shall complete an Operation Change Report to update the Department's records on the establishment.

*** Establishment Type Code**

The conduct of licensable activities without the required license is a violation of the Agriculture and Markets Law and is to be reported by the inspector either as a deficiency, if a sanitary inspection is being conducted, or fully described on a Report of Investigation if no inspection is being performed.

Whenever the inspector has determined that unlicensed operations are being conducted by an establishment, the inspector should attempt to obtain a completed license application and license fee via check or money order payable to the Department of Agriculture and Markets and review the licensing procedures and requirements with the operator/owner.

Inspectors can contact the Albany Office to inquire if an establishment has applied for the required license.

REPORTING UNLICENSED OPERATIONS

1. Critical Deficiency (Items 5B & 21A): When conducting a sanitary inspection and the establishment is conducting unlicensed operations for which specialized inspection guidelines exist, as outlined on the back of form FSI-898, the lack of a license is to be reported as a Critical Deficiency (Items 5B and 21A) and fully explained on the Supplemental Sanitary Inspection Report form (FSI-898).
2. General Deficiency (Items 13A & 21B): When conducting a sanitary inspection and the establishment is found to be conducting unlicensed operations (other than those outlined above) it shall be marked as General Deficiency 13A and 21B and fully described on the Supplemental Sanitary Inspection Report Form (FSI-898).

A report documenting licensable activities and written either as a deficiency on a Sanitary Inspection Report (FSI-894 & FSI-898) or on a Report of Investigation (FSI-30), must provide the following information:

1. What licensable activity or operation is being conducted? For Article 20-C activities or operations, list the commodities.
2. How did you determine that this licensable operation was being conducted?
3. What Agriculture and Markets Law is being violated and what license is needed?
4. Have you:
 - A. obtained a completed application and fee (FSI-303A).
 - B. provided the operator with an application and instructions (FSI-303).

**LICENSING
LICENSES AND PERMITS
SUB-SECTION 4065**

C. been informed by the operator/owner that an application was already submitted.

FOR NEW BUSINESSES ONLY

The inspector shall instruct the operator that licensable operations cannot be conducted if they have not submitted the application and fee and/or if critical sanitary deficiencies are found during the inspection. This information shall also be included in whatever report(s) the inspector submits.

As with all reports, license information must be clearly written, complete and not contain unsubstantiated statements.

ARTICLE 20-C FOOD PROCESSING ESTABLISHMENTS

Circulars 951 and 938 fully explain the requirements of Article 20-C. The definition of “Processing” includes treating food in such a way as to create a risk that it may become adulterated if improperly handled.

EXAMPLES OF LICENSABLE PROCESSING ACTIVITIES

1. Grinding and Mixing: fresh meat of any species, poultry, fish, cheese or nuts, alone or in combination, with any other food or ingredient.
2. Freezing: frozen dessert products, of any type, including shaved ice, slush, yogurt, etc. or, retail ice production packed for resale.
3. Bottling, Rebottling or Dispensing: cider, flavored water, fruit or vegetable juices, soft drinks, beer, wine, cappuccino or hot chocolate.
4. Smoking, Pickling, Brining, Marinating or Dehydrating: meat, fish, poultry, eggs, fruit, vegetables or herbs.
5. Packing/Repacking or Packaging for Direct or Self-Service Sale: any ready-to-eat exposed food or, food products, including unwrapped candies, honey, oils, cheese, cereals, salads, nut meats, dry fruits, bread, pastries, etc.
6. Slicing, Cutting, Eviscerating or Shucking: bread, cheese, cold cuts, fruit, vegetables, bagels, fudge, fish, clams, oysters, etc.
7. Catering off premises: food prepared at establishment and served at another location.
8. Wholesale Operations: any processing, packaging or repackaging involving any exposed food, food chemical, ingredient or food compound, except raw agricultural commodities other than sprouts that are ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public.

**LICENSING
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9. Reduced Oxygen or Vacuum Packaging: any food or food product - special approval for processing procedures is needed – Wholesale via Scheduled Process, Retail via retail approval from the License Unit.
10. Exempt Operations from Article 20-C licensing include: establishments licensed under specified Agriculture and Markets Laws, State Health Agency or a Federal Agency as outlined in Section 251-z-2. Also, bottled and bulk water facilities and retail meat cutting operations.
11. Exempt under Part 276 of the A & M Regulations from Article 20-C licensing: certain home processed foods and maple syrup and honey processors that do not purchase syrup or honey for repackaging or mix honey or maple syrup with any other substance, and farm winery operations licensed by the New York State Liquor Authority. Refer to the specific requirements under Part 276.4.

PLANNED LICENSABLE ACTIVITIES

If, while at an establishment, you learn they plan to start a licensable activity in the near future, follow these procedures:

1. If the establishment has all of the required facilities and equipment to conduct the intended operation, complete a sanitary inspection of the establishment and on the lower part of the Inspection Report write: “The establishment intends to (explain activity) a licensable activity under Article _____ and has the appropriate facilities and equipment to obtain this license.” “No licensable activity was being conducted on this date.” Do not write it as a deficiency.
2. Submit an OCR, changing the establishment and IPH types on both to reflect the new activity. Explain in the Remarks section.
3. If the licensable activity requires an Article 20-C License, give the establishment representative an application.
4. If the firm is a retail food store and sells potentially hazardous foods, give the establishment representative an application. Make a reasonable effort to obtain the completed application with a check or money order for the license fee.
5. If the activity is other than an Article 20-C food processing operation or Article 28A retail food store, give the establishment representative the Central Office License Unit telephone number and advise them to call the License Unit for the proper application form and guidance.
6. If the establishment does not have the required facilities and equipment:
 - A. Submit this information on a Report of Investigation. Make no changes or additions to the Sanitary Inspection Report. Do not submit an OCR reflecting any licensable activities.

**LICENSING
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- B. Do not give an Article 20-C License Application to the establishment representative.
- C. Advise the operator to contact the regional office or the inspector to arrange an inspection after the required facilities and equipment have been installed.
- D. If the establishment is a new business and not yet open, complete a Report of Investigation, not a Sanitary Inspection Report.
- E. If the establishment is found conducting an unlicensed activity, report it as described in the prior sections.
- F. If the establishment is or will engage in reduced oxygen food processing or packing, the inspector shall ask the License Unit, by note or telephone, to send the appropriate information to the establishment.

INSPECTOR PROVIDED INFORMATION ON INITIAL LICENSE APPLICATIONS (FSI-303-A)

When an inspector is obtaining a completed initial license application or, is providing the establishment with a blank application at the time of an initial inspection, the Inspector should put the following information on the license application:

- 1. The Date an OCR was prepared
- 2. The Establishment Number if assigned
- 3. The Establishment Type Codes - (i.e., JABC, A3, D, etc.)
- 4. If the establishment passed or failed the inspection
- 5. The Pro-rated License Fee

This practice will help to eliminate some requests for inspections from the License Unit when the application is received.

WHEN PROCESSING OPERATIONS ARE DISCONTINUED

When an establishment discontinues all licensable food processing operations, the Inspector shall submit the OCR changing the Establishment Type, the IPH. The Inspector should also state on the OCR the processing activities that were discontinued.

**LICENSING
LICENSES AND PERMITS
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FSI 303A (2/05)

NYS DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
108 AIRLINE DRIVE
ALBANY, NY 12235

**ARTICLE 20-C
FOOD PROCESSING ESTABLISHMENT LICENSE APPLICATION
LICENSE FEE \$200.00**

FOR INSPECTORS USE ONLY

Est. No: _____ Date: _____

Inspected: _____ OCR: _____ Est. Type: _____

License Expires: _____ Fee: _____

Owners Name: _____

Office Use Only

Est. No. _____

Receipt No. _____

Validation No. _____

INSTRUCTIONS

Read and complete both sides of this application.
Prepare a separate application for each location.

Include license fee by check or money order payable to
"Department of Agriculture and Markets"

Section (1) enter and explain all business names or
facility address.

Sections (2) through (4) must be completed.

Section (9) an original signature of owner or corporate
officer is required.

(1) Applicant(s): (If Partnership, Name All Partners, if a Corporation, Enter Full Name of the Corporation)		County	
Trade Name		Business Telephone Number	
Street	City	State	Zip
(2) Federal ID Number*		Social Security Number(s)*	
**Reason for not providing Federal ID No. and/or Social Security Number			
(3) Business Mailing address if different from above		Attention	
Street:	City	State:	Zip:

(4) IF APPLICANT IS AN INDIVIDUAL OR PARTNERSHIP or LIMITED LIABILITY COMPANY THE FOLLOWING MUST BE COMPLETED:

Full Name of Owner or Name of each Partner	Residence – Home Address (Street & No., City, State, Zip)	Date of Birth

(5) IF APPLICANT IS A CORPORATION or LIMITED LIABILITY COMPANY THE FOLLOWING MUST BE COMPLETED:

Full Name of Officers	Residence – Home Address (Street & No., City, State, Zip)	Date Took Office	Date of Birth
President			
Vice Pres.			
Secretary			
Treasurer			
Directors (attach list if necessary)			

(5a.) Principal Corporate Office Address: _____

(5b.) In what state incorporated? _____ (5c.) Date of Incorporation _____

(5d.) Foreign or out-of-state corporation: Date of filing in New York State? _____

(5e.) Name of New York State resident upon whom service of process may be made? _____

(OVER)

**LICENSING
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APPLICANTS MUST PROVIDE ALL REQUESTED INFORMATION

SHOULD YOU FAIL TO DO SO, YOUR APPLICATION MAY NOT BE PROCESSED. IF YOU HAVE QUESTIONS CONCERNING THE INFORMATION REQUESTED, CALL (518) 457-1215 OR WRITE TO THE ADDRESS ON THE FRONT OF THIS FORM.

(6) Has the applicant or any partner, officer, director or stockholder been convicted of, or pleaded guilty to, a felony in any court in the United States? Yes ☐ No ☐ If yes, state the full name of the person _____ Name of Court and its location? _____ Date of Conviction? _____ and attach a "Certificate of Conviction" if not provided on a prior application. If a "Certificate of Conviction" has been provided and a license issued on a prior application, check this box. ☐ (7) List all food preparation or processing activities and the foods prepared or processed at this location to be covered by the license. For example: cook or heat foods, grind meats, slice cold cuts, cheese, fish, fruit, etc., repack ready-to-eat foods or ice. Any wholesale food production or packaging. _____ _____ _____ _____ _____		
(8) Workers Compensation Law requires that businesses seeking to issue permits demonstrate that they have appropriate Workers Compensation Insurance (WCI). Indicate your WCI status: ☐ Insured with _____ Name of Insurance Provider _____ ☐ Self Insured ☐ Exempt from WCI The undersigned applies for a license to conduct the food processing operations listed above, at this location only, pursuant to Article 20-C of the Agriculture and Markets Law of the State of New York and, in support of the application, makes the above statements and agrees to comply with the requirements of Article 20-C. The applicant represents that adequate physical facilities, equipment, sanitary controls, records and practices exist to maintain the establishment in a clean and sanitary condition. The cleaning, maintenance and operation of the establishment is such that products produced and handled therein will not be adulterated. The issuance of a license is based upon continued compliance with all requirements associated with the processing operations performed at the establishment. New or additional food processing activities are to be reported to this Department for approval prior to the start of the processing operation. Applicant consents to free entrance and permit free access to the licensed premises, buildings and offices to the Commissioner, the Commissioner's agents and inspectors in pursuance of the Commissioner's duty to supervise and regulate the production, storage, sale and use of articles subject to the Commissioner's jurisdiction. I understand the statements made in this application will be accepted, for all purposes, as the equivalent of an Affidavit. Any false statements made herein in addition to being the possible basis for a revocation on any license issued as a result of this application may be punishable under the provisions of Section 210.45 of the Penal Law of the State of New York.		
(9) ORIGINAL SIGNATURE OF OWNER, PARTNER OR CORPORATE OFFICER _____	TITLE _____	DATE _____
AUTHORIZATION AND PURPOSE * Disclosure of your federal social security and federal employer identification numbers is mandatory and is authorized by Section 5 of the New York State Tax Law. This information is collected to enable the Department of Taxation and Finance to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liability and to generally identify persons affected by the Tax Law administered by the Commissioner of Taxation and Finance administering the Tax Law and for any other purpose authorized by the Tax Law. ** The authority to solicit the information requested above is found in Section 16 of the Agriculture and Markets Law in the sections relating to the specific license you are seeking. This information is collected to enable the Department to evaluate your application, to determine if it should be issued and to assist in the enforcement and administration of the Agriculture and Markets Law.		

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**20-C LICENSING
LICENSABLE FOOD PROCESSING ACTIVITIES
SUB-SECTION 4070**

<u>Examples of Activities</u>	<u>Licensable Operation</u>		<u>Process and Commodity Code</u>
	Yes	No	Code
Baking: bread, rolls, pastries, pies, cookies, etc., wholesale or retail in-store bakery operations, including bake-off operations	X		A-05
Blending: spices, herbs, seasonings at retail or wholesale	X		B-24
Retail Repackaging without Blending: spices, herbs, seasonings		X	
Bottling at Retail or Wholesale: fresh fruit juices soft drinks apple cider	X X X		D-27 D-01 D-53
Catering: off-site service of foods prepared at establishment (off –site preparation may require local H.D. Permit)	X		T-45
Cooking or Heat Treatment - Retail or Wholesale: frying or cooking fish cooking lobster, shrimp raw pretzels re-warming pretzels - popcorn retail popcorn popping wholesale popcorn popping chocolate candy molds or forms melting chocolate, hot chocolate unit cooking chicken wings, meat products, hot dogs, meat loaf, sausage eggs	X X X X X X X X X X X		G-21 G-22 G-10 G-10 G-10 G-10 G-13 G-13 G-35 G-20

LICENSING
LICENSABLE FOOD PROCESSING ACTIVITIES
SUB-SECTION 4070

<u>Examples of Activities</u>	<u>Licensable Operation</u>		<u>Process and Commodity Code</u>
	Yes	No	Code
Cooking or Heat Treatment: lasagna, pasta and sauce, complete dinners, pizza, nachos and cheese, soups, meat pies, knishes cappuccino units	X X		G-45 G-03
Curing or Brining: retail ham, corned beef briskets, pigs knuckles, feet, tail wholesale U.S.D.A. processing plant salted fish	X X	 X	H-35 H-21
Cutting, slicing, eviscerating or shucking: cold cuts, ready-to-eat meat cheeses bread, rolls, bagels fish filleting, shellfish shucking, whole fish eviscerating cut fruit or melon cut vegetables into ready-to-eat sizes	X X X X X X		U-35 U-16 U-05 U-21, U-22, U-21 U-27 U-39
Dehydrating: fruit vegetables beef jerky herbs and spices	X X X X		I-30 I-42 I-35 I-24
Freezing: frozen dessert machine, ice cream, yogurt, slush, ice milk shaved ice, serving dish or cone hard ice cream retail ice production and packaging	X 		K-19 K-01
Grinding: poultry or meat at retail grating cheeses retail coffee grinding, wholesale coffee grinding	X X X		L-35 L-16 L-03
Heating or Microwave Self-Service by Customer: dinners, lunches, sandwiches or other pre-packaged foods manufactured by some other establishment		X	

LICENSING
LICENSABLE FOOD PROCESSING ACTIVITIES
SUB-SECTION 4070

<u>Examples of Activities</u>	<u>Licensable Operation</u>		<u>Process and Commodity Code</u>
	Yes	No	Code
Mixing Meat & Grinding with: seasoning, meat loaf mix, meatball mix, pan sausage or patties	X		M-35
Mixing Salad Items: tuna fish, macaroni, potato, coleslaw	X		M-45
fruit salad	X		M-27
vegetable salad mix	X		M-39
Packing/Repacking from Bulk at Retail or Wholesale: exposed candy	X		N-13
cheese curd	X		N-16
salads; tuna, chicken, egg, mixed foods and pasta, etc.	X		N-45
pasta - cooked or dry	X		N-07
dried fruit	X		N-30
dried vegetables	X		N-42
cereals	X		N-08
ready-to-eat sprouts or cut vegetables	X		N-39
acidified foods - vegetables	X		N-43
exposed ready-to-eat foods	X		N- --
Retail Repacking of: stuffing sausage into casings	X		N-35
Repacking from Bulk at Retail into Labeled Self-Service Containers: coffee and tea		X	
whole or ground grains		X	
spices, herbs, sugars, rice		X	
wrapped candy		X	
whole fresh fruits & vegetables		X	
salted codfish		X	
raw fish or seafood		X	
Pickling or Marinating: fish, herrings,	X		O-21
meat, poultry,	X		O-35
vegetables, cabbage,	X		O-43
fruit, olives	X		O-27

LICENSING
LICENSABLE FOOD PROCESSING ACTIVITIES
SUB-SECTION 4070

<u>Examples of Activities</u>	<u>Licensable Operation</u>		<u>Process and Commodity Code</u>
	Yes	No	Code
Roasting: beef and meats coffee nuts barbecue chicken, ribs, beef	X X X X		P-35 P-03 P-36 P-35
Smoking: fish meat and meat products cheeses	X X X		Q-23 Q-35 Q-16
Specific activities that do not require an Article 20-C License: trimming produce, brewing coffee, self-serve bulk food		X	

Article 28
Retail Food Store License

Products	Licensable	
	YES	NO
Fluid milk, Shell eggs, Refrigerated meats	X	
Ice Cream		X
Candy, Soda, Potato Chips		X

Article 28-D
Food Warehouse License

Products	Licensable	
	YES	NO
Soda, Beer**, Water	X	
Condiments	X	
Vitamins, Diet Supplements		X

**LICENSING
LICENSABLE FOOD PROCESSING ACTIVITIES
SUB-SECTION 4070**

****Beer Stores, Beverage Centers, etc. are precluded from selling foods other than snack foods. If the firm has a retail area and warehouse, they must have wholesale accounts with dedicated delivery vehicles (trucks, vans) for the firm to be licensed as an Article 28-D Food Warehouse.**

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**MEAT AND POULTRY
INSPECTION AND LICENSING OF SLAUGHTERHOUSES
SUB-SECTION 4090**

OVERVIEW

One of the more vital aspects of Food Safety and Inspection activities is the regulation of the meat and poultry processing industry. Over the years, meat and poultry products have been implicated in innumerable cases of food borne illnesses, contamination from filth and foreign matter and consumer fraud. It is our continuing responsibility to prevent these abuses from recurring.

Within New York State, there are many establishments that fall under the provisions of Article 5-A of the Agriculture and Markets Law and Part 245 of 1 NYCRR. Sanitary inspections are to be conducted at these establishments in accordance with established guidelines, using the Electronic Sanitary Inspection Report along with other appropriate forms, e.g., ROI's, OCR's, etc.

Article 5-A of the New York State Agriculture and Markets Law requires that no person or firm, unless exempted, shall conduct slaughter operations until they are licensed by this Department.

Establishments exempted from this requirement are:

1. Establishments under the jurisdiction of the Federal Meat and Poultry Act.
2. A bona fide farmer who slaughters his own animals or fowl on his farm for use by himself, members of his family, or non-paying guests and employees.
3. Persons who slaughter not more than 250 turkeys or 1000 chickens and/or other small fowl per year, provided the species are raised by him/her on his/her own farm.
4. Any custom slaughterer of red meat, i.e. cattle, swine, sheep, or goat. (Businesses that operate as custom slaughterers/processors are covered under a USDA exemption, which mandates all meat is marked "Not for Sale." The USDA currently contracts with us to conduct reviews of these facilities.)

License applications must be submitted to the Division no later than May 1 every other year for a two-year license period commencing on the first day of June. A license fee of two hundred dollars (\$200) must be submitted with the application.

Animal species covered by Article 5-A:

For general purposes, animal species are classified as amenable to USDA inspection or non-amenable to USDA inspection.

Article 5-A allows species amenable to the USDA (i.e. chickens, turkeys, ducks, geese, guineas, ratites, or squabs) to be slaughtered/processed provided the business operates within the parameters of an exemption allowed under the Federal Poultry Products Inspection Act (PPIA). (See Federal/State Contract-USDA section for which firm's will also require a USDA Exempt Review.)

**MEAT AND POULTRY
INSPECTION AND LICENSING OF SLAUGHTERHOUSES
SUB-SECTION 4090**

Article 5-A allows species non-amenable to the USDA (i.e. rabbit, pheasant, quail, farm-raised deer/elk, and bison) to slaughtered/processed under the authority of the state. These animals and animal products may be sold at retail or wholesale (intrastate).

Article 5-A **does not** cover the slaughter of any red meat (i.e. cattle, swine, goat, and sheep). Red meat intended for commerce must be slaughtered under USDA inspection. See the Federal/State Contract-USDA section regarding the custom slaughter of red meat.

FACILITY AND PROCESSING REQUIREMENTS

Part 245 of the New York Code of Rules and Regulations requires that Article 5-A slaughterhouses meet certain facility and processing requirements. **Note:** See Circular 925 - Licensing of Slaughterhouses.

Prior to conducting a slaughterhouse inspection you should review and become familiar with the regulations. You should also use the following inspection checklist with scoring aids and legal references as a guide during your inspection.

**MEAT AND POULTRY
INSPECTION AND LICENSING OF SLAUGHTERHOUSES
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**ARTICLE 5-A INSPECTION CHECK LIST
WITH LEGAL REFERENCES, SCORING AIDS AND DEFICIENCY DESCRIPTIONS**

LEGAL REFERENCE	SCORING	LIVE BIRD/ANIMAL HOLDING AREA
245.2 (a) (e) (g) (h) (j)	10-C	1. Floors, walls and ceilings not of suitable construction, clean or well maintained.
245.2 (d) (e)	4-G, 9-D	2. Plumbing not properly sized, installed or maintained.
245.2 (e)	3-D, 4-H	3. Inadequate hot water.
245.2 (a)	10-C	4. Bird and animal holding cages and pens unclean and in disrepair.
Article 5-A , 96-d Article 17, 199-a, 200	2-D, 9-F	5. Dead birds and animals not effectively denatured to prevent their use for human consumption - lack of denaturant.
245.5 (i) (j)	10-D, 16-B	6. Inadequate removal of waste - waste containers unclean, uncovered, in disrepair and not properly labeled.
245.2 (c)	9-E	7. Inadequate lighting or ventilation.

LEGAL REFERENCE	SCORING	SLAUGHTER/PICKING AREA
245.2 (m)	4-E	1. Inadequate separation from live bird/animal holding area and/or eviscerating, cutting or picking area.
245.2 (a) (f) (g) (h)	10-C	2. Floors, walls and ceilings not of suitable construction, in disrepair and/or unclean.
245.2 (d) (e)	4-G, 9-D	3. Plumbing not properly sized, installed or maintained.
245.2 (e) (l)	3-D, 4-H	4. Inadequate hot water.
245.2 (l), 245.3 (c)	3-D, 9-A	5. Inadequate handwashing facilities.
245.4 (a) (b) (c)	4-A, 4-B, 4-E, 15-B, 15-C	6. Equipment not of suitable construction, in disrepair or unclean.
245.5 (a)	4-E	7. Insufficient overflow of scalding tank water.
245.4 (i) (j)	10-D	8. Inadequate removal of feathers and other waste material.

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LEGAL REFERENCE	SCORING	EVisCERATING/CUT-UP AREA
245.2(m)	4-E	1. Inadequate separation from slaughter/picking area and/or live bird area.
245.2 (a) (f) (g) (h)	10-C	2. Floors, walls and ceilings not of suitable construction, in disrepair and/or unclean.
245.2 (d) (e)	4-G, 9-D	3. Plumbing not properly sized, installed or maintained.
245.2 (l), 245.3 (c)	3-D, 9-A	4. Inadequate handwashing facilities.
245.2 (e) (l)	3-D, 4-H	5. Inadequate hot water.
245.4 (a) (b) (c)	4-A, 4-B, 4-E	6. Contact equipment not of suitable construction, in disrepair and unclean.
245.4 (a) (b) (c)	15-B, 15-C	6a. Non-contact equipment not of suitable construction, in disrepair and unclean.
245.5 (a)	5-B	7. Inadequate eviscerating, cut-up washing and or chilling procedures whereby product may become contaminated.
245.4 (i) (j)	10-D	8. Inadequate removal of waste material.

LEGAL REFERENCE	SCORING	GENERAL PREMISES
245.2 (e), 245.5 (e)	1-B, 9-H	1. Water or ice is not potable.
245.6 (a) (b) (c) (d) (e) (f), 245.7	3-A, 3-B, 3-C, 3-D, 11-A, 11-B, 11-C, 11-D	2. Food not protected from contamination by workers.
245.2 (i)	4-F, 14-A, 14-B	3. Insect, rodent or vermin activity likely to result in product contamination.
245.3 (a) (b) (c) (d)	3-D, 9-A, 9-C, 11-D	4. Toilet and locker room facilities improperly installed, equipped or maintained.
245.2 (a), 245.5 (i)	16-B	5. Outside premises improperly maintained.

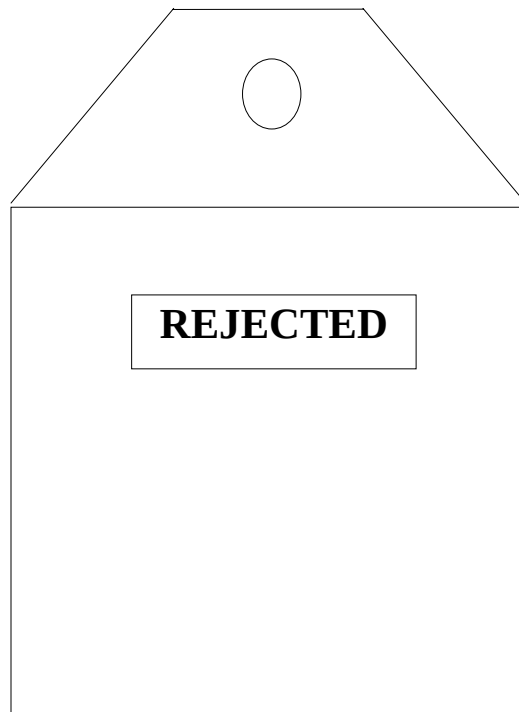
**MEAT AND POULTRY
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Rejecting Improper Facilities and Equipment

Reject tags are authorized for use in establishments licensed pursuant to Article 5-A of the NYS Agriculture and Markets Law. They may be used on rooms, compartments, equipment or utensils found to be improper, unclean or insanitary. When a "Reject" tag is used, it should be securely attached to the rejected item with string, tape, etc. The stub shall be removed and completed by the inspector. Notation of use of a reject tag or tags shall be made on the Sanitary Inspection Report.

In the event the "Reject" tag is removed without authorization or the rejected facility equipment or utensil is used without having the "Reject" tag removed by a Department employee, a report shall be made on a Report of Investigation. Sufficient information should be provided to support penalty action pursuant to Section 245.9 of 1NYCRR.

REJECT TAG



**MEAT AND POULTRY
INSPECTION AND LICENSING OF SLAUGHTERHOUSES
SUB-SECTION 4090**

FSI-1200 (Rev. 8/00) pm4

NYS DEPARTMENT OF AGRICULTURE AND MARKETS DIVISION OF FOOD SAFETY AND INSPECTION 10B AIRLINE DRIVE, ALBANY, NY 12235 POULTRY-SMALL ANIMAL SLAUGHTERHOUSE LICENSE APPLICATION Article 5-A of the Agriculture and Markets Law <i>FOR THE LICENSE PERIOD ENDING MAY 31, _____ FEE \$200.00</i>		OFFICE USE ONLY Est. No.: _____ Receipt No.: _____ Validation No.: _____	
		INSTRUCTIONS Read and Complete BOTH SIDES of this application. Prepare a separate application for each location Send license fee, payable to "Department of Agriculture and Markets," using check or money order. Original signature of an owner or corporate official required in Section 8 on the reverse side of this form.	
(1) Owner Name: (If Partnership, Name All Partners. If a Corporation, Enter Full Name of the Corporation)		County: _____	
Trade Name: _____		Business Tel. No.: _____ ()	
Street: _____	City: _____	State: _____	Zip: _____
Federal * ID No.: _____	Social Security Number(s): _____		
(3) Business Mailing Address if Different From Above:		Attention: _____	
Street: _____	City: _____	State: _____	Zip: _____
(4) IF APPLICANT IS AN INDIVIDUAL OR PARTNERSHIP THE FOLLOWING MUST BE COMPLETED			
Full Name of Owner or Name of Each Partner		Residence - Home Address (street, no., city, state, zip)	
(5) IF APPLICANT IS A CORPORATION THE FOLLOWING MUST BE COMPLETED			
Full Name of Officers		Residence-Home Address (street, no., city, state, zip)	
President			
Vice Pres.			
Secretary			
Treasurer			
Directors (attach list if necessary)			
(5-a) Principal Corporate Office Address? _____			
(5-b) In What State Incorporated? _____ (5-c) Date of Incorporation? _____			
(5-d) Foreign or Out-of-State Corporation: Date of Filing in New York State? _____			
5-e) Name of New York Resident Upon Whom Service of Process May be Made? _____			

-OVER-

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(6) Has the applicant or any partner, officer, director or stockholder been convicted of, or pleaded guilty to, a felony in any court in the United States? Yes ☐ No ☐

If yes, state the full name of the person _____

Name of Court and its location? _____ Date of Conviction? _____

Attach a "Certificate of Conviction" to this application.

If provided on a prior application, under what establishment number? _____

(7) Type of slaughtering to be done: Turkey ☐ Chicken ☐ Duck ☐ Rabbits ☐ Deer ☐

Other (identify) _____

Applicant represents that there are adequate physical facilities and equipment sufficient to maintain adequate sanitation for the activities conducted; that the establishment will be maintained in a clean and sanitary condition and operated in a sanitary and proper manner; and that the maintenance and operation of the establishment will be such that the product produced therein will not be adulterated.

Applicant consents to free entry and will permit free access to the licensed premises, buildings and offices to the Commissioner, the Commissioners agents and inspectors in pursuance of the Commissioners duties to supervise and regulate the production, storage, sale and use of articles subject to the Commissioners jurisdiction.

I understand the statements made in this application will be accepted, for all purposes, as the equivalent of an Affidavit.**

Any false statements made herein, in addition to being the possible basis for a revocation on any license issued as a result of this application may be punishable under the provisions of Section 210.45 of the Penal Law of the State of New York.

(8) ORIGINAL SIGNATURE OF OWNER, PARTNER OR CORPORATE OFFICER

TITLE

DATE

AUTHORIZATION AND PURPOSE

* Disclosure of your federal social security and federal employer identification numbers is mandatory and is authorized by Section 5 of the New York State Tax Law. This information is collected to enable the Department of Taxation and Finance to identify individuals, businesses and others who have been delinquent in filing tax returns or may have understated their tax liability and to generally identify persons affected by the Tax Law administered by the Commissioner of Taxation and Finance administering and Tax Law and for any other purpose authorized by the Tax Law.

** The authority to solicit the information requested above is found in Section 16 of the Agriculture and Markets Law in the sections relating to the specific license you are seeking. This information is collected to enable the Department to evaluate your application, to determine if it should be issued and to assist in the enforcement and administration of the Agriculture and Markets Law.

APPLICANTS MUST PROVIDE ALL REQUESTED INFORMATION

SHOULD YOU FAIL TO DO SO, YOUR APPLICATION MAY NOT BE PROCESSED. IF YOU HAVE QUESTIONS CONCERNING THE INFORMATION REQUESTED, CALL (518) 457-1215 OR WRITE TO THE ADDRESS ON THE FRONT OF THIS FORM

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**MEAT AND POULTRY
TRICHINAE CONTROL FOR READY-TO-EAT PORK PRODUCTS
SUB-SECTION 4095**

OVERVIEW

All forms of fresh pork including fresh unsmoked sausage containing pork muscle tissue and pork such as bacon and jowls are classified as products that are customarily well cooked, in the home or elsewhere, prior to consumption. Therefore, the treatment of such products for the destruction of trichinae is not required.

Products containing pork shall be effectively heated; frozen or cured to destroy any possible live trichinae. This treatment shall consist of one or more of the following:

Heating

All parts of the pork product shall be heated to an internal temperature of 150°F. Time and temperature records shall be maintained for each batch of product and available for review by this Department's representative.

Freezing

All parts of the pork muscle tissue shall be subjected continuously to a temperature not higher than one of those specified in the following table:

REQUIRED PERIOD OF FREEZING AT TEMPERATURE INDICATED		
Temperature °F	Pork Products That Do Not Exceed 6 Inches (Days)	Pork Products Greater Than 6 Inches (Days)
5	20	30
-10	10	20
-20	6	12

During the period of refrigeration the products shall be kept separate from other products and secured in rooms or compartments with a seal. The rooms or compartments containing the pork shall be equipped with accurate recording thermometers.

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Curing Sausage

Sausage may be stuffed in animal casings, hydrocellulose casings or cloth bags. During any stage of treating the sausage for the destruction of live trichinae, except in Method #5, these coverings shall not be coated with paraffin or like substance, or shall any sausage be washed during any prescribed period of drying.

In the preparation of sausage, one of the following methods may be used:

Method #1

1. Grind or chop meat into pieces not exceeding 3/4 inch in diameter.
2. Add dry curing mixture containing not less than 3 1/3 pounds of salt per hundred weight of unstuffed sausage.
3. After stuffing, sausage not exceeding 3 1/2 inches in diameter shall be held in a drying room for not less than 20 days at a temperature not lower than 45°F. In no case shall the sausage be released from the drying room in less than 25 days from the time the curing materials were added to the product.

Exception: - Pepperoni

Sausage of the variety known as pepperoni, with casings not exceeding 1 3/8 inch in diameter, measured at the time of stuffing, may reduce the drying period to 15 days. However, in no case shall the sausage be released from the drying room in less than 20 days from the time the curing materials were added to the product.

Sausages in casing between 3 1/2 and 4 inches in diameter shall be held in a drying room not less than 35 days at a temperature not lower than 45°F and in no case shall the sausage be released from the drying room in less than 40 days from the time the curing materials are added to the product.

Method #2

1. Grind or chop meat into pieces not exceeding 3/4 inch in diameter.
2. Add dry curing mixture containing not less than 3 1/3 pounds of salt per hundred weight of unstuffed sausage.
3. After stuffing, sausage having a diameter not exceeding 3 1/2 inches shall be smoked not less than 40 hours at a temperature not lower than 80°F and finally

MEAT AND POULTRY
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held in a drying room not less than 10 days at a temperature no lower than 45°F. However, in no case shall the sausage be released from the drying room in less than 18 days from the time the curing material was added to the product.

Sausage in casings with a diameter between 3 1/2 and 4 inches shall be held in a drying room following smoking as indicated above, not less than 25 days at a temperature not lower than 45°F. However, in no case shall the sausage be released from the drying room in less than 33 days from the time the curing materials are added to the product.

Method #3

1. Grind or chop meat into pieces not exceeding 3/4 of an inch in diameter.
2. Add dry-curing mixture containing not less than 3 1/3 pounds of salt per hundred weight of unstuffed sausage.
3. After mixture of curing materials and prior to stuffing, the sausage mixture shall be held at a temperature not lower than 34°F for not less than 36 hours.
4. After stuffing, the sausage shall be held at a temperature not lower than 34°F for an additional period of time sufficient to make a total of not less than 144 hours from the time the curing materials are added to the product or the sausage shall be held for the time specified in a pickle-curing medium of not less than 50° strength salometer reading at a temperature not lower than 44°F.

Sausage having a diameter not exceeding 3 1/2 inches shall be smoked for not less than 12 hours. The temperature of the smokehouse during this period at no time shall be lower than 90°F and for 4 consecutive hours of this period the smokehouse shall be maintained at a temperature not lower than 128°F. Sausage in casings between 3 1/2 and 4 inches in diameter shall be smoked, following the prescribed curing, for not less than 15 hours. The temperature of the smokehouse during the 15-hour period shall at no time be lower than 90°F and for 7 consecutive hours of this period the smokehouse shall be maintained at a temperature not lower than 128°F. In regulating the temperature under this method the 128°F temperature shall be attained gradually during a period of not less than 4 hours.

Method #4

1. Grind or chop meat into pieces not exceeding 1/4 inch in diameter.
2. A dry-curing mixture containing not less than 2 1/2 pounds of salt to each hundred weight of sausage. The ground sausage shall be held as a compact mass, not more than 6 inches in depth, at a temperature not lower than 36°F for not less

MEAT AND POULTRY
TRICHINAE CONTROL FOR READY-TO-EAT PORK PRODUCTS
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than 10 days. At the end of the holding period the sausage shall be stuffed into casings

not exceeding 3 1/2 inches in diameter. After stuffing, the sausage shall be held in a drying room at a temperature not lower than 45°F for the remainder of a 35-day period, measured from the time the curing materials are added to the meat. At any time after stuffing, if the establishment operator deems it desirable, the product may be heated in a water bath for a period not to exceed 3 hours at a temperature not lower than 85°F or subject to smoking at a temperature not lower than 80°F or the product may be heated and smoked as specified. The time consumed in heating and smoking shall be in addition to the 35-day holding period.

Method #5

1. The meat shall be ground or chopped into pieces not exceeding 3/4 inch in diameter.
2. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundred weight of product.
3. After stuffing, the sausage shall be held for not less than 65 days at a temperature not lower than 45°F.
4. The coverings for sausage prepared according to this method may be coated at any stage of the preparation before or during the holding period with paraffin or other approved substance.

Method #6

1. The meat shall be ground or chopped into pieces not exceeding 3/4 inch in diameter.
2. A dry-curing mixture containing not less than 3 1/3 pounds of salt shall be added to each hundred weight of unstuffed sausage.
3. After the curing mixture has been added, the sausage shall be held for two time periods, a holding period and a drying period. The holding period will be for a minimum of 48 hours at a room temperature not lower than 35°F.

Note: This holding period and then the remainder, if any, after the drying period or as an extension of the drying period.

During the drying period, the sausage shall be held in a drying room at a temperature not lower than 50°F for a period of time determined in the following tables. The length of the drying period established in Table A may be modified as provided in Tables B and C.

MEAT AND POULTRY
TRICHINAE CONTROL FOR READY-TO-EAT PORK PRODUCTS
SUB-SECTION 4095

TABLE A - SAUSAGE DRYING ROOM TIMES BY METHOD #6

Diameter of Casing at Time of Stuffing	Days in Drying Room
1 inch	14
1 1/2 inches	15
2 inches	16
2 1/2 inches	18
3 inches	20
3 1/2 inches	23
4 inches	25
4 1/2 inches	30
5 inches	35
5 1/2 inches	43
6 inches	50

Reduction in Drying Room Time: During the holding period, the sausage may be smoked or fermented. If the temperature is increased to 70°F or higher while the sausage is being held after adding curing materials but before the drying period, the subsequent drying room times prescribed for this method may be reduced according to the schedule in Table B. No interpolation of values is permissible.

TABLE B - PERCENTAGE REDUCTION IN DRYING ROOM TIME

**(TABLE A) PERMITTED BY HOLDING TIMES AND
TEMPERATURES PRIOR TO DRYING**

Minimum Time	Minimum Temperature									
	70°F	75°F	80°F	85°F	90°F	95°F	100°F	105°F	110°F	120°F
	21.1°C	23.9°C	26.7°C	29.5°C	32.2°C	35.0°C	37.8°C	40.6°C	43.3°C	48.9°C
24 hrs.	4%	5%	8%	10%	15%	23%	37%	57%	90%	100%
48 hrs.	9%	12%	18%	25%	35%	49%	88%	100%	100%	100%
72 hrs.	14%	19%	28%	39%	55%	74%	100%	100%	100%	100%
96 hrs.	19%	26%	38%	53%	75%	98%	100%	100%	100%	100%
120 hrs.	24%	33%	48%	67%	95%	100%	100%	100%	100%	100%

MEAT AND POULTRY
TRICHINAE CONTROL FOR READY-TO-EAT PORK PRODUCTS
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1. In computing the days to be deducted, the number with any fraction shall be rounded to the next lower whole number and shall be deducted from the required total drying time. Example: Sausage stuffed in 3" diameter casing requires 20 days in the drying room (from Drying Room Times, Table A). If allowed to ferment, after addition of curing materials, at 80°F for 48 hours, the 20-day fermenting time may be reduced 18% (from Table B). Eighteen percent of 20 days equals 3.6 days. Twenty days minus 3 days equals 17 days. The total drying time required in the drying room, therefore, will be 17 days.
2. Either room temperature or internal product temperature shall be used for sausages that will be subsequently dried to a moisture-protein ration of 2.3:1 or less. Internal product temperature shall be used for all other sausages.
3. Trichinae will be destroyed during fermentation or smoking at the temperature and length of time indicated. Therefore, no drying room period is required for products so treated.

Reduced Salt Content - Drying Room Times

Salt content of less than 3.33 pounds for each hundred weight of sausage formulation, excluding dry ingredients (such as salts, sugars, and spices) may be permitted provided the drying time is increased according to the schedule contained in Table C.

TRICHINA TREATMENT OF SAUSAGE BY METHOD #6
TABLE C - REDUCED SALT CONTENT - DRYING ROOM TIMES

(Required percentage increase in drying room time (Table A) for added salt of less than 3.3 pounds per hundred weight of sausage).

Minimum Pounds of Salt	Increase in Drying Room Time
3.3	1%
3.2	4%
3.1	7%
3.0	10%
2.9	13%
2.8	16%
2.7	19%
2.6	22%
2.5	25%
2.4	28%
2.3	31%
2.2	34%
2.1	37%
2.0	40%

MEAT AND POULTRY
TRICHINAE CONTROL FOR READY-TO-EAT PORK PRODUCTS
SUB-SECTION 4095

1. Calculate the salt content for column 1 as follows: Multiply the pounds of salt in the sausage formulation by 100. Then divide this number by the total weight of sausage formulation minus the weight of dry ingredients and round down to the next lowest 0.1%. Percents may be substituted for pounds.

Example: 120 lbs. pork, 3.56 lbs. salt, 2 lbs. spices, 0.5 lbs. wine, 1 lb. water and starter culture, 0.8 lbs. sugar, 0.12 lbs. sodium nitrite. Total weight is 127.872 lbs.

$$(3.56 \times 100) / (127.872 - 3.56 - 2 - 8 - 0.12) = 356 / 121.5 = 2.93$$

Therefore, the sausage drying time is increased by 13 percent.

2. In computing the days to be added to the required total drying time, fractions shall be rounded to the next higher whole number and added to the required total drying time.

Example: Sausage stuffed in 3 1/2 inch diameter casing requires 23 days in the drying room (from Drying Room Times). If the quantity of salt added per hundred weight of sausage is 2 pounds instead of 3.33 pounds, the drying room time must be increased by 40% (from Reduced Salt Content - Drying Room Times), or 9.2 days. The 9.2 is rounded up to 10 days and is added to the 23 days to equal 33 days. The total drying time required in the drying room, therefore, will be 33 days.

Method #7 (Dry Sausages)

1. Meat ground or chopped into pieces not exceeding 1/4" in diameter.
2. Not less than 2.7 pounds of salt added to each hundred weight of unstuffed sausage.
3. The establishment shall hold, heat and dry the product according to one of the following procedures:
 - a) **Holding, heating and drying treatment - Large sausages:** Except as permitted in (b) below, the establishment shall subject sausages in casings not exceeding 105 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods:

TREATMENT SCHEDULE FOR SAUSAGES
105 MILLIMETERS (4 1/8 INCHES) OR LESS IN DIAMETER

Minimum Chamber Temperature		Minimum Time (Hours)
(°F)	(°C)	
50	10	12
90	32.2	1
100	37.8	1
110	43.3	1
120	48.9	1
125	51.7	7

MEAT AND POULTRY
TRICHINAE CONTROL FOR READY-TO-EAT PORK PRODUCTS
SUB-SECTION 4095

Following the preceding treatment, the establishment shall dry the sausages at a temperature not lower than 50°F (10°C) for not less than 7 days.

- b) **Heating and drying treatment - Small sausages:** Alternatively, the establishment may subject sausages in casings not exceeding 55 mm in diameter, at the time of stuffing to all of the following minimum chamber temperatures and time periods.

TREATMENT SCHEDULE FOR SAUSAGES
55 MILLIMETERS (2 1/8 INCHES) OR LESS IN DIAMETER

Minimum Chamber Temperature		Minimum Time (Hours)
(°F)	(°C)	
50	10	12
100	37.8	1
125	51.7	6

Following the preceding heat treatment, the establishment shall dry the sausages at a temperature not lower than 50°F (10°C) for not less than 4 days.

Cured and/or smoked hams, shoulders and loins must comply with trichinae control procedures outlined in 9CFR Section 318.10.

Scheduled Process (When other methods are not used)

A scheduled process shall include a description of the processing methods, procedures, and critical controls for each ready-to-eat pork product. It shall be produced by a competent processing authority, and shall include supportive data to demonstrate the effects of this process on total destruction of live trichinae that may be present in the pork.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF DRY FERMENTED SAUSAGE
SUB-SECTION 5000**

DEFINITION

Dry Fermented Sausages are chopped or ground meat products that, as a result of bacterial action, reach a pH of 5.3 or less and are then dried to remove 25 to 50 percent of the moisture to have a moisture/protein ratio in compliance with Meat & Poultry Inspection requirements.

FERMENTATION CRITICAL CONTROL POINTS

pH Control

1. Dry Fermented Sausages shall attain a pH of 5.3 or lower through the action of lactic acid-forming bacteria. The lactic acid-forming bacteria used for fermentation in the chopped or ground meat may be added by:

- A. A commercially prepared culture at levels recommended by the culture manufacturer

Note: In using commercially prepared cultures which require special handling, proper frozen or refrigerated storage as specified by the manufacturer must be observed.

- B. A back inoculum from a previously fermented and controlled mother batch

Note: A product made by back inoculation, where each batch receives a percentage of the formula from a bred and fermented mother batch, the mother batch shall have attained a pH of 5.3 and shall be monitored on a regular basis for lactic acid producing bacteria and coagulase positive Staphylococci.

The same processing guidelines as outlined in these Good Manufacturing Practices should be employed in the manufacture of the back inoculum.

Fermentation can also be initiated by lactic acid bacteria which occur naturally in meat. This practice has been largely replaced by the development of consistently reliable starter cultures or back inoculum, but its limited use continues within certain segments of the industry. Good Manufacturing Practices encourage manufacturers to use controlled procedures in that they minimize risk. The requirements for developing the optimum pH to 5.3 or below during fermentation is needed regardless of the inoculum source. Product which depends upon a natural inoculation should be held below the critical temperature 60°F before and/or after stuffing for a minimum of 48 hours.

Consistent quality of this sausage is also closely associated with the raw materials employed. Routine evaluation of formulated materials and microbiological monitoring of supplies are recommended for all manufacturers.

MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF DRY FERMENTED SAUSAGE
SUB-SECTION 5000

Fermentation is that part of the process in which the pH is reduced in the meat mixture by lactic acid bacteria. Once the pH reached 5.3 or less, the potential for Staphylococcus aureus growth is effectively controlled, thus minimizing the ability for growth to a dangerous level. During fermentation of sausages to a pH of 5.3, it is necessary to limit the time during which the sausage meat is exposed to temperatures exceeding 60°F or higher. A controlled environment of 60°F or less minimizes the opportunity of Staphylococcus aureus reaching levels of public health significance.

TIME-TEMPERATURE CONTROL

Degree/Hours Defined

A process can be judged acceptable as long as the product consistently reaches a pH of 5.3 using:

1. Fewer than 1200 degree/hours when the highest fermentation temperature is less than 90°F.
2. Fewer than 1000 degree/hours when the highest fermentation temperature is between 90° and 100°F.
3. Fewer than 900 degree/hours when the highest fermentation temperature is greater than 100°F.

Note: Degrees are measured as the excess over 60°F (the critical temperature at which staphylococcal growth effectively begins). Degree/Hours are the product of time in hours at a particular temperature and the “degrees”. Degree/Hours are calculated for each temperature used in the process. The limitation of the number of degree/hours indicated in points (1), (2) and (3) depend upon the highest temperature in the fermentation process prior to the time that a pH of 5.3 or less is attained. Processes exceeding 89°F prior to reaching a pH of 5.3 are limited to 1000 degree/hours; processes exceeding 100°F prior to reaching pH 5.3 are limited to 900 degree/hours.

Manufacturers are encouraged to measure temperatures at the surface of the product. Where this is not possible, manufacturers should utilize fermentation room temperatures. The table and examples are predicated on fermentation room temperatures. Temperatures and humidities should be balanced throughout the fermentation room.

MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF DRY FERMENTED SAUSAGE
SUB-SECTION 5000

Constant Temperature Processes

The time-temperature relationships for constant temperature processes are as follows:

Degree/Hours	Temperature Degrees F	Allowed Hours By Guideline
1200	75	80
1200	80	60
1200	85	48
1000	90	33
1000	95	28
1000	100	25
900	105	20
900	110	18

EXAMPLES OF CONSTANT TEMPERATURE PROCESSES

Process A: Constant 80⁰F temperature for 55 hours with a pH decline to 5.3
Degrees: 80 - 60 = 20
Hours: 55
Degree/Hours: (20) x (55) = 1100 degree/hours

Process A **passes** the guideline (Limit: 1200 degree/hours)

Process B: Constant 90⁰F temperature for 40 hours with a pH decline to 5.3
Degrees: 90 - 60 = 30
Hours: 40
Degree/Hours: (30) x (40) = 1200 degree/hours

Process B **fails** the guideline (Limit: 1000 degree/hours)

MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF DRY FERMENTED SAUSAGE
SUB-SECTION 5000

Variable Temperature Processes

In testing each process, each step-up in the progression is analyzed for the number of degree/hours it contributes, with the highest temperature used in the fermentation process determining the degree/hour limitation as follows:

Process C:

Hours	Temperature Degrees F	Critical Temperature Adjustment	Degrees	Degree/Hours
10	75	75 - 60	15	150
10	85	85 - 60	25	250
16	95	95 - 60	35	560

pH = 5.3

Total 960

Process D:

Hours	Temperature Degrees F	Critical Temperature Adjustment	Degrees	Degree/Hours
10	75	75 - 60	15	150
10	85	85 - 60	25	250
18	98	98 - 60	38	684

pH = 5.3

Total 1084

Process D **fails** the guideline because the guideline limit is set at 1000 degree/hours for times and temperatures and it has taken 1084 degree/hours to attain pH 5.3.

PROCESSING SCHEDULE ADJUSTMENT

If a sausage manufacturer's regular or new processing schedule fails to meet the above guidelines, suggestions on potential process improvements may be obtained from consultants from industry, academia or trade associations. These experts can also provide technical assistance in evaluating the accuracy of temperature sensing devices and pH measuring equipment that are critical to evaluating a production process.

LOTS FALLING OUTSIDE GUIDELINE LIMITATIONS

Once a manufacturer has a processing schedule which will meet these guidelines, pH readings from each lot produced must be taken to assure that the product pH continues to develop normally. It is

MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF DRY FERMENTED SAUSAGE
SUB-SECTION 5000

important that all pH readings are recorded before the product surface temperature reached 110 degrees and/or before the degree/hour limitation has been reached.

If the pH has not reached 5.3 by the time the guideline limitations are met, samples should be taken from the fermentation room before the temperature is advanced. It is recommended that one sample be obtained from each mixer/batch of product.

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**MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF SEMI-DRY FERMENTED SAUSAGE
SUB-SECTION 5005**

DEFINITIONS

Semi-Dry Fermented Sausages are chopped or ground meat products that, as a result of bacterial action, reach a pH of 5.3 or less and undergo up to 15 percent removal of moisture during the fermentation/heating process. In general, the semi-dry sausages are not subsequently dried in a dry room but they are packaged soon after the fermentation/heating process is completed. They are generally smoked during the fermentation cycle and have moisture/protein ratios in compliance with Meat & Poultry Inspection requirements.

FERMENTATION CRITICAL CONTROL POINTS

pH Control

Semi-Dry Fermented Sausages shall attain a pH of 5.3 or lower through the action of lactic acid bacteria. The lactic acid bacteria used for fermentation in the chopped or ground meat may be added by:

1. A commercially prepared culture at levels recommended by the culture manufacturer.

Note: In using commercially prepared cultures which require special handling, proper frozen or refrigerated storage as specified by the manufacturer must be observed.

2. A back inoculum from a previously fermented and controlled mother batch.

Note: A product made by back inoculation, where each batch receives a percentage of the formula from a bred and fermented mother batch, the mother batch shall have attained a pH of 5.3 and shall be monitored on a regular basis for lactic acid bacteria and coagulase positive Staphylococci. The same processing guidelines as outlined in these Good Manufacturing Practices should be employed in the manufacture of the back inoculum.

Fermentation can also be initiated by lactic acid bacteria which occur naturally in meat. This practice has been largely replaced by the development of consistently reliable starter cultures or back inoculum, but its limited use continues within certain segments of the industry. Good Manufacturing Practices encourage manufacturers to use controlled procedures in that they minimize risk. The requirements for developing the optimum pH to 5.3 or below during fermentation is needed regardless of the inoculum source. Product which depends upon a natural inoculation should be held below the critical temperature 60°F before and/or after stuffing for a minimum of 48 hours.

MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF SEMI-DRY FERMENTED SAUSAGE
SUB-SECTION 5005

Consistent quality of this sausage is also closely associated with the raw materials employed. Routine evaluation of formulated materials and microbiological monitoring of supplies are recommended for all manufacturers.

Fermentation is that part of the process in which the pH is reduced in the meat mixture by acid producing bacteria. Once the pH reached 5.3 or less, the environment for Staphylococcus aureus growth is effectively controlled, thus minimizing the potential for growth to a dangerous level.

During fermentation of sausages to a pH of 5.3, it is necessary to limit the time during which the sausage meat is exposed to temperatures exceeding 60°F or higher. A controlled environment of 60°F or less minimizes the opportunity of Staphylococcus aureus reaching levels of public health significance.

TIME-TEMPERATURE CONTROL

Degree/Hours Defined

A process can be judged acceptable as long as the product consistently reaches a pH of 5.3 using:

1. Fewer than 1200 degree/hours when the highest fermentation temperature is less than 90°F.
2. Fewer than 1000 degree/hours when the highest fermentation temperature is between 90°F and 100°F.
3. Fewer than 900 degree/hours when the highest fermentation temperature is greater than 100°F.

Note: Degrees are measured as the excess over 60°F (the critical temperature at which staphylococcal growth effectively begins). Degree/Hours are the product of time in hours at a particular temperature and the “degrees”. Degree/Hours are calculated for each temperature used in the process. The limitation of the number of degree/hours indicated in points (1), (2) and (3) depend upon the highest temperature in the fermentation process prior to the time that a pH of 5.3 or less is attained.

Processes exceeding 89°F prior to reaching a pH of 5.3 are limited to 1000 degree/hours; processes exceeding 100°F prior to reaching pH 5.3 are limited to 900 degree/hours.

Manufacturers are encouraged to measure temperatures at the surface of the product. Where this is not possible, manufacturers should utilize fermentation room temperatures. The table and examples are predicated on fermentation room temperatures. Temperatures and humidities should be balanced throughout the fermentation room.

Constant Temperature Processes

MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF SEMI-DRY FERMENTED SAUSAGE
SUB-SECTION 5005

The time-temperature relationships for constant temperature processes are as follows:

Degree/ Hours	Temperature Degrees F	Allowed Hours By Guideline
1200	75	80
1200	80	60
1200	85	48
1000	90	33
1000	95	28
1000	100	25
900	105	20
900	110	18

EXAMPLES OF CONSTANT TEMPERATURE PROCESSES

Process A: Constant 80⁰F temperature for 55 hours with a pH decline to 5.3
Degrees: 80 - 60 = 20
Hours: 55
Degree/Hours: (20) x (55) = 1100 degree/hours

Process A **passes** the guideline (Limit: 1200 degree/hours)

Process B: Constant 90⁰F temperature for 55 hours with a pH decline to 5.3
Degrees: 90 - 60 = 30
Hours: 40
Degree/Hours: (30) x (40) = 1200 degree/hours

Process B **fails** the guideline (Limit: 1000 degree/hours)

Variable Temperature Processes

In testing each process, each step-up in the progression is analyzed for the number of degree/hours it contributes, with the highest temperature used in the fermentation process determining the degree/hour limitation as follows:

Process C:

MEAT AND POULTRY
GUIDELINES FOR THE PRODUCTION OF SEMI-DRY FERMENTED SAUSAGE
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Hours	Temperature Degrees F	Critical Temperature Adjustment	Degrees	Degree/Hours
10	75	75 - 60	15	150
10	85	85 - 60	25	250
16	95	95 - 60	35	560

pH = 5.3

Total 96

Process D:

Hours	Temperature Degrees F	Critical Temperature Adjustment	Degrees	Degree/Hours
10	75	75 - 60	15	150
10	85	85 - 60	25	250
18	98	98 - 60	38	684

pH = 5.3

Total 1084

Process D **fails** the guideline because the guideline limit is set at 1000 degree/hours for times and temperatures and it has taken 1084 degree/hours to attain pH 5.3.

PROCESSING SCHEDULE ADJUSTMENT

If a sausage manufacturer's regular or new processing schedule fails to meet the above guidelines, suggestions on potential process improvements may be obtained from consultants from industry, academia or trade associations. These experts can also provide technical assistance in evaluating the accuracy of temperature sensing devices and pH measuring equipment that are critical to evaluating a production process.

LOTS FALLING OUTSIDE GUIDELINE LIMITATIONS

Once a manufacturer has a processing schedule which will meet these guidelines, pH readings from each lot produced must be taken to assure that the product pH continues to develop normally. It is important that all pH readings are recorded before the product surface temperature reached 110 degrees and/or before the degree/hour limitation has been reached.

MEAT AND POULTRY
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If the pH has not reached 5.3 by the time the guideline limitations are met, samples should be taken from the fermentation room before the temperature is advanced. It is recommended that one sample be obtained from each mixer/batch of product.

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**MEAT AND POULTRY
DISPOSAL AND TRANSPORTATION SERVICES
SUB-SECTION 5010**

Overview

Our authority to license and audit Rendering Plants, Disposal Plants and Transportation Services is covered by Article 5-C of the Agriculture and Markets Law, Sections 96, 320 and 325.

From Section 96x, “The general purpose of this article is to protect the public health, safety and welfare by controlling the use, movement and disposition of dead, dying, disabled, diseased or condemned animals and the meat and meat products derived therefrom.”

Note: This article does not include the transportation and/or disposal of used vegetable oils, provided no meat or meat products have been incorporated into the vegetable oils.

Disposal and Transportation Service Establishment Audits

- These facilities are currently classified as I.P.H. 5 and require 3 audits per year.
- Audits of these facilities may be conducted by any trained inspector from Food Inspection or Farm Products.
- Form, FSI-1006 (11/05) shall be completed for each audit. (Example on Page 3)

Form FSI-1006 (11/05)

This is a one page form that requires the following areas be addressed:

- Informational section – Complete owner’s name, trade name, address, inspection date, license expiration date, person interviewed/title, and time in/out.
- Operation Type – A firm is classified as either a Transportation Service or a Disposal Plant (not both). If the firm is a Disposal Plant a sub-category which best identifies the activities conducted at the plant shall be marked.
- Vehicle Information – List all license plate numbers and make of vehicles used by the firm to transport product.
- Deficiencies – Deficiencies for these facilities are based on required recordkeeping, decharacterization of product and proper labeling. Whenever a deficiency is noted the appropriate box should be marked and the deficiency described in the “Remarks” section. If more space is needed a paper FSI-898 should be used.

**MEAT AND POULTRY
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The inspector(s) conducting the audit will sign the form. A representative of the firm will be informed of the findings. A signature by the representative and leaving a copy with him/her, is not required. If a copy of the audit is requested by the firm, it may be given at the time of the audit, when possible, or mailed to the firm.

**MEAT AND POULTRY
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SUB-SECTION 5010**

FSI-1006 (11/05)

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
10B Airline Dr.
Albany, NY 12235**

EST.
NO.

DISPOSAL AND TRANSPORTATION SERVICE ESTABLISHMENT AUDIT

Owner:		Inspection Date:	
Trade Name:		Article 5-C License Expiration Date:	
Street:	City:	Zip Code:	
Interviewed:	Title:	Time In:	Time Out:

Operation Types

- ☐ Transportation Service
- ☐ Disposal Plant
- ☐ Inedible Rendering Only
- ☐ Inedible Rendering and Processing of Meat Derived from 4-D Animals for Animal Foods
- ☐ Processing Only of Meat Derived from 4-D Animals for Animal Foods

License Numbers/Make of Vehicles used for Transport of 4-D Animals:

_____	_____	_____
_____	_____	_____

Deficiencies

1. Records for the handling of 4-D animals fail to show for each animal:
- ☐ Date of Pick-Up
 - ☐ Species of Animal
 - ☐ Name and Address of person from which Animal(s) was obtained
 - ☐ Amount and Date of payment for Animal
 - ☐ Name of person or firm to whom delivered and Date of Delivery
- 2.
- ☐ Meat Derived from 4-D animals not properly decharacterized
 - ☐ All containers of inedible meat not properly identified

Remarks

Inspector's Signature

ID No.

☐ Continued on FSI 898

- ☐ License Review
- ☐ Compliance Review
- ☐ Files

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**FEDERAL-STATE CONTRACTS
FDA FOOD CONTRACT
SUB-SECTION 5020**

FDA FOOD CONTRACT OBJECTIVES

1. To make inspections at FDA selected establishments in order to ascertain compliance with the Federal Food, Drug, and Cosmetic Act, State law, or both.
2. To collect samples and follow-up samples.
3. Analysis of collected samples using AOAC or FDA methodology.
4. To furnish the FDA with reports of the inspections and sample examinations, as well as reports on compliance actions, such as penalties, seizures, and hearings taken by the State under its own programs.

RESPONSIBILITY

The Division of Food Safety and Inspection has been charged with conducting inspections of food establishments to determine compliance with the food provisions of the Federal Food, Drug, and Cosmetic Act, State law, or both. (**Note:** These inspections are to be made under the authority of New York State Law). Inspectional emphasis is to be placed upon identifying insanitary conditions which have caused foods to become filthy, putrid, decomposed, or contaminated with foreign objects or which present a reasonable possibility of causing the contamination of food. Compliance with the Federal Food, Drug, and Cosmetic Act, and Regulations promulgated thereunder, will be determined by the FDA.

Samples of raw materials, processed foods, etc., necessary to determine compliance are to be collected and analyzed by the State. These samples are to be collected in order to demonstrate, through laboratory analysis, violations of State and/or Federal law. These samples must be of sufficient size, units, etc., necessary for official methodology to be used.

REPORTING

When reporting FDA contract work, the inspector must complete a detailed State inspection report for the establishment. This establishment inspection report, plus form FDA 481 (A) CG (Cover Sheet), are to be submitted to Albany for each firm inspected under the contract.

The inspection reports are to detail conditions found, with sufficient narrative to enable an evaluation of the significance of any insanitary conditions found.

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Reports must be submitted to the Albany Office as soon as possible so that they can be reviewed and recorded. The reports must be forwarded to the FDA District Office, by the Albany Office, as soon as possible, but no later than 15 working days after the date of the inspection.

All samples analyzed are reported by Albany to the FDA on State forms. Worksheets or other detailed information on the analysis are submitted to the FDA for those samples found out of compliance with FDA administrative guidelines, or when a question exists as to whether or not a sample is violative.

Compliance actions, such as penalties, seizures, hearings, etc., are reported to the FDA by means of copies of the documents recording these actions. The reproduction costs of these documents, detailing State initiated warning letters, seizures, court actions, etc., are charged to the contract.

Monthly summaries of all inspections, samples and actions for each industry category, are prepared by the Albany Office and submitted by the 1st of the following month to the designated FDA Office.

AUDITS AND REVIEWS

The overall performance of the State is evaluated by the FDA throughout the contract period. This is accomplished by a variety of techniques, including a review of reports, joint inspections, and audits by the FDA. Sufficient audits are to be made by the FDA to enable an evaluation of the overall performance by State field personnel. The results of all FDA quality assurance reviews are furnished to the State for review and information.

FDA CONTRACT INSPECTION PROCEDURES

It is of utmost importance that all contract inspections be given high priority. It is imperative that all computer generated cover sheets be maintained in good condition. It is very easy for these documents to become torn, wrinkled or smudged.

Computer generated cover sheets, for manufacturing and repacking firms, will consist of a Form FDA 481 (A), cover sheet (EXHIBIT 1), and Form DMD 32, NLEA (EXHIBIT 2).

COMPLETION OF FORM - FDA 481 (A)

The following information is to be verified during the inspection:

Name	ZIP Code
Street	Total Establishment Size
City	Estab-Types/In-Codes on OEI
State	Telephone Number

If changes in any of the above must be made, a **single line** should be made through the incorrect information and the correct information **printed** adjacent to it.

**FEDERAL-STATE CONTRACTS
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The following information is to be completed during the inspection by the inspector:

1. Date Inspected: Place the date inspected here; e.g., 02-01-95.
- 2&3. Establishment Changes: Circle **all** appropriate changes. Enter appropriate changes in section 6 of report.
4. Inspection Basis: Put a 2 for inspection or a 1 for reinspection.
5. Employee 1, 2, or 3: Fill in your employee number next to NO: Fill in the hours spent on the inspection on the first line. **(Hours are to be listed in quarter hours; e.g., 2.25. Listing them any other way is unacceptable).**
6. Lower Blank Section: Enter/describe appropriate changes circled in sections 2 and 3 above.
- 7& 8. Inspector's Name/Signature: Print and sign your name here.
9. FD 483 Issued: If deficiencies were noted, circle "Yes". If no deficiencies were found circle "No".
10. Supervisor's Name/Signature: Compliance Unit Signature. **Do not write in this space.**

The endorsement work sheet is used to write an endorsement and must be filled out completely (EXHIBIT 3).

COMPLETION OF COST SUMMARY SHEET - (FSI-25I) (EXHIBIT 4)

1. Travel by: Place an "X" in the appropriate (). Indicate if a State or private vehicle was used.
2. Put the New York State Agriculture and Markets establishment number here.
3. Print the name and address of the firm here.
4. Put the date of the inspection here; e.g., 02-05-95. **(This is the only acceptable way to write the date).**
5. Hours Traveled: This is travel time only. It is to be written in quarter hours. **The only acceptable way to write it is; e.g., 1.25.**
6. Hours Inspection: This is hours inspecting. This should include sample collection time and time writing reports. **(The only acceptable way to write this is; e.g., 2.75).**

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7. Miles: Indicate the total miles traveled here.
8. Meals: Indicate allowable meal expenses here.
9. Sample Cost: Indicate the total cost of samples taken here.
10. Shipping Charges: Enter any shipping charges here.
11. Photo Charges: Put charges for film, developing, etc., here.
12. Public Transportation: Enter public transportation charges such as bus, subway, etc., here.
13. Tolls: Enter thruway tolls, bridge expenses, etc., here.
14. Other Expenses: Enter any miscellaneous expenses here.
15. Signature & ID No: Sign your name and place your ID number here.

NUTRITION LABELING OF FOOD AND FOOD PRODUCTS

As part of the current contract we are required to review food labels of the inspected establishment to determine if they are in compliance with the Federal labeling requirements. The Nutrition Labeling and Education Act of 1990 (NLEA), mandates specific requirements for the nutrition labeling of food and food products.

During a contract inspection of manufacturers or repackers/relabelers, inspectors are to review all labels being used to determine if they comply with the nutrition labeling regulations. Initially, emphasis should be directed at major violations involving non-exempt products that fail to bear information required by NLEA that was not required previously, products bearing approved claims but fail to qualify for the claims, and products that bear nutrition labeling with major format deviations. Guidance on the major violations is included further on.

The labels shall be submitted with the inspection report on the USFDA-NYSA & M/FSI NLEA LABEL REVIEW (DMD-32) form (EXHIBIT 2). Follow up action, if any, will be coordinated with the appropriate FDA District Office. Four original samples of each violative label are to be submitted.

Specific questions regarding label claims are to be directed to the Economic Unit at 518- 457-1762.

MAJOR NUTRITION LABELING VIOLATIONS

1. Non-exempt products that fail to bear nutrition labeling; e.g., the absence of a "Nutrition Facts" panel on the label when required.

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Exempt products include those meeting the small business provisions, restaurant foods and other foods sold or served for immediate consumption; e.g., school cafeterias, trains, deli's, bakeries, foods that contain insignificant amounts of all nutrients; e.g., coffee, spices, infant formulas, dietary supplements not in conventional food form, medical foods, bulk foods for further manufacturing, etc.

Note: Be aware of the fact that a health claim or nutrient content claim made on an exempt product negates that product's exempt status and the product must then bear complete nutrition labeling.

2. Products bearing health claims or nutrient content claims that have **not** been authorized by FDA such as:

A. Health Claims; e.g.,

1. Fiber and risk of Coronary Heart Disease
2. Omega-3 Fatty Acids and Coronary Heart Disease

B. Nutrient Content Claims; e.g.,

1. Low Sugar
2. Contains Omega-3 Fatty Acids
3. High in Complex Carbohydrates

Unauthorized health claims on food products may be considered violative as a misbranded food and an unapproved drug. Conventional foods in which the labels and/or labeling bear health claims that are authorized by FDA, but the products fail to qualify for the claims or that the claims are inappropriately stated are misbranded foods.

3. Products that fail to bear information required by NLEA that was not required previously such as:

A. Ingredient Declaration on Standardized Foods

B. Percent of Juice

C. Listing of certified colors, by their exact name, in the ingredient statement

4. Products bearing approved claims but that fail to qualify for the claims such as:

A. Health Claims; e.g.,

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1. Claim for fat and cancer but the product is not a “lowfat” food
 2. Claim for calcium and osteoporosis, but the product contains less than 20 percent of the daily value for calcium
- B. Nutrient Content Claims; e.g.,
1. “Fat Free” claim, but, the product does not contain less than 0.5 grams of fat per reference amount
 2. “Reduced Calorie” claim, but, the product is not 25 percent reduced in calories
5. Products that bear nutrition labeling with major format deviations such as:
- A. Nutrition information not set in a box
 - B. Headings and nutrients not separated by bars

This does not imply that we will not take legal action for egregious (excessive, flagrant, glaring) non-NLEA label violations, such as the lack of an ingredient listing or significantly misleading product names.

Examples of egregious violations of non-NLEA requirements include:

1. A lack of mandatory label information
2. Statement of identity
3. Declaration of net quantity of contents
4. Manufacturer’s name and place of business
5. Ingredient statement
6. Significantly misleading statement of identity

NLEA EXEMPTIONS GUIDELINES

A product is exempt from nutrition labeling if:

1. No nutrition information is declared, and
2. No nutrient content claim or health claim is made and,

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3. The manufacturer/packer or distributor meets one or more of the following provisions:

A. Small Business Exemption based on value of gross sales (retailers only); e.g.,

1. The firm whose name appears on the label has an annual gross sales of food to consumers of not more than \$50,000, or
2. The firm whose name appears on the label has total annual gross sales to consumers of not more than \$500,000.

B. Small Business Exemption based on the number of Full Time Equivalent Employees (FTE's) and Units of Sales of Food Product.

For products marketed prior to May 8, 1994:

1. Effective date delayed until May 8, 1995. The firm had fewer than 300 FTE's and less than 600,000 units of the product were sold between May 8, 1993 and May 7, 1994.
2. Effective date delayed from May 8, 1995 until May 8, 1996. The firm had fewer than 300 FTE's and less than 400,000 units of the product were sold between May 8, 1994 and May 7, 1995.
3. Effective date delayed from May 8, 1996 until May 8, 1997. The firm had fewer than 200 FTE's and less than 400,000 units of the product were sold between May 8, 1995 and May 8, 1996.
4. Exemption after May 8, 1997. The firm had fewer than 100 FTE's and less than 100,000 units were sold in previous year.

C. For products initially marketed after May 8, 1994:

The firm had fewer than 100 FTE's and less than 100,000 units are projected for marketing in the first 12 months.

Note: For foreign firms importing food, this exemption is based on the total amount of sales to consumers in the United States.

The following products or product categories are also exempt:

1. Foods served or sold in restaurants
2. Foods served and sold for immediate consumption; e.g., schools, cafeterias, trains, airplanes, and retail stores; e.g., deli's., where there are facilities for immediate consumption (see 21CFR Sec. 101.9 (j) (2) (ii) for complete list)

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3. Foods that are processed and prepared primarily in a retail establishment and not offered for sale outside that establishment; e.g., bakery
4. Foods that are packaged and portioned on consumers' request
5. Foods that contain insignificant amounts of all nutrients required to be listed on nutrient labeling; e.g., coffee and most spices
6. Infant formula subject to the Infant Formula Act
7. Dietary supplements of vitamins and minerals not in conventional food form
8. Medical foods
9. Bulk foods for further manufacturing
10. Raw fruits and vegetables (covered by voluntary program for display at retail level). However, when a claim is made, nutrition information must be displayed by the retailer.
11. Custom processed fish and game meat
12. Packages with available label space of less than 12 square inches (e.g., 5 stick pack of gum), provided that if they are not otherwise exempt, the label must provide a means for consumers to obtain nutrition information (e.g., address, phone number)
13. Food sold from bulk containers, provided that nutrition information is provided at point of sale
14. Shell eggs packed in a carton that has a top lid designed to conform to the shape of the egg are exempt from outer carton label requirements when the required information is presented beneath the carton lid or in an insert.

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FDA FOOD CONTRACT
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EXHIBIT 1

Date of Inspection: _____

1

FEI Number	Firm Name and Address	Phone Number	County Code	JD-TA	Establishment Size
1234567890	Name Address City, NY zip code	(123)456-7890	1	24	3

2

(CIRCLE & LIST CHANGES BELOW)

Establishment changes: NONE NAME ADDRESS SIZE
INDUSTRY CODE ESTABLISHMENT TYPE 0/B
INACTIVE NOT OEI AUX FIRM OTHER

3

Establishment Type / Industry Codes

M
03

PAC	PROCESS (PRODUCT) CODE	EST TYP	INSP BASIS	EMPL1 PC:S NO:717	EMPL2 PC:S NO:	EMPL3 PC:S NO:	PRODUCT DESCRIPTION	PR IT Y	RESC HED DATE	INSP CONC	DIST DCSN
03S001			2	2.25							
03S003				1.00							
03S004			4	5							

6

(SEE ENDORSEMENT WORKSHEET)

FD-483 ISSUED: YES NO

9

INSPECTOR'S NAME/SIGNATURE

SUPERVISOR'S NAME/SIGNATURE:

7 & 8

10

**FEDERAL-STATE CONTRACTS
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EXHIBIT 2

DMD-32 (8/94, PM4)

USFDA - NYSA&M / FSI NLEA LABEL REVIEW

STATE EST. NO:			DATE INSPD:	
CENTRAL FILE NO:	JD / TA:	COUNTY:	PHONE :	
NAME:		STREET:		
CITY:			STATE:	ZIP CODE:
ATTACH SUSPECT LABEL(S) BELOW:	NO. OF LABELS REVIEWED:	NO. OF LABELS COLLECTED:	EMPL. NO:	
COMMENTS:				
INSPECTOR(S):				

**FEDERAL-STATE CONTRACTS
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SUB-SECTION 5020**

EXHIBIT 3

Rev. 5/06

ENDORSEMENT WORKSHEET

Is the firm a registered food facility with FDA ☐ Yes ☐ No
BT registration requirements discussed with firm management ☐ Yes ☐ No
BT registration booklet given to firm management ☐ Yes ☐ No
Firm's Registration number _____

Type of Business: _____

Products Produced/Repacked/Wholesaled and Type Packaging Used (ie. Acidified onions in glass jar):

Ingredients Received From (Include Name, City, State): _____

Related Firms (Include Name, City, State): _____

Geographic Area Served: _____

Types of Customers (Markets, Restaurants, Etc.): _____

Gross Annual Sales: \$ _____ % Sold Outside N.Y.: _____ %

% Sold Wholesale: _____ % Other Gov't. Agencies Inspecting: _____

NLEA Required? (Circle one): Yes No Number of Labels Reviewed: _____

Why is Required or Not Required: _____

List of Corporate Officers: _____

Building Description: Construction Material: Brick _____ Concrete _____ Wood _____ Steel _____

Metal _____ No. of Stories: _____ Square Ft.: _____ Other Occupants: _____

Location (circle): Industrial Park Commercial/Residential Rural Other: _____

Specialized Processing Equipment: _____

Distribution: No. of Vehicles: _____ Type: _____

Common Carrier: _____ UPS: _____ Mail Order: _____ Air Freight: _____ Customer pick-up _____

No. of Employees: Full: _____ Part: _____ Seasonal: _____

Hours of Operation: _____ Days (circle): S M T W T F S Seasonal: _____

.....
Additional Comments:

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EXHIBIT 4

FSI 251 (Rev. 4/95)

NEW YORK STATE
DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY & INSPECTION
ALBANY, NEW YORK 12235

COST SUMMARY: FEDERAL-STATE INSPECTION AND SAMPLING FORM

INSTRUCTIONS:

1. Hours-travel time and inspection time
2. Attach to inspection report-**ONE STAPLE ONLY**
3. Other Expenses: Samples, tolls, per diem, etc.
4. Signature and ID number

TRAVEL BY:

State Car () 1
Personal Car ()

NOTE: Inspection hours consist of actual inspection and/or sample collection time plus writing of reports. **DO NOT INCLUDE TRAVEL TIME.**

② Establishment No. _____	Date: _____ ④
③ Name and Address: _____	Hours(Travel): _____ ⑤
_____	Hours(Inspection): _____ ⑥
_____	Miles _____ ⑦
_____	Meals _____ ⑧
_____	Sample Cost _____ ⑨
	Shipping Charges _____ ⑩
	Photo Supplies _____ ⑪
	Public Transportation _____ ⑫
	Tolls _____ ⑬
	Other Expenses _____ ⑭

⑮

SIGNATURE & ID NO.

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**FEDERAL - STATE CONTRACTS
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MEDICATED FEED INSPECTIONS
(General)

Contract inspections for medicated feed work are to be given inspection priority. Food and Drug Administration Forms, FDA-481 (A), (C), and (E) are to be completed following the COMPLETION OF FORMS instructions in Sub-Section 5020, FDA Food Contract section. In addition, DMD-130, the Medicated Feed Work Sheet, (page 9 in this Sub-Section), is to be used in order that consistency in information reported is attained.

Specific questions regarding Medicated Feed Inspections should be directed to the Director of Field Operations at 518-457-5380 or in his absence the person overseeing FDA Contracts at 518-457-2840.

FDA MEDICATED FEED PROGRAM
(An Overview)

Part I Background

Animal drugs are incorporated into animal feeds to produce medicated animal feeds because feed is the most feasible route of administering animal drugs on a daily basis. Medicated feeds have grown in volume and variety of medication over the past four decades, and today are used in much of animal production. Consequently, most feed production facilities continue to use a wide variety of animal drugs to produce medicated feeds.

The Second Generation Medicated Feeds Regulations, published by the FDA in 1986, set forth revised requirements concerning approval procedures for the manufacture of animal feeds containing new animal drugs. These regulations focus on high-risk drugs, i.e., carcinogens and drugs requiring withdrawal times at their lowest use level. Firms using Category II, Type A medicated articles to make medicated feeds are required by FDA to hold approved Medicated Feed Applications (MFA's). FDA is required to inspect these firms once every two years.

A comprehensive review of the medicated feeds program was undertaken in Fiscal Year 89 (FY 89). The revision and updating of the compliance program is based on that review. The pass/fail determination has been eliminated. The Center for Veterinary Medicine (CVM) will now use the Current Good Manufacturing Practices (CGMP) inspection classification in determining approval decisions for pending MFA's. A classification of Official Action Indicated (OAI) will result in recommendations to refuse approval, while classifications of No Action Indicated (NAI), Voluntary Actions Indicated (VAI-1, VAI-2, and VAI-3) will not.

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Part II - Inspectional

INSPECTIONAL OPERATIONS

1. CGMP Inspections

Manufacturers of medicated animal feeds are expected to comply with the requirements of CGMP regulations to ensure that the animal feeds they manufacture are safe, have the identity and strength, and meet the quality and purity characteristics they purport or are represented to possess. Those firms planning to manufacture medicated feeds which require approved MFA's must comply with the requirements of 21 CFR 225.1 - 225.115 and be registered in accord with 21 CFR 207. FDA determines whether a medicated feed firm is complying with requirements of the CGMP regulations by inspecting the firm's controls, operations and facilities at periodic intervals, depending on the nature of the firm's activities and resources available. Registered firms are to be inspected at least once every two years.

Free-choice administration of animal drugs in feeds involves feeds that are placed in feeding or grazing areas and are not intended to be consumed fully at a single feeding or do not constitute the entire diet of the animal; (e. g., lick tanks, blocks, mineral mixes, etc.). A new animal drug administered to animals, as a component of free choice feeds must be the subject of an approved new animal drug application. Additionally, an approved MFA (512 (m) of the Act) is required for the use of all drugs (Category I and II) in the manufacture of all free-choice medicated feeds.

a. SURVEILLANCE INSPECTIONS

Surveillance inspections are conducted to determine whether a firm is substantially in compliance with CGMP requirements. Overall compliance is determined by review of certain portions of the firm's operations using the form FDA 248l as a guide to CGMP evaluation. **EACH "NO" ANSWER MUST BE FULLY EXPLAINED *** (AND DOCUMENTED, IF POSSIBLE)*** IN THE NARRATIVE SECTION OF THE FORM.**

The key CGMP elements (12) are designated on the form FDA 248l with an asterisk. The asterisked questions on the form FDA 2481 must be addressed and adequately documented in the narrative portion of the form to enable the District reviewer to classify the firm.

A suggested approach is to select at least two drugs and trace these drugs through the system, from receipt of the raw material to shipment of the medicated feed. In addition, ascertain if the establishment can locate and recall its product, and if the establishment can trace its product from the field back through the production system.

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Pre-approval inspections of new applicants submitting MFA's will be requested by CVM. The investigators performing these inspections must determine whether the firm has the knowledge of CGMP requirements, adequate equipment, drug receipt and inventory controls, formula and production instructions/records, and sampling and assay plans to substantially comply with the CGMP requirements.

Surveillance inspections can be converted to comprehensive inspections when significant objectionable deviations from CGMP requirements are encountered.

b. Comprehensive Inspections

Comprehensive inspections are conducted to evaluate, in depth, a firm's compliance with all the provisions of the CGMP regulations and to document the inspectional observations to support possible enforcement action.

Comprehensive follow-up CGMP inspections are to be conducted at firms where previous CGMP inspections have been classified by the District Office as OAI.

c. Guidance

Some background information and interpretation of CGMP regulations for the asterisked questions in the form FDA 2481 are listed below. Numbers in parenthesis refer to sections of Title 21, CFR.

Subpart B - Construction and Maintenance of Facilities and Equipment

Buildings (225.20) - Facilities used for the storage and mixing operations for medicated feeds shall be maintained in a reasonably clean and orderly manner. Accumulated dust or residues will be considered objectionable when there is a likelihood that the material could contribute to significant contamination of animal feeds.

Equipment (225.30) - All equipment used in the manufacture of medicated feed shall be suitable for its intended use and shall have the capability to produce a homogeneous medicated feed of the intended potency. The capability of the mixing equipment should be demonstrated upon installation and periodically as needed to ensure proper adjustments during operation.

Scales and metering devices shall be of suitable size and accuracy to make accurate measurements of the critical feed components. Test the accuracy of the drug ingredient scales, when feasible, with a known calibrated weight, at the firm's normal use level, to respond to the asterisked questions V. 7b. Inaccurate measuring devices can significantly affect the potency of the finished medicated feed. Some firms may use pre-weighed packages of drug ingredients. If only pre-weighed packages are used, then the questions concerning scales on the form FDA 2481 are not applicable (N/A) and

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should be so marked. However, determine and report what controls the firm has to assure that the proper number of packages is used in a specific lot of medicated feed. (Question X1.2.)

Use of the work/storage areas and equipment for other purposes (225.35)

Determine if Type A articles and medicated feeds are stored and handled in a manner to prevent mix-ups and contamination in the case of leakage or breakage. When other products such as pesticides and industrial chemicals are stored and/or handled in the same general facility, determine if the physical separation is adequate to avoid mix-up and contamination problems. (Asterisked question VI.2.)

Subpart C - Product Quality Control

Drug Components (225.42) - A firm is required to inspect and record the inspection of all incoming shipments of drug components for medicated feeds to assure that packages are intact and properly identified, and that the drug contents are not damaged. Unacceptable containers are to be returned to the shipper and a record of such transaction is to be maintained in the firm's receipt record files.

Type A medicated articles shall be stored and handled in a manner to prevent mix-ups and contamination, which may adversely affect finished animal feeds. The asterisked question, VII. 1., deals with how drugs are handled by a medicated feed firm. Failure to adequately identify, store, handle and control drug components could cause serious defects in finished animal feeds, and could adversely affect animals and humans consuming the edible products thereof.

A record of each lot of drug component received shall be established and maintained so that adequate investigations of product defects can be accomplished and adequately resolved.

A firm must establish and maintain a daily inventory record for each drug used. This record is required to show when and which drug lot was used in specific batches or production runs of medicated feed, how much was used, and how much remains in inventory after each daily use to cross check drug usage with production records. The inventory records are intended to serve a useful quality control function; to detect errors in drug usage. The term "daily" means each 24-hour period a drug source component is used. The inventory record may be several records that interrelate to provide the needed information. An individual at the manufacturing site should be able to demonstrate how the system works. The asterisked questions VII.3. a, b and c and VII.4. a, b and c deal with daily drug inventory procedures. These are critically important elements.

Laboratory control (225.58) - The firm's assay procedures and sampling schedules shall conform to commitments on the FDA 1900 and 225.58 (b) (1), which is at least three samples per approved FDA 1900 per calendar year. Assays conducted by State laboratories may be included when considering whether the requirement for three assays is being met. The requirement to assay the first medi-

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cated feed batch using the drug means the first batch of that medicated feed ever produced by the firm. This is to provide timely evidence of the firm's capability to manufacture that particular medicated feed. Asterisked question VIII. 1. on form FDA 2481 deals with the firm's adherence to assay requirements as to the number of samples collected and examined.

Because assays are after the fact in nature, they provide a measure of performance of the manufacturing process, but they are not suitable as a process control. The daily drug inventory procedure and yield is considered a far more effective control than assays. Nevertheless, when the results of sample analysis reveal that a drug level in a batch of medicated feed is out-of-limits, adequate investigation and corrective action shall be undertaken by the firm to comply with 225.58 (d) and (e). Asterisked question VIII.2. deals with these requirements. Out-of-limits assay results may indicate a serious problem.

Note that some assay results showing drug levels out-of-limits may be due to problematic methodology. Microbiological methods have presented many problems, especially methods for neomycin, penicillin, chlortetracycline, oxytetracycline, the bacitracins, lasalocid and monensin.

In all cases where assay results show drug levels out-of-limits, the firm shall conduct an investigation. An adequate investigation and corrective action includes:

- recheck of the critical manufacturing steps to determine whether the proper amount and kind of drug was used;
- ascertain whether all manufacturing steps were completed;
- examination of the daily drug inventory record;
- check of yields of preceding, target, and subsequent batches;
- quarantine of available stocks of out-of-limits feed.

With respect to a medicated feed containing a combination of drugs provided by a single Type A medicated article and an out-of-limits drug level involving problematic methodology, the firm may at its discretion assay the retained portion of the sample for both that drug and the second drug having a definitive assay method. Where a medicated feed with a drug level reported out-of-limits involving a problematic method cannot be confirmed by other methodology on the second assay, greater reliance may be placed upon the results of the records investigation. Confirmed out-of-limits results are to be taken seriously and under usual circumstances indicate that the batches or production runs are to be removed from the market.

The firm must have a written record of the complete investigation and all analytical results, the conclusion reached, and the action taken. Review the record to determine if the samples were analyzed as required, whether the investigation was complete, if any remaining feed from the batch was held pending completion of the investigation, and whether the conclusion and action appears appropriate. Under the MFA commitments and 21 CFR 510.301 (a) (2), a firm is required to report to CVM any confirmed assay results showing drug levels out-of-limits in feeds which have been distributed.

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Equipment Clean-out Procedures (225.65) - The firm must have written procedures to prevent unsafe carry-over of drugs into subsequent production of animal feeds. These procedures may include flushing, physical clean-out, sequencing or any other procedure which has been shown to prevent carry-over of unsafe drug residues into animal feeds. These procedures should be based upon adequate documentation that unsafe contamination will not occur from batch to batch of animal feed. It is the manufacturer's responsibility to prove that its procedures and practices are effective to prevent unsafe contamination. Determine whether the firm's standard operating procedures appear adequate to prevent unsafe carry-over of drug residues into other feeds and whether the firm follows the written procedures. Asterisked question V. 5 . on form FDA 2481 deals with whether the firm's clean-out procedures appear adequate to prevent unsafe contamination of feeds.

If the firm uses a flushing procedure to prevent unsafe carry-over, determine and report how the firm has established the kind and quantity of flush material to be used, and how the flush materials are used, recovered, stored, and identified for subsequent use. If there is potential that use of flush materials may result in unsafe contamination of feeds, include the observation on the FDA 483.

Physical clean out of medicated feed mixing and handling equipment may include vacuuming or sweeping. The regulation also provides for washing however, this procedure raises environmental safety questions and normally should not be utilized. The specific procedure used by a firm should be determined by the firm to be effective to prevent unsafe contamination of animal feeds.

Sequencing allows the predetermined disposition of residual drug carry-over. As discussed in Chapter 6, Section 680.600 of the Compliance Policy Guide, sequencing must be based upon a valid rationale to prevent unsafe contamination in subsequently produced animal feeds. For instance, a sequencing procedure that allows for mixing a swine finishing feed after a medicated feed containing sulfamethazine is not acceptable since it has been shown that a very low concentration of sulfamethazine consumed up to slaughter can result in illegal residues in edible tissues. It is also unacceptable to mix a horse feed subsequent to mixing a monensin or lasalocid containing feed due to severe or fatal effects of these drugs in horses.

Determine and report whether all written flushing, clean-out, and/or sequencing procedures are routinely followed.

Packaging and Labeling

Labeling (225.80) (including placards and invoices when used in lieu of bag labels) must contain adequate directions and warnings for the safe and effective use of medicated feeds. Check labeling for proper withdrawal times (verify using label of approved MFA). Determine whether mixer-feeders are knowledgeable of and following proper withdrawal times. The asterisked question IX. 4. a, b and c deals with the firm's labeling practices.

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Recording and Reports

Master record file and production records (225.102) - Master Record files shall contain, among other things, the name of the medicated feed, an accurate formula (which agrees with the approved FDA 1900), a copy or description of approved labeling, and manufacturing instruction. Asterisked question X.2. a, b, c, d, e, and f deals with the firm's master file records. Failure to comply with the minimum master file requirements could result in production of medicated feeds, which do not meet specifications.

Some firms develop/amend their feed formulas at one location and transmit them via computerized systems to a number of feed manufacturing facilities. Most of the time, it has been difficult for the investigator to verify that each master file record has been checked, dated, and signed or initialed by a qualified person. When this scenario is encountered, mark item X. 3. "No", indicating why in the comments section. Although this is a non-asterisked item, the information should be provided in the EIR for possible inspection of the site that develops/amends the formulas.

Production records for each medicated feed shall include information to accurately reflect:

- the date of production;
- quantity and name of drug components used;
- theoretical and actual quantity of medicated feed produced;
- evidence that a responsible individual has reviewed the records to determine whether all production steps have been performed.

The records must provide enough information to identify the lot or lots of drug components used in the medicated feed so that adequate trace back or recalls can be performed if problems develop and to cross-check the accuracy of drug inventory usage records.

Review a representative number of production records for correct drug levels, agreement with the master formula and completion of all production steps. Asterisked question XI.2. a, b, c, d, e, and f deals with production records.

Custom formula medicated feeds made to the specifications of the customer must conform to approved drug levels, labeling, and indications. Master Record File information and production record information may be combined on the customer's purchase order and the manufacturer's invoice, however, complete required information must be included to comply with 225.102 (b) (3).

Distribution records (225.110) - Distribution records must contain enough information to enable the manufacturer to trace specific batches of medicated feeds should there be reason for such efforts; e.g. complaints, recalls, etc. Asterisked question XIII.1. deals with the adequacy of distribution records.

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Complaint file (225.115) - A medicated feed firm must maintain a complaint file at the plant. Determine whether the firm is aware of its commitment in the approved MFA's for timely filing of experience reports to CVM concerning medicated feeds which are the subject of the approved MFA's and whether necessary reports have been submitted. Note that the firms are obligated to report to CVM whenever a distributed lot of medicated feed fails to meet the specifications provided in the approved MFA.

2. NON - CGMP INSPECTIONS

If a feed mill has a Type A medicated article requiring an approved MFA in its inventory and the mill does not have an approved MFA, the receipt of the drug, the mixing of the drug into medicated feed, and the distribution of the medicated feed are violations that warrant regulatory action. The manufacturer of the unapproved medicated feed causes the feed to be adulterated. The shipper of the drug causes the drug to be adulterated if the receiver and user do not have the required approved MFA for such use.

After authorization from your supervisor, perform a follow-up investigation at the shipper of the Type A medicated article. Complete documentation of the responsibility and the violation may support regulatory action against both the consignee/user and the shipper/distributor. Document (e.g., affidavits, freight bills, receiving tickets) shipments of Type A medicated articles requiring approved MFA's from the distributor to unauthorized consignees, including the consignee/user mill just inspected.

Fully document the mixing and distribution of unapproved drugs or the manufacture and distribution of medicated feeds containing unapproved combinations of new animal drugs. The Agency's extra-label use policy does not apply to the manufacture of medicated feeds.

Investigators should also look for other non-CGMP violations such as the use of drugs for medicated feeds from unapproved sources, the use of soluble powders intended for use in drinking water and bulk drug substances, and the illegal sale or distribution of veterinary RX drugs.

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**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Federal/State Contract**

MEDICATED FEED WORK SHEET

DMD-130 (rev. 11/95) msw

Type of feed manufactured: _____

Annual Production: Total (in tons): _____ Medicated (in
tons): _____

Drugs used: _____

Total Annual Sales: _____

Number of Category II drugs: _____ Number of Category I drugs: _____

Ingredients received from: _____

Ingredients received by: _____

Where are feeds sold: _____

Vehicles used for delivery and number: _____

Mill Description: Construction Material: _____

Number of Stories: _____ Square Footage: _____ Cubic Capacity: _____

Number of Silos: _____ Production Equipment: _____

Number of Employees: Full: _____ Part: _____ Operating Hours: _____

Days of Operation: _____ Corporate Structure: _____

Related Firms: _____

% Sold out of State: _____ Other Gov't. Agencies Inspecting: _____

NOTES

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Division of Food Safety and Inspection
Field Operations Manual**

**FEDERAL-STATE CONTRACTS
USDA EXEMPT REVIEW INSPECTIONS
SUB-SECTION 5030**

OVERVIEW

New York, California and Colorado are the only three States that perform Exempt Establishment Reviews for the USDA/FSIS, under cooperative agreement.

Reviews are conducted at establishments exempt from routine USDA inspections as per Section 23 of the Federal Meat Inspection Act (FMIA) or Section 15 of the Poultry Products Inspection Act (PPIA).

Reviews are conducted to determine if operations exempt from inspection requirements comply with the applicable adulteration and misbranding provisions of the FMIA and PPIA and sanitation requirements in the Meat and Poultry Inspection (MPI) regulations.

Regulatory enforcement actions, (i.e. warning letters or revocation of exempt status) are the responsibility of the USDA. This is most commonly handled through joint inspections after critical deficiencies are noted on a repeat basis.

PROCESS FOR CONDUCTING USDA EXEMPT REVIEWS

Reviews are to be conducted according to the risk assigned to each firm which is based on the previous review. Instructions along with a copy of the previous Exempt Review Report are sent by memorandum from the Albany Office. Should a critical deficiency be cited, the completed Exempt Review Report is to be faxed to the names and numbers listed on the memorandum. 5 day follow-up reports also need to be faxed in. (See Example #1).

The Exempt Establishment Review Report shall be completed at the time of the review and according to the instructions provided: (See Example #2, 3, 4 & 5).

1. Region/Area/Circuit Code – should list the county the firm resides in, i.e., Kings, Yates
2. Date of Review
3. Establishment Name
4. Location

The Exempt Establishment Review Report divides the review findings in the categories listed below. General overviews of each category are provided:

- A. Sanitation and Facilities – Sanitation procedures and maintenance of the facilities during slaughtering and processing must be accomplished in a manner to ensure the production of wholesome, unadulterated product. Product must be handled and processed without becoming adulterated.

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B. Pest Control – The establishment’s pest control operation must be capable of preventing product adulteration. Establishment management must make every effort to prevent entry of rodents, insects, or animals into areas where products are handled, processed or stored. Openings (doors and windows) leading to outside or to inedible areas must have effective closures. Areas inside and outside the establishment must be maintained to prevent harborage of rodents and insects.

*The absence of a professional pest control company is not in itself a deficiency.

C. Inedible Materials – The inedible material control program must prevent the diversion of inedible animal products into human food channels.

D. Marking and Labeling

1. All red meat products must be legibly marked “NOT FOR SALE”. Each carcass or quarter, if appropriate, must be marked with an ink brand before leaving the kill floor. Livers, hearts and tongues must also be legibly marked “NOT FOR SALE” before leaving the kill floor. Recordkeeping also falls under this category. Red meat custom slaughter records require the name, address and telephone number of the owner of each of the animals slaughtered. The date the animal was slaughtered and species shall also be recorded.

2. Poultry labeling requirements differ depending on the exemption being used.

a) Personal Use, Custom, Producer/Grower 1,000 bird limit, Producer/Grower 20,000 bird limit require that the shipping container bears:

- i. The producer’s name
- ii. The producer’s address,
- iii. The statement ‘Exempt P.L., 90-492’

b) The Small Enterprise and Retail Store Exemptions require all the features of a label for inspected product with the exception that the labeling does not indicate that the product was inspected and passed. Label requirements for this exempt uninspected product include the following:

- Name of the product;
- Ingredient statement;
- Statement of the quantity of the contents in terms of weight or measure;
- Name and address of manufacturer;
- Handling statement;
- State handling instructions that comply with the requirements of Title 9 CFR 381.125(b)(2)(ii);
- Date of packing

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- E. Raw Pork Control – Meat food products containing raw pork, including poultry product that may contain pork, must be treated to destroy trichinae (excluding fresh pork products as defined by Section 381.10 of the regulations) and are subject to the control of restricted ingredients.
- F. Water Supply – Potable water must be used in areas where animals are slaughtered, eviscerated, and dressed and where edible products are processed, handled and stored. The distribution system within the establishment must preclude contamination of the water supply. Firms utilizing well water are required to test the water for potability every 6 months. Firms with municipal water are no longer required to obtain a yearly letter of water potability from their municipality; however, a one-time letter should be on file at the firm.
- G. Sewage and Waste Disposal – Sewage and waste disposal must properly remove sewage and waste materials – manure, feces, feathers, paunch, trash, garbage, and paper – from the establishment. Systems must be approved by local or State authorities.

Note: An establishment representative should sign the bottom of the report.

USDA EXEMPT ESTABLISHMENT PICK LIST

Attached is a USDA Exempt Establishment Pick List. The goal of this pick list is to increase uniformity on how the most common deficiencies are scored.

A. Sanitation and Facilities

- **Product Contact Surfaces** (process equipment, utensils, hooks, etc.)

***Critical**

1. Dried dark brown organic residues, scraps on product contact surfaces.
2. Dirt, (rust-flaking foreign substances), heavily scored and unclean.
3. Pest: rodent, insect on product contact surfaces (includes hoist rails)
4. Utensils on floor being used.
5. Cross contamination of meat and poultry on unsanitized equipment.
6. Non-food grade materials (cutting boards, etc.) IN USE.
7. Rusty, flaking overhead rails.

***Major**

- Equipment Disrepair
 1. Chipped/Bent blades
 2. Minor rust buildup on product contact equipment
 3. Rust/residues on utensils NOT IN USE< utensils on floor not in use
 4. Spotted rusting on overhead rails

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***Minor**

1. Light to moderate build-up of dirt and/or staining on floor, walls and ceiling

- **Process Rooms**

***Critical**

1. No handwash sink available in facility process rooms (see below for major)
2. Sewage backup in process rooms
3. No hot water at handwash (below 90⁰F)
4. No hot water for clean/sanitize (150⁰F w/sanitizer) or 180⁰F

***Major**

1. No handwash sink/hot or cold water in one of the process rooms
2. Improper sloped floor to drain
3. Peeling paint walls/ceiling (if excessive and over product contact surfaces it may be critical)
4. Hose-connected lines lacking backflow prevention device
5. Doors to process rooms open (if open doors contribute to a critical problem [i.e., flies, filth] entering process rooms, score open doors as critical noting contributing condition)
6. Inadequate/no ventilation
7. Dried product residues, dirt, etc., on process room walls

***Minor**

1. Slow drainage, missing drain cover
2. No coving
3. Dust laden vents, cabinets, etc.; doors/plastic strips unclean/discolored

B. Pest Control

***Critical**

1. Several (6-10) live flies noted in process room are observed landing on product contact surfaces.
2. Live flies observed landing on product – exposed flesh portion (retain)
3. Rodent droppings in/on (location) in process room(s)
4. Live cockroaches in/on (location) in process room(s)
5. Live birds in process room(s). (*Red meat/poultry not birds for slaughter not in dressing room)
6. Pesticide on product contact surfaces

***Major**

1. Rodent droppings in live animal area or non-food storage areas
2. Pesticide exposed on floor in process rooms
3. Littered pest strips in process rooms

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C. Inedible Material

***Critical**

1. Consumer intended product observed stored in a bucket marked INEDIBLE

***Major**

1. Firm fails to properly denature product placed in waste dumpster
2. Edible/Inedible buckets not properly labeled/designated
3. Inedible material not removed from firm at sufficient intervals

***Minor**

1. Inedible buckets not covered/have soiled exteriors

D. Marking and Labeling Control

***Critical**

1. Product (flesh) stamped with non-food grade ink not for sale

***Major**

1. Firm fails to mark processed product as, "Not for Sale"
2. Cubed and packaged (bagged) product lacking stamp on bag/label
3. Firm lacks stamp and/or ink (formal grade) on premises

***Minor**

1. Lack of customer records/inadequate recordkeeping
(Customer information not complete)

E. Water Supply

***Critical**

1. Firm's water source tested positive for E. coli
2. Firm's water source has two consecutive samples that are positive for coliform

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***Major**

1. Firm's most recent sample tested positive for coliform

***Minor**

1. Firm lacks potability certificate/letter of municipality
2. Firm lacks up-to-date certificate/letter of municipality

F. Sewage and Waste Disposal

***Critical**

1. Excessive buildup of waste material not picked up at sufficient intervals – improperly stored in firm (Process rooms/unrefrigerated)

***Minor**

1. Waste/dumpsters stored outside of firm

Product (under sanitation)

***Critical** – Product adulterated by means of:

1. Fecal material – improper slaughter/cross contamination (hide hair)
2. Unclean equipment, foreign matter (filth, paint, pesticide, etc.)
3. Rodent, insect, bird contamination
4. Evidence of temperature abuse
5. Offering carcass PARTS for sale (heads, meat, entrails, etc.)
6. Unapproved source (Animal Industry)

Workers (under sanitation)

***Critical**

1. Ill workers (flu, diarrhea, etc.), cuts, sores on hands, etc.

***Major**

1. Workers eating/smoking in exposed food areas
2. Worker processing meat with unclean apron (not changing aprons between processes)

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***Minor**

1. Workers not wearing effective hair restraint

A Cost Summary sheet shall be filled out for each review conducted. If more than one Inspector conducts the review, than one Cost Summary per Inspector shall be completed. See Example #6

All new businesses or businesses that have made pertinent information changes require a USDA Custom Exempt Establishment Information sheet be completed. See Example #7

Examples #8, 9 and 10 are excerpts from the USDA/FSIS Guidance for determining whether a Poultry Slaughter or Processing Operation is exempt from inspection requirements of the PPIA. To review the entire document visit:

http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/Poultry_Slaughter_Exemption_0406.pdf

As always quality inspection work is best displayed through quality report writing. Here are some basic reminders:

- Print clearly.
- Critical deficiencies corrected during the inspection are to be recorded on the Review Report.
- Use the FSI-898 whenever you have more than three deficiencies in one category.
- You are not required to state whether each deficiency written is critical, major or minor. Simply make sure that the first deficiency you write in any category is that of the most severe deficiency noted in that category.

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Example #1

**DEPARTMENT OF AGRICULTURE AND MARKETS
Division of Food Safety and Inspection**

Albany Office

M E M O R A N D U M

TO: Chief Food Inspector Bill Kalabanka
FROM: John J. Arnold
DATE: April 6, 2006
SUBJECT: **USDA Custom Follow-up Inspection**
Madison County

Re: Larry & Deborah Processor
ABC Poultry Market
387 Feather Lane
Chickenville, New York 12345

Based upon the conditions noted during the inspection of February 9, 2006, please schedule a follow-up inspection within the next 12 months.

If there are any critical deficiencies noted during the inspection, please check Assigned Risk Category One located at the bottom of Page Two and fax the report within 24 hours to the following:

FAX Number - Herb Vedder, USDA - 518-452-3118

FAX Number - John Arnold, Food Safety & Inspection - 518-485-8986

As a note, follow-up inspections should be conducted within 5 working days. If critical deficiencies are again noted, repeat the process. If no critical deficiencies are noted, score the inspection report Assigned Risk Category Two and fax a copy of the report to the above noted individuals within 24 hours.

Supervising Food Inspector

JJA:kg
Attachments

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Example #2

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE EXEMPT ESTABLISHMENT REVIEW REPORT (for meat and poultry operations)	1. REGION / AREA/ CIRCUIT CODE	2. DATE OF REVIEW (MM/DD/YYYY)
3. ESTABLISHMENT NAME	4. LOCATION (Street Address, City, State, Zip Code)	

INSTRUCTIONS AND DEFINITIONS: See reverse side of this form. Attach a separate sheet, if more space is needed.

A. SANITATION AND FACILITIES: ☐ Acceptable ☐ Unacceptable		DECISION AREAS		
		Certain	Likely	Potential
Classification Guide Analysis	1) Will the "deficiency" result in adulterated or misbranded / mislabeled product?			
	2) Will the adulterated or misbranded / mislabeled product reach consumers?			
	3) Will the product have a detrimental effect upon the consumers?			
Deficiency classification (check one) ☐ Critical ☐ Major ☐ Minor				
DESCRIPTION OF DEFICIENCY				

B. PEST CONTROL: ☐ Acceptable ☐ Unacceptable		DECISION AREAS		
		Certain	Likely	Potential
Classification Guide Analysis	1) Will the "deficiency" result in adulterated or misbranded / mislabeled product?			
	2) Will the adulterated or misbranded / mislabeled product reach consumers?			
	3) Will the product have a detrimental effect upon the consumers?			
Deficiency classification (check one) ☐ Critical ☐ Major ☐ Minor				
DESCRIPTION OF DEFICIENCY				

C. INEDIBLE MATERIAL: ☐ Acceptable ☐ Unacceptable		DECISION AREAS		
		Certain	Likely	Potential
Classification Guide Analysis	1) Will the "deficiency" result in adulterated or misbranded / mislabeled product?			
	2) Will the adulterated or misbranded / mislabeled product reach consumers?			
	3) Will the product have a detrimental effect upon the consumers?			
Deficiency classification (check one) ☐ Critical ☐ Major ☐ Minor				
DESCRIPTION OF DEFICIENCY				

FSIS FORM 5930-1.1 (8/25/2004)

REPLACES FSIS FORM 5930-1.1 (10/91), WHICH MAY BE USED UNTIL EXHAUSTED.

Designed in FormFlow software

☐ DISTRICT OFFICE

☐ OWNER/OPERATOR

☐ REVIEWER

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Example #3

INSTRUCTIONS AND DEFINITIONS: See reverse side of this form. Attach a separate sheet, if more space is needed.			
ESTABLISHMENT NAME		DATE OF REVIEW	
D. MARKING AND LABELING CONTROL: ☐ Acceptable ☐ Unacceptable		DECISION AREAS Certain Likely Potential	
Classification Guide Analysis	1) Will the "deficiency" result in adulterated or misbranded / mislabeled product?		
	2) Will the adulterated or misbranded / mislabeled product reach consumers?		
	3) Will the product have a detrimental effect upon the consumers?		
Deficiency classification (<i>check one</i>) ☐ Critical ☐ Major ☐ Minor			
DESCRIPTION OF DEFICIENCY			
E. RAW PORK CONTROL (not applicable to Poultry Operations): ☐ Acceptable ☐ Unacceptable		DECISION AREAS Certain Likely Potential	
Classification Guide Analysis	1) Will the "deficiency" result in adulterated or misbranded / mislabeled product?		
	2) Will the adulterated or misbranded / mislabeled product reach consumers?		
	3) Will the product have a detrimental effect upon the consumers?		
Deficiency classification (<i>check one</i>) ☐ Critical ☐ Major ☐ Minor			
DESCRIPTION OF DEFICIENCY			
F. WATER SUPPLY: ☐ Acceptable ☐ Unacceptable		Deficiency classification (<i>check one</i>): ☐ Critical ☐ Major ☐ Minor	
DESCRIPTION OF DEFICIENCY			
G. SEWAGE AND WASTE DISPOSAL ☐ Acceptable ☐ Unacceptable		Deficiency classification (<i>check one</i>): ☐ Critical ☐ Major ☐ Minor	
DESCRIPTION OF DEFICIENCY			
ASSIGNED RISK CATEGORY (Refer to FSIS Directive 5930.1, Attachment 1): (<i>Check one</i>) ☐ 1 ☐ 2 ☐ 3 ☐ 4		SIGNATURE OF REVIEWER	
COPY GIVEN TO OWNER/OPERATOR Yes ☐ No ☐		DATE GIVEN	
PREVIOUS RATING (<i>last review</i>)		DATE OF LAST REVIEW	
FSIS FORM 5930-1.2 (6/08/2004) REPLACES FSIS FORM 5930-1.2 (10/91), WHICH MAY BE USED UNTIL EXHAUSTED.			
☐ DISTRICT OFFICE		☐ OWNER/OPERATOR ☐ REVIEWER	

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FSI-898 (REV. 6/93)

DATE:

07/11/2006

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Example #5

REVERSE OF FSIS 5930-1.1 AND 1.2 (10/91)

INSTRUCTIONS FOR COMPLETING:

1. General: Identify each item as either being acceptable or unacceptable. For items identified as unacceptable, complete Classification Analysis and Deficiency Classification Rating, as appropriate.
2. Classification Guide Analysis Section: Answer the three questions by placing a check mark in the appropriate column. CERTAIN means inevitable or seems inevitable; LIKELY means reasonable to assume, but not certain; and POTENTIAL means low probability. DETRIMENTAL means injurious health or significant departure from product owner's and/or consumer expectations.

3. Deficiency Classification Rating:

A. For Items A thru E, mark the appropriate rating based on the following:

<u>Assigned Rating</u>	<u>Description</u>
Critical	All three questions have been answered as CERTAIN
Major	Any one of the questions has been answered as LIKELY, with no question answered as POTENTIAL
Minor	Any one of the questions is answered as POTENTIAL

B. For Items F and G, determine the rating based on the following:

<u>Item</u>	<u>Guideline</u>
Water Supply	CRITICAL--When there is evidence that the owner/operator has never secured a certification from the responsible authority on the analysis of water samples taken from within the facility or there is evidence to judge the water supply (public or well) as being nonpotable or there is a history of potability problems. MAJOR--For public water supply, when the water certificate has been out-of-date for more than six months. For private (well) water supply, when there is evidence that the water has not been sampled for more than three months. MINOR--Same as for the major classification, except the period of time for public water supply is "less" than six months and for private water supply is "less" than three months.
Sewage and Waste	MINOR--Licensed by the State and No permit on file No sewage/drainage problems observed MAJOR--Licensed by the State and No sewage permit on file Sewage/Drainage problems observed in inedible and non-production areas CRITICAL-- Licensed by the State and No sewage permit on file Sewage/Drainage problem observed in production and production related areas including employees welfare rooms, dry storage areas.

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Example #6

COMPLETE THIS FORM FOR EACH INSPECTION

FSI 251 (9/97)

USDA CUSTOM SLAUGHTER
PROCESSING COST SUMMARY

NEW YORK STATE
DEPARTMENT OF AGRICULTURE AND MARKETS
DIVISION OF FOOD SAFETY AND INSPECTION
ALBANY, NEW YORK 12235

Establishment County Code _____

Date: _____

Name and Address:

Hours (Inspection): _____

Hours (Travel): _____

Miles: _____

Meals: _____

Tolls: _____

SIGNATURE

ID NO.

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Example #7

*** PLEASE COMPLETE FOR EACH ESTABLISHMENT ***

USDA CUSTOM EXEMPT ESTABLISHMENT INFORMATION

Date _____

1. REGIONAL OFFICE: _____
2. ESTABLISHMENT NAME AND ADDRESS: _____

3. NAME OF OWNER _____
HOME TELEPHONE NUMBER: (_____) _____
BUSINESS TELEPHONE NUMBER: (_____) _____
4. TYPE OF OPERATION:
SPECIES SLAUGHTERED _____
LIST OPERATIONS _____
5. HOURS OF OPERATION: S M T W TH F S _____ TO _____
SEASONAL OPERATION: NO __ YES__ DATES OF OPERATION _____
6. COMMENTS: _____

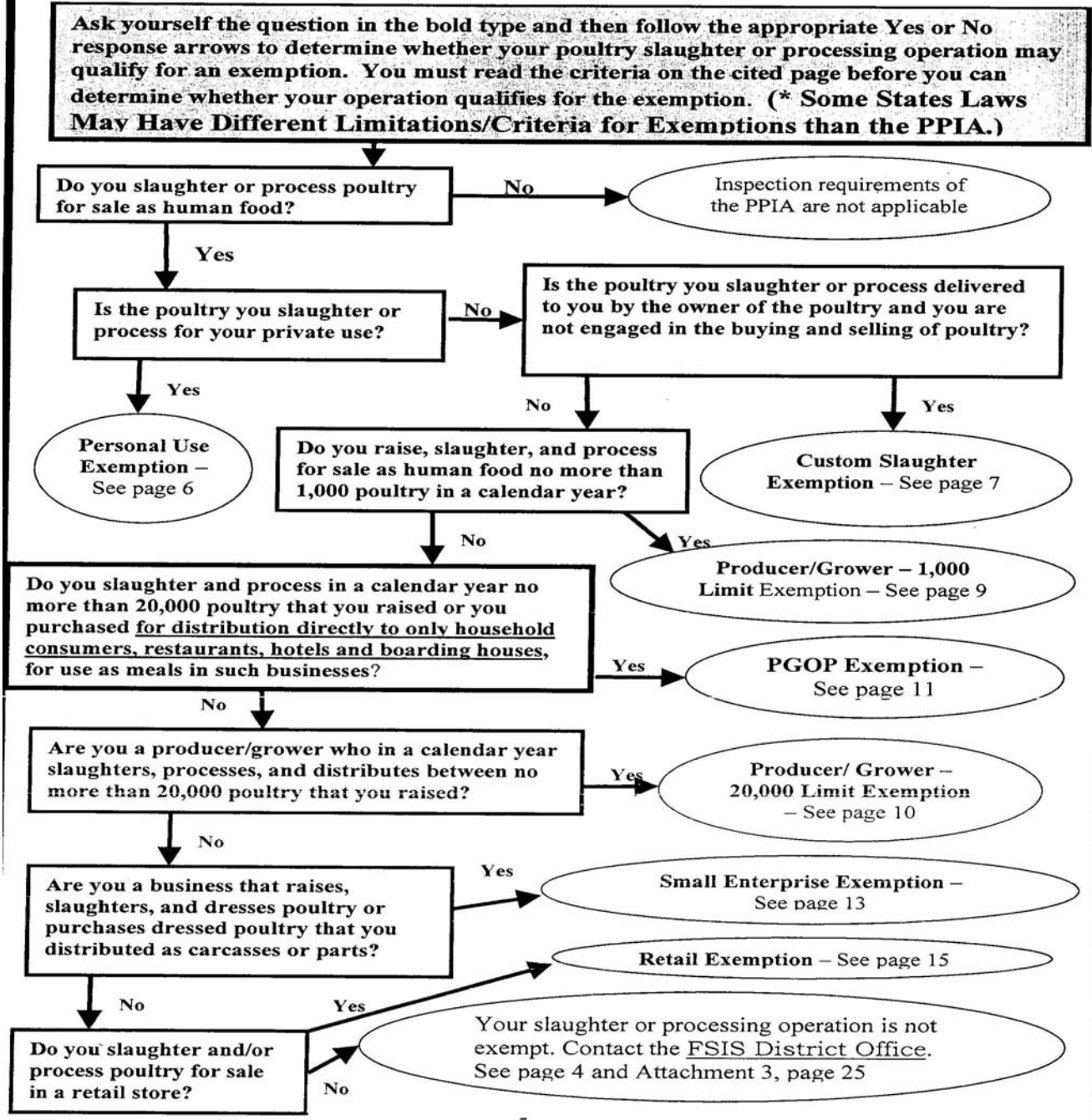
INSPECTOR SIGNATURE

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Example #8

Figure 1 Decision Flow Chart for Poultry Exemptions Under the PPIA *



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Example #9

Attachment 1. A Summary Table of Exemptions and Limitations

Summary Table of Exemptions and Limitations								
Criteria	Personal Use	Custom	Produce Grower – 1,000 Bird Limit	Producer Grower – 20,000 Bird Limit	Producer Grower or Other Person	Small Enterprise 20,000 Bird Limit	Retail Dealer	Retail Store
Slaughter Limit	NONE	NONE	YES 1,000	YES 20,000	YES 20,000	YES 20,000	Yes ZERO	NONE
Processing	YES	YES	YES	YES	YES	CUT UP ONLY	CUT UP ONLY	YES
75 lb. Sale Limit to Consumer	NO SELLING	NO SELLING	NO LIMIT	NO LIMIT	NO LIMIT	NO LIMIT	NO LIMIT	YES
150-lb. Limit to HRI	NO SELLING	NO SELLING	NO LIMIT	NO LIMIT	NO LIMIT	NO LIMIT	NO LIMIT	YES
25% of Total product/75% HRI Sale	NO SELLING	NO SELLING	NO LIMIT	NO LIMIT	NO LIMIT	N/A	YES	YES
Can Sell to any customer	NO	NO	YES	YES	NO	YES	NO	NO
Can Sell to HRI	NO	NO	YES	YES	NOT TO ALL HRIs ¹	YES	YES	YES
Sell to Distributor	NO	NO	YES	YES	YES	YES	NO	NO
Sell to Retail Store	NO	NO	YES	YES	NO	YES	NO	NO
Intra-State Distribution	NO	NO	YES	YES	YES	YES	YES	YES
Inter-State Distribution	NO	NO	NO	NO	NO	NO	YES ²	NO ²

1. Product produced under the Producer/Grower or Other Person Exemption may not be sold to institutions.

2. Only poultry products derived from federally inspected and passed poultry may be transported in interstate commerce.

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Example #10

Attachment 1 B Table of Exemptions and Limitation

EXEMPTION	Customer(s) that the exempted poultry may be sold to.	Limitations: 1. on amount poultry product produced under the exemption 2. 25% or less exempt sales to HRIs 3. calendar year total sales dollar limitation 4. Identification/labeling requirements	Type of operations exempt: 1. Slaughter, 2. Processing, 3. Cut-up only.
Personal Use	Personal Use exempt poultry products may not be sold or donated for use as human food to any customer or consumer. The poultry is for the exclusive private use of the owner.	1 – No limit 2 & 3 – No sales of poultry permitted 4 – The statement "Exempt P.L. 90-492" and producer's name and address on shipping contains	1. Slaughter 2. Processing.
Custom Slaughter/ Processing	Custom Slaughtered exempt poultry products may not be sold or donated for use as human food. A custom slaughter may not engage in the business of buying or selling poultry used for human food	1 – No limit 2 & 3 – No sales permitted 4 – The statement "Exempt P.L. 90-492" and the producer's name and address on shipping containers.	1. Slaughter, 2. Processing other person's poultry.
Producer Grower 1,000 bird limit	Limited Provision of the Act apply May sell to any person, must keep records -of sales (Title 9 CFR 381.175)	1 – Yes, no more than 1,000 poultry in calendar year. Of their own raising on their own farm	1. Slaughter 2. Processing of poultry grower's raised poultry for sale to customers.
Producer Grower 20,000 bird limit	Slaughters & processes on his/her premises poultry for distribution by him/her to any person The product may only be distributed in the State, territory, or DC where it was prepared	1 – Yes, may slaughter and process no more than 20,000 poultry in calendar year of their raising on their own premises. 2 – 25% HRI limitation does not apply 3 – Dollar limitation not applicable. 4 – The statement "Exempt P.L. 90-492" and producer's name and address on product when it is distributed.	1. Slaughter & 2. Processing of poultry grower's raised poultry.
Producer Grower or Other Person (PGOP)	Slaughters & processes poultry for distribution to only household consumers, restaurants, hotels, or boarding houses. The exempt product may only be distributed in the State, territory, or District of Columbia where it is prepared.	1 – Yes, no more than 20,000 poultry in calendar year. 2 & 3 – not applicable. 4 – The statement "Exempt P.L. 90-492" and producer's name and address are required on product when it is distributed. 5 – May not slaughter or process poultry at a facility used for slaughtering or processing by another person.	1. Slaughter 2. Processing of raised or purchased (live) poultry
Small Enterprise	No restrictions on type of customer A small enterprise may not use or distribute products from, PGOP, Retail Dealer, or Retail Store exemptions The exempt product may only be distributed in the State, territory, or DC where it is prepared.	1 – Yes no more than 20,000 poultry in a calendar year. 2 & 3 – not applicable. 4 – All the features of an official label when distributed, with the exceptions that the official inspection legend cannot be used, modification of the safe handling instructions and the nutrition facts are optional, provided, the labeling does not bear nutrition or health claims. 5 – May not slaughter or process poultry at a facility used for slaughtering or processing by another person.	1. Slaughter 3. Cut-up only
Retail Dealer	Sales limited to household consumers, hotels, or restaurants, or similar institutions. Sales to household consumers in store must be 75% of total sales. Sales to retail markets or distributors disqualify an establishment from a Retail Exemption. Product prepared from poultry previously inspected and passed by USDA permitted to cross Stateline, move in "Commerce."	1 – No limit on pounds sold to consumers. 2 – 25% HRI limitation applies 3 – Dollar limitation not applicable. 4 – All the features of an official label, with the exceptions that the official inspection legend cannot be used, modification of the safe handling instructions and the nutrition facts are optional, provided, the labeling does not bear nutrition or health claims.	1. No Slaughter. 3. Processing limited to cutting up of previously UDSA Inspected and Passed Poultry
Retail Store	Sales limited to household consumers, hotels, or restaurants, or similar institutions. Sales to household consumers in store must be 75% of sales. Sales to retail markets or distributors disqualify an operation from a Retail Store exemption. Product prepared from product previously inspected and passed by USDA permitted to cross Stateline, move in "Commerce " Other, exempt product may only be distributed in the State, territory, or DC where it is prepared.	1 – Yes, there is a limit of 75 lbs. for household sales and a 150 lbs. limit for HRI sales. 2 – 25% HRI limitation does apply 3 – Dollar limitation applicable.	1. Slaughter of live poultry purchased by consumer at the retail store and processed by the retail store operator in accordance with the consumer's instructions. 2. Processing

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**FEDERAL-STATE CONTRACTS
ALLERGEN INSPECTION
SUB-SECTION 5035**

**GUIDANCE ON INSPECTIONS OF FIRMS PRODUCING FOOD PRODUCTS
SUSCEPTIBLE TO CONTAMINATION WITH ALLERGENIC INGREDIENTS**

INTRODUCTION

Prior to conducting inspections involving any manufacturer using ingredients that are considered allergens, review the general inspectional instructions in the FDA Investigations Operations Manual (IOM) Chapter 5 - Establishment Inspections, particularly those in IOM 530 — Food Inspections; and review Compliance Program 7321.005 - Domestic NLEA, Nutrient Sample Analysis and General Food Labeling Program and Compliance Policy Guide Section 555.250, titled "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens".

Each year there are reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially the production of allergen-specific IgE antibodies to naturally occurring proteins in certain foods that most individuals can eat safely. Frequently such reactions occur because the presence of the allergenic substance in the food is not declared on the label. Current regulations require that all added ingredients be declared on the label, yet there are a number of issues that have arisen in connection with undeclared allergens that are not clearly covered by label regulations. This guidance covers the following problem areas:

1. Products that contain one or more allergenic ingredients, but the label does not declare the ingredient in the ingredient statement;
2. Products that become contaminated with an allergenic ingredient due to the firm's failure to exercise adequate control procedures, e.g. improper rework practices, allergen carry-over due to use of common equipment and production sequencing, inadequate cleaning;
3. Products that are contaminated with an allergenic ingredient due to the nature of the product or the process; i.e., use of common equipment in chocolate manufacturing where interim wet cleaning is not practical and only dry cleaning and product flushing is used;
4. A product containing a flavor ingredient that has an allergenic component, but the label of the product only declares the flavor, e.g., natural flavor. Under current regulations, firms are not required to declare the individual components of flavors, certain colors, and spices. However, firms are encouraged to specifically label allergenic components/ingredients that are in spices, flavors, and colors;
5. Products that contain a processing aid that have an allergenic component, but the

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label does not declare it. Processing aids that contain allergenic ingredients are not exempt from ingredient declaration under the incidental additives regulation (21 CFR 101.100 (a)(3)), and therefore, must be declared.

There is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies:

Peanuts
Eggs
Tree nuts
Soybeans
Fish
Wheat
Milk
Crustacea

PRODUCT DEVELOPMENT

Determine whether the firm identifies potential sources of allergens starting in the product developmental stage. For example, do they identify for each product all ingredients, ingredient components, processing aids, rework, processing steps, environmental conditions, and product carry over due to use of common equipment? Are potential sources of allergen contamination identified at each step?

Determine whether the products contain allergenic ingredients. For the most frequently produced products, request formulas. If formula information is refused, construct formulations by observing production.

Determine if the firm has assessed whether the packaging material used in direct contact with the product contains an allergen; e.g., foil coated with wheat ingredient as releasing agent.

Does the firm use processing aids in the manufacture of the food? If so, do the processing aids contain allergenic ingredients? If so, what are the allergenic ingredients?

Does the firm use spices, flavors, or colors that contain allergenic components? If so, do these spices, flavors, or colors contain allergenic ingredients? If so, what are the allergenic ingredients?

RECEIVING

Determine whether the firm uses allergenic ingredients.

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Determine how these allergenic ingredients are handled at receiving and how they are identified and/or segregated in raw material storage.

Determine if the firm stores any of these allergenic ingredients in bulk tanks. If yes, how are the contents of the bulk tanks identified?

Determine what the firm's procedure is for receiving ingredients into the bulk tank and what controls are in place to ensure proper product identity at all times.

Determine if the firm receives any raw materials that are labeled with a statement, such as "this product was processed on machinery that was used to process products containing (allergen)" or "may contain (allergen)." If so what ingredients? How are such statements reflected on the label of the firm's finished product?

Determine whether a label from each incoming lot of finished product labels is visually checked, either upon receipt or during production, to ensure the ingredient statement is correct for the intended product and that it is not a carton of mixed labels.

EQUIPMENT

Try to inspect the equipment before processing begins and document the adequacy of clean up. For example, is there a build up of residual materials or pockets of residue in corners that may contain an allergen from previous runs? What is the condition of the conveyor belts? Is there any product buildup above processing zones? Also observe whether the firm checks the processing lines for cleanliness prior to production and whether they maintain a record of the check. Is this simply a visual check or does the firm use another method?

Determine whether the firm uses a Clean-In-Place system for cleaning fixed lines, e.g. pipelines and tanks. If so, how do they ensure that the interior surfaces of the welds in the lines are smooth and will not entrap material during operation? Are the pipes free from dents?

Determine if equipment is cleanable, e.g. stainless steel, accessible for cleaning.

Determine if the firm has a written procedure for cleaning. Does the cleaning procedure include how to clean and at what frequency the equipment is cleaned? Describe procedure.

Determine if equipment and production lines are shared to process different products.

Determine if shared equipment is cleaned in between production of a product that contains allergens and one that does not, e.g. full clean up with detergent and water.

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PROCESSING

Determine what control measures, if any, are used by the firm to prevent the contamination of products that do not contain allergens? What control measures does the firm employ? At what steps in production are the control measures instituted?

Determine how the firm separates the production of those products that contain allergens from those that do not contain such ingredients. Is cross-contact likely to occur, e.g., airborne food particles, dust, allergen product residues from equipment, etc.?

Determine if unpackaged, exposed product on the processing line is handled in a way that protects it against contamination.

Determine if shared processing lines (equipment) are used. If yes, is allergen-containing product processed first or last?

Determine what is done with the portion of the product that is a mixture of the non-allergen product, e.g., is it sent to waste or for animal feed or reworked?

Determine whether the firm reworks product, and if they only rework like products. How is rework controlled? Is rework inventory reconciled at the end of the day?

Determine how product to be reworked is stored and identified. Are rework containers clearly labeled?

Determine how such rework holding vessels and containers are cleaned and stored.

FINAL PRODUCT TESTING

Determine if the firm performs final product testing for the presence of allergens in products not intended to contain allergens. If so, for which allergens, and how is the testing documented?

Determine what method of analysis is used and the sensitivity of that method.

Determine if the testing is routine or periodic.

LABELING

Determine if finished product label controls are employed, e.g., how are labels delivered to the filling and/or packaging area?

Determine if product labels with similar appearances but different ingredients are controlled to ensure that the correct label is applied to correct product.

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Determine if finished product packages are inspected prior to distribution to ensure that an allergen containing product is labeled properly, or that labels are inspected during production. Is that inspection documented?

Determine if secondary ingredients are incorporated in the final product ingredient statement, e.g. the raw material mayonnaise, which contains eggs, oil, and vinegar.

Determine if the firm uses a statement such as "this product was processed on machinery that was used to process products containing (allergen)" or a statement such as "may contain (allergen)" if the firm uses shared equipment for products that contain and products that do not contain allergens. Any other such statement? Ask the firm why they believe they have to use the advisory statement.

Determine if the finished product reflects any advisory statements that were on the raw material labels, e.g., "this product was processed on machinery that was used to process products containing (allergen)".

Determine if the firm has a system to identify finished products made with rework containing allergenic ingredients. Does the final product label identify the allergens that may have been in the reworked product?

INSPECTION/DOCUMENTATION/ESTABLISHMENT INSPECTION REPORT

It is extremely important that each Establishment Inspection Report (EIR) contain complete, precise, and detailed descriptions of the entire operation. The investigator must attempt to fully identify or demonstrate the likely sources of and possible routes of contamination of the product with undeclared allergen ingredients.

The critical points in the food manufacturing operation should be identified and special attention given to these areas.

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**PATHOGENS AND VECTORS
DISEASE AND POISON PRODUCING ORGANISMS
SUB-SECTION 5050**

OVERVIEW

Food Inspectors must become acquainted with microorganisms associated with foods, at least to the extent that they will be able to identify the main types encountered. While many organisms are useful in food, it is foodborne pathogens that represent an enormous threat to the consuming public. Every inspector should know how disease may be spread via food and how such transmission can be prevented. The purpose of this section is to provide inspection personnel information on selected disease causing and food poisoning organisms.

1. NAME OF TOXIN: Aflatoxins

Name of the Acute Disease: Aflatoxicosis

Aflatoxicosis is poisoning that results from ingestion of aflatoxins in contaminated food or feed. The aflatoxins are a group of structurally related toxic compounds produced by certain strains of the fungi *Aspergillus flavus* and *A. parasiticus*. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. The major aflatoxins of concern are designated B1, B2, G1, and G2. These toxins are usually found together in various foods and feeds in various proportions; however, aflatoxin B1 is usually predominant and is the most toxic. When a commodity is analyzed by thin-layer chromatography, the aflatoxins separate into the individual components in the order given above; however, the first two fluoresce blue when viewed under ultraviolet light and the second two fluoresce green. Aflatoxin M a major metabolic product of aflatoxin B1 in animals and is usually excreted in the milk and urine of dairy cattle and other mammalian species that have consumed aflatoxin-contaminated food or feed.

Nature of the Disease: Aflatoxins produce acute necrosis, cirrhosis, and carcinoma of the liver in a number of animal species; no animal species is resistant to the acute toxic effects of aflatoxins; hence it is logical to assume that humans may be similarly affected. The toxicity can be influenced by environmental factors, exposure level, and duration of exposure, age, health, and nutritional status of diet. Aflatoxin B1 is a very potent carcinogen in many species, including nonhuman primates, birds, fish, and rodents. In each species, the liver is the primary target organ of acute injury.

Normal Course of the Disease: In well-developed countries, aflatoxin contamination rarely occurs in foods at levels that cause acute aflatoxicosis in humans. In view of this, studies on

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human toxicity from ingestion of aflatoxins have focused on their carcinogenic potential. The relative susceptibility of humans to aflatoxins is not known, even though epidemiological studies in Africa and Southeast Asia, where there is a high incidence of hepatoma, have revealed an association between cancer incidence and the aflatoxin content of the diet. These studies have not proved a cause-effect relationship, but the evidence suggests an association.

One of the most important accounts of aflatoxicosis in humans occurred in more than 150 villages in adjacent districts of two neighboring states in northwest India in the fall of 1974. According to one report of this outbreak, 397 persons were affected and 108 persons died. In this outbreak, contaminated corn was the major dietary constituent, and aflatoxin levels of 0.25 to 15 mg/kg were found. The daily aflatoxin B1 intake was estimated to have been at least 55 ^{ae}g/kg body weight for an undetermined number of days. The patients experienced high fever, rapid progressive jaundice, edema of the limbs, pain, vomiting, and swollen livers. One investigator reported a peculiar and very notable feature of the outbreak; the appearance of signs of disease in one village population was preceded by a similar disease in domestic dogs, which was usually fatal. Histopathological examination of humans showed extensive bile duct proliferation and periportal fibrosis of the liver together with gastrointestinal hemorrhages. A 10-year follow-up of the Indian outbreak found the survivors fully recovered with no ill effects from the experience.

Diagnosis of Human Illnesses: Aflatoxicosis in humans has rarely been reported; however, such cases are not always recognized. Aflatoxicosis may be suspected when a disease outbreak exhibits the following characteristics:

- the cause is not readily identifiable
- the condition is not transmissible
- syndromes may be associated with certain batches of food
- treatment with antibiotics or other drugs has little effect
- the outbreak may be seasonal, i.e., weather conditions may affect mold growth

The adverse effects of aflatoxins in animals (and presumably in humans) have been categorized in two general forms:

- A. Acute aflatoxicosis is produced when moderate to high levels of aflatoxins are consumed. Specific, acute episodes of disease ensue may include hemorrhage, acute liver damage, edema, alteration in digestion, absorption and/or metabolism of nutrients, and possibly death.
- B. Chronic aflatoxicosis results from ingestion of low to moderate levels of aflatoxins. The effects are usually subclinical and difficult to recognize. Some of the common symptoms

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are impaired food conversion and slower rates of growth with or without the production of an overt aflatoxin syndrome.

Associated Foods: In the United States, aflatoxins have been identified in corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination.

Relative Frequency of Disease: The relative frequency of aflatoxicosis in humans in the United States is not known. No outbreaks have been reported in humans. Sporadic cases have been reported in animals.

History of Recent Outbreaks: Very little information is available on outbreaks of aflatoxicosis in humans because medical services are less developed in the areas of the world where high levels of contamination of aflatoxins occur in foods, and, therefore, many cases go unnoticed.

2. NAME OF THE ORGANISM: Anisakis simplex and related worms

Anisakis simplex (herring worm), *Pseudoterranova* (*Phocanema*, *Terranova*) *decipiens* (cod or seal worm), *Contracaecum* spp., and *Hysterothylacium* (*Thynnascaris*) spp. are anisakid nematodes (roundworms) that have been implicated in human infections caused by the consumption of raw or undercooked seafood. To date, only *A. simplex* and *P. decipiens* are reported from human cases in North America.

Name of the Acute Disease: Anisakiasis is generally used when referring to the acute disease in humans. Some purists utilize generic names (e.g., *contracaeciasis*) in referring to the disease, but the majority consider that the name derived from the family is specific enough. The range of clinical features is not dependent on species of anisakid parasite in cases reported to date.

Nature of the Acute Disease: In North America, anisakiasis is most frequently diagnosed when the affected individual feels a tingling or tickling sensation in the throat and coughs up or manually extracts a nematode. In more severe cases there is acute abdominal pain, much like acute appendicitis accompanied by a nauseous feeling. Symptoms occur from as little as an hour to about 2 weeks after consumption of raw or undercooked seafood. One nematode is the usual number recovered from a patient. With their anterior ends, these larval nematodes from fish or shellfish usually burrow into the wall of the digestive tract to the level of the muscularis mucosae (occasionally they penetrate the intestinal wall completely and are found

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in the body cavity). They produce a substance that attracts eosinophils and other host white blood cells to the area. The infiltrating host cells form a granuloma in the tissues surrounding the penetrated worm. In the digestive tract lumen, the worm can detach and reattach to other sites on the wall. Anisakids rarely reach full maturity in humans and usually are eliminated spontaneously from the digestive tract lumen within 3 weeks of infection. Penetrated worms that die in the tissues are eventually removed by the host's phagocytic cells.

Diagnosis of Human Illness: In cases where the patient vomits or coughs up the worm, the disease may be diagnosed by morphological examination of the nematode. (*Ascaris lumbricoides*, the large roundworm of humans, is a terrestrial relative of anisakines and sometimes these larvae also crawl up into the throat and nasal passages). Other cases may require a fiber optic device that allows the attending physician to examine the inside of the stomach and the first part of the small intestine. These devices are equipped with a mechanical forceps that can be used to remove the worm. Other cases are diagnosed upon finding a granulomatous lesion with a worm on laparotomy. A specific radioallergosorbent test has been developed for anisakiasis, but is not yet commercially marketed.

Associated Foods: Seafoods are the principal sources of human infections with these larval worms. The adults of *A. simplex* are found in the stomachs of whales and dolphins. Fertilized eggs from the female parasite pass out of the host with the host's feces. In sea water, the eggs embryonate, developing into larvae that hatch in sea water. These larvae are infective to copepods (minute crustaceans related to shrimp) and other small invertebrates. The larvae grow in the invertebrate and become infective for the next host, a fish or larger invertebrate host such as a squid. The larvae may penetrate through the digestive tract into the muscle of the second host. Some evidence exists that the nematode larvae move from the viscera to the flesh if the fish hosts are not gutted promptly after catching. The life cycles of all the other anisakid genera implicated in human infections are similar. These parasites are known to occur frequently in the flesh of cod, haddock, fluke, pacific salmon, herring, flounder, and monkfish.

Relative Frequency of the Disease: Fewer than 10 cases are diagnosed in the U.S. annually. However, it is suspected that many other cases go undetected. The disease is transmitted by raw, undercooked or insufficiently frozen fish and shellfish, and its incidence is expected to increase with the increasing popularity of sushi and sashimi bars.

Usual Disease Course and Complications: Severe cases of anisakiasis are extremely painful and require surgical intervention. Physical removal of the nematode(s) from the lesion is the only known method of reducing the pain and eliminating the cause (other than waiting for the worms to die). The symptoms apparently persist after the worm dies since some lesions are found upon surgical removal that contain only nematode remnants. Stenosis (a

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narrowing and stiffening) of the pyloric sphincter was reported in a case in which exploratory laparotomy had revealed a worm that was not removed.

Outbreaks: This disease is known primarily from individual cases. Japan has the greatest number of reported cases because of the large volume of raw fish consumed there.

A recent letter to the editor of the New England Journal of Medicine (319:1128029, 1988) stated that approximately 50 cases of anisakiasis have been documented in the United States, to date. Three cases in the San Francisco Bay area involved ingestion of sushi or undercooked fish. The letter also points out that anisakiasis is easily misdiagnosed as acute appendicitis, Crohn's disease, gastric ulcer, or gastrointestinal cancer.

3. NAME OF THE ORGANISM: *Bacillus cereus* and other *Bacillus* spp.

Bacillus cereus is a Gram-positive, facultatively aerobic sporeformer whose cells are large rods and whose spores do not swell the sporangium. These and other characteristics, including biochemical features, are used to differentiate and confirm the presence *B. cereus*, although these characteristics are shared with *B. cereus* var. *mycoides*, *B. thuringiensis* and *B. anthracis*. Differentiation of these organisms depends upon determination of motility (most *B. cereus* are motile), presence of toxin crystals (*B. thuringiensis*), hemolytic activity (*B. cereus* and others are beta hemolytic), and rhizoid growth which is characteristic of *B. cereus* var. *mycoides*.

Name of the Illness: *B. cereus* food poisoning is the general description, although two recognized types of illness are caused by two distinct metabolites. The diarrheal type of illness is caused by a large molecular weight protein while the vomiting (emetic) type of illness is believed to be caused by a low molecular weight, heat-stable peptide.

Nature of the Illness: The symptoms of *B. cereus* diarrheal type food poisoning mimic those of *Clostridium perfringens* food poisoning. The onset of watery diarrhea, abdominal cramps, and pain occurs 6-15 hours after consumption of contaminated food. Nausea may accompany diarrhea, but vomiting (emesis) rarely occurs. Symptoms persist for 24 hours in most instances.

The emetic type of food poisoning is characterized by nausea and vomiting within 0.5 to 6 hours after consumption of contaminated foods. Occasionally, abdominal cramps and/or diarrhea may also occur. Duration of symptoms is generally less than 24 hours. The symptoms of this type of food poisoning parallel those caused by *Staphylococcus aureus* foodborne intoxication. Some strains of *B. subtilis* and *B. licheniformis* have been isolated from lamb and chicken incriminated in food poisoning episodes. These organisms demonstrate the production of a highly heat-stable toxin which may be similar to the vomiting type toxin produced by *B. cereus*.

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The presence of large numbers of *B. cereus* (greater than 10(6) organism/g) in a food is indicative of active growth and proliferation of the organism and is consistent with a potential hazard to health.

Diagnosis of Human Illness: Confirmation of *B. cereus* as the etiologic agent in a foodborne outbreak requires either (1) isolation of strains of the same serotype from the suspect food and feces or vomitus of the patient, (2) isolation of large numbers of a *B. cereus* serotype known to cause foodborne illness from the suspect food or from the feces or vomitus of the patient, or (3) isolation of *B. cereus* from suspect foods and determining their enterotoxigenicity by serological (diarrheal toxin) or biological (diarrheal and emetic) tests. The rapid onset time to symptoms in the emetic form of disease, coupled with some food evidence, is often sufficient to diagnose this type of food poisoning.

Foods Incriminated: A wide variety of foods including meats, milk, vegetables, and fish have been associated with the diarrheal type food poisoning. The vomiting-type outbreaks have generally been associated with rice products; however, other starchy foods such as potato, pasta and cheese products have also been implicated. food mixtures such as sauces, puddings, soups, casseroles, pastries, and salads have frequently been incriminated in food poisoning outbreaks.

Relative Frequency of Illness: In 1980, 9 outbreaks were reported to the Centers for Disease Control and included such foods as beef, turkey, and Mexican foods. In 1981, 8 outbreaks were reported which primarily involved rice and shellfish. Other outbreaks go unreported or are misdiagnosed because of symptomatic similarities to *Staphylococcus aureus* intoxication (*B. cereus* vomiting-type) or *C. perfringens* food poisoning (*B. cereus* diarrheal type).

Typical Food Poisoning Outbreak: On September 22, 1985, the Maine Bureau of Health was notified of gastrointestinal illness among patrons of a Japanese restaurant. Because the customers were exhibiting symptoms of illness while still on the restaurant premises, and because uncertainty existed as to the etiology of the problem, the local health department, in concurrence with the restaurant owner, closed the restaurant at 7:30 p.m. that same day.

Eleven (31%) of the approximately 36 patrons reportedly served on the evening of September 22, were contacted in an effort to determine the etiology of the outbreak. Those 11 comprised the last three dining parties served on September 22. Despite extensive publicity, no additional cases were reported.

A case was defined as anyone who demonstrated vomiting or diarrhea within 6 hours of dining at the restaurant. All 22 individuals were interviewed for symptoms, time of onset of illness, illness duration, and foods ingested. All 11 reported nausea and vomiting; nine reported

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diarrhea; one reported headache; and one reported abdominal cramps. Onset of illness ranged from 30 minutes to 5 hours (mean 1 hour, 23 minutes) after eating at the restaurant. Duration of illness ranged from 5 hours to several days, except for two individuals still symptomatic with diarrhea 2 weeks after dining at the restaurant. Ten persons sought medical treatment at local emergency rooms on September 22; two ultimately required hospitalization for rehydration.

Analysis of the association of specific foods with illness was not instructive, since all persons consumed the same food items; chicken soup, fried shrimp, stir-fried rice, fried zucchini, onions, bean sprouts, cucumber, cabbage and lettuce salad, ginger salad dressing, hibachi scallops, and one person ordered hibachi swordfish. However, most individuals sampled each other's entrees. One vomitus specimen and two stool specimens from the three separate individuals yielded an overgrowth of *B. cereus*, although an accurate bacterial count could not be made because an inadequate amount of the steak remained for laboratory analysis. No growth of *B. cereus* was reported from the fried rice, mixed fried vegetables, or hibachi chicken.

According to the owner, all meat was delivered 2-3 times a week from a local meat supplier and refrigerated until ordered by restaurant patrons. Appropriate-sized portions for a dining group were taken from the kitchen to the dining area and diced or sliced, then sautéed at the table directly in front of restaurant patrons. The meat was seasoned with soy sauce salt and white pepper, open containers of which had been used for at least 2 months by the restaurant. The hibachi steak was served immediately after cooking.

The fried rice served with the meal was customarily made from leftover boiled rice. It could not be established whether the boiled rice had been stored refrigerated or at room temperature.

Fresh, rapidly cooked meat, eaten immediately, seems an unlikely vehicle of *B. cereus* food poisoning. The laboratory finding of *B. cereus* in a foodstuff without quantitative cultures and without accompanying epidemiologic data is insufficient to establish its role in the outbreak. Although no viable *B. cereus* organisms were isolated from the fried rice eaten with the meal, it does not exclude this food as the common vehicle. Reheating during preparation may have eliminated the bacteria in the food without decreasing the activity of the heat-stable toxin. While the question of the specific vehicle remains incompletely resolved, the clinical and laboratory findings substantially support *B. cereus* as the cause of the outbreak.

Most episodes of food poisoning undoubtedly go unreported, and in most of those reported, the specific pathogens are never identified. Alert recognition of the clinical syndrome and appropriate laboratory work permitted identification of the role of *B. cereus* in this outbreak.

4. NAME OF THE ORGANISM: *Campylobacter jejuni*

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Campylobacter jejuni is a Gram-negative slender, curved, and motile rod. It is a microaerophilic organism, which means it has a requirement for reduced levels of oxygen. It is relatively fragile, and sensitive to environmental stresses (e.g., 21% oxygen, drying, heating, disinfectants, acidic conditions). Because of its microaerophilic characteristics the organism requires 3 to 5% oxygen and 2 to 10% carbon dioxide for optimal growth conditions. This bacterium is now recognized as an important enteric pathogen. Before 1972, when methods were developed for its isolation from feces, it was believed to be primarily an animal pathogen causing abortion and enteritis in sheep and cattle. Recent surveys have shown that *C. jejuni* is the leading cause of bacterial diarrheal illness in the United States. It causes more disease than *Shigella* spp. and *Salmonella* spp. combined.

Although *C. jejuni* is not carried by healthy individuals in the United States or Europe, it is often isolated from healthy cattle, chickens, birds and even flies. It is sometimes present in non-chlorinated water sources such as streams and ponds.

Because the pathogenic mechanisms of *C. jejuni* are still being studied, it is difficult to differentiate pathogenic from nonpathogenic strains. However, it appears that many of the chicken isolates are pathogens.

Name of the Disease: Campylobacteriosis is the name of the illness caused by *C. jejuni*. It is also often known as campylobacter enteritis or gastroenteritis.

Major Symptoms: *C. jejuni* infection causes diarrhea, which may be watery or sticky and can contain blood (usually occult) and fecal leukocytes (white cells). Other symptoms often present are fever, abdominal pain, nausea, headache and muscle pain. The illness usually occurs 2-5 days after ingestion of the contaminated food or water. Illness generally lasts 7-10 days, but relapses are not uncommon (about 25% of cases). Most infections are self-limiting and are not treated with antibiotics. However, treatment with erythromycin does reduce the length of time that infected individuals shed the bacteria in their feces.

The infective dose of *C. jejuni* is considered to be small. Human feeding studies suggest that about 400-500 bacteria may cause illness in some individuals, while in others, greater numbers are required. A recently conducted volunteer human feeding study suggests that host susceptibility also dictates infectious dose to some degree. The pathogenic mechanisms of *C. jejuni* are still not completely understood, but it does produce a heat-labile toxin that may cause diarrhea. *C. jejuni* may also be an invasive organism.

Isolation Procedures: *C. jejuni* is usually present in high numbers in the diarrheal stools of individuals, but isolation requires special antibiotic-containing media and a special

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microaerophilic atmosphere (5% oxygen). However, most clinical laboratories are equipped to isolate *Campylobacter* spp. if requested.

Associated Foods: *C. jejuni* frequently contaminates raw chicken. Surveys show that 20 to 100% of retail chickens are contaminated. This is not overly surprising since many healthy chickens carry these bacteria in their intestinal tracts. Raw milk is also a source of infections. The bacteria are often carried by healthy cattle and by flies on farms. Non-chlorinated water may also be a source of infections. However, properly cooking chicken, pasteurizing milk, and chlorinating drinking water will kill the bacteria.

Frequency of the Disease: *C. jejuni* is the leading cause of bacterial diarrhea in the U.S. There are probably numbers of cases in excess of the estimated cases of salmonellosis (2- to 4,000,000/year).

Isolation of *C. jejuni* from food is difficult because the bacteria are usually present in very low numbers (unlike the case of diarrheal stools in which 10⁶ bacteria/gram is not unusual). The methods require an enrichment broth containing antibiotics, special antibiotic-containing plates and a microaerophilic atmosphere [generally a microaerophilic atmosphere with 5% oxygen and an elevated concentration of carbon dioxide (10%)]. Isolation can take several days to a week.

Recent Cases: Usually outbreaks are small (less than 50 people), but in Bennington, Vermont, a large outbreak involving about 2,000 people occurred while the town was temporarily using a non-chlorinated water source as a water supply. Several small outbreaks have been reported among children who were taken on a class trip to a dairy and given raw milk to drink. An outbreak was also associated with consumption of raw clams. However, a recent survey showed that about 50% of infections are associated with either eating inadequately cooked or recontaminated chicken meat or handling chickens. It is the leading bacterial cause of sporadic (non-clustered cases) diarrheal disease in the U.S.

In April 1986, an elementary school child was cultured for bacterial pathogens (due to bloody diarrhea), and *C. jejuni* was isolated. Food consumption/gastrointestinal illness questionnaires were administered to other students and faculty at the school. In all, 32 of 172 students reported symptoms of diarrhea (100%), cramps (80%), nausea (51%), fever (29%), vomiting (26%), and bloody stools (14%). The food questionnaire clearly implicated milk as the common source, and a dose/response was evident (those drinking more milk were more likely to be ill). Investigation of the dairy supplying the milk showed that they vat pasteurized the milk at 135°F for 25 minutes rather than the required 145°F for 30 minutes. The dairy processed surplus raw milk for the school, and this milk had a high somatic cell count. Cows from the herd supplying the dairy had *C. jejuni* in their feces. This outbreak points out the variation in symptoms which may occur with campylobacteriosis and the absolute need to

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adhere to pasteurization time/temperature standards. Although other *Campylobacter* spp. have been implicated in human gastroenteritis (e. g., *C. laridis*, *C. hyointestinalis*), it is believed that 99% of the cases are caused by *C. jejuni*.

5. NAME OF TOXIN: Ciguatera

Name of the Disease: Ciguatera Fish Poisoning

Ciguatera is a form of human poisoning caused by the consumption of subtropical and tropical marine finfish which have accumulated naturally occurring toxins through their diet. The toxins are known to originate from several dinoflagellate (algae) species that are common to ciguatera endemic regions in the lower latitudes.

Nature of the Disease: Manifestations of ciguatera in humans usually involves a combination of gastrointestinal, neurological, and cardiovascular disorders. Symptoms defined within these general categories vary with the geographic origin of toxic fish.

Normal Course of Disease: Initial signs of poisoning occur within six hours after consumption of toxin fish and include perioral numbness and tingling (paresthesia), which may spread to the extremities, nausea, vomiting and diarrhea. Neurological signs include intensified paresthesia, arthralgia, myalgia, headache, temperature sensory reversal and acute sensitivity to temperature extremes, vertigo, and muscular weakness to the point of prostration. Cardiovascular signs include arrhythmia, bradycardia or tachycardia, and reduced blood pressure. Ciguatera poisoning is usually self-limiting, and signs of poisoning often subside within several days from onset. However, in severe cases the neurological symptoms are known to persist from weeks to months. In a few isolated cases neurological symptoms have persisted for several years, and in other cases recovered patients have experienced recurrence of neurological symptoms months to years after recovery. Such relapses are most often associated with changes in dietary habits or with consumption of alcohol. There is a low incidence of death resulting from respiratory and cardiovascular failure.

Diagnosis of Human Illness: Clinical testing procedures are not presently available for the diagnosis of ciguatera in humans. Diagnosis is based entirely on symptomology and recent dietary history. An enzyme immunoassay (EIA) designed to detect toxic fish in field situations is under evaluation by the Association of Official Analytical Chemists (AOAC) and may provide some measure of protection to the public in the future.

Associated Foods: Marine finfish most commonly implicated in ciguatera fish poisoning include the groupers, barracudas, snappers, jacks, mackerel, and triggerfish. Many other

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species of warm-water fishes harbor ciguatera toxins. The occurrence of toxic fish is sporadic, and not all fish of a given species or from a given locality will be toxic.

Relative Frequency of Disease: The relative frequency of ciguatera fish poisoning in the United States is not known. The disease has only recently become known to the general medical community, and there is a concern that incidence is largely under-reported because of the generally non-fatal nature and short duration of the disease.

History of Recent Outbreaks: Isolated cases of ciguatera fish poisoning have occurred along the eastern coast of the United States from south Florida to Vermont. Hawaii, the U.S. Virgin Islands, and Puerto Rico experience sporadic cases with some regularity. A major outbreak of ciguatera occurred in Puerto Rico between April and June, 1981 in which 49 persons were afflicted and two fatalities occurred. This outbreak prompted government officials of the Commonwealth of Puerto Rico to ban the sale of barracuda, amberjack, and blackjack.

In February-March of 1987 a large common-source outbreak of ciguatera occurred among Canadian vacationers returning from a Caribbean resort. Of 147 tourists, 61 ate a fish casserole shortly before departure, resulting in 57 identified cases of ciguatera.

In May of 1988 several hundred pounds of fish (primarily hogfish) from the Dry Tortuga Bank were responsible for over 100 human poisonings in Palm Beach County, Florida. The fish were sold to a seafood distributor after the fishermen (sport spearfishermen) themselves were first afflicted but dismissed their illness as seasickness and hangover. The poisonings resulted in a statewide warning against eating hogfish, grouper, red snapper, amberjack, and barracuda caught at the Dry Tortuga Bank.

6. NAME OF THE ORGANISM: Clostridium botulinum

Clostridium botulinum is an anaerobic, Gram-positive, spore-forming rod that produces a potent neurotoxin. The spores are heat-resistant and can survive in foods that are incorrectly or minimally processed. Seven types (A, B, C, D, E, F and G) of botulinum are recognized, based on the antigenic specificity of the toxin produced by each strain. Types A, B, E and F cause human botulism. Types C and D cause most cases of botulism in animals. Animals most commonly affected are wild fowl and poultry, cattle, horses and some species of fish. Although type G has been isolated from soil in Argentina, no outbreaks involving it have been recognized.

Foodborne botulism (as distinct from wound botulism and infant botulism) is a severe type of food poisoning caused by the ingestion of foods containing the potent neurotoxin formed

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during growth of the organism. The toxin is heat labile and can be destroyed if heated at 80°C for 10 minutes or longer. The incidence of the disease is low, but the disease is of considerable concern because of its high mortality rate if not treated immediately and properly. Most of the 10 to 30 outbreaks that are reported annually in the United States are associated with inadequately processed, home-canned foods, but occasionally commercially produced foods have been involved in outbreaks. Sausages, meat products, canned vegetables and seafood products have been the most frequent vehicles for human botulism.

The organism and its spores are widely distributed in nature. They occur in both cultivated and forest soils, bottom sediments of streams, lakes, and coastal waters, and in the intestinal tracts of fish and mammals, and in the gills and viscera of crabs and other shellfish.

Name of the Disease: Four types of botulism are recognized: foodborne, infant, wound, and a form of botulism whose classification is as yet undetermined. Certain foods have been reported as sources of spores in cases of infant botulism and the undetermined category; wound botulism is not related to foods.

Foodborne botulism is the name of the disease (actually a foodborne intoxication) caused by the consumption of foods containing the neurotoxin produced by *C. botulinum*.

Infant botulism, first recognized in 1976, affects infants under 12 months of age. This type of botulism is thought to be caused by the ingestion of *C. botulinum* spores which colonize and produce toxin in the intestinal tract of infants (toxicoinfectious botulism). Honey is the only implicated food source for *C. botulinum* spores. The number of confirmed infant botulism cases has increased significantly as a result of greater awareness by health officials since its recognition in 1976. It is now internationally recognized, with cases being reported in more countries.

Wound botulism is the rarest form of botulism. The illness results when *C. botulinum* by itself or with other microorganisms infects a wound and produces toxins which reach other parts of the body via the blood stream. Foods are not involved in this type of botulism.

Undetermined category of botulism involves adult cases in which a specific food or wound source cannot be identified. It has been suggested that some cases of botulism assigned to this category might result from intestinal colonization in adults, with in vivo production of toxin. Reports in the medical literature suggest the existence of a form of botulism similar to infant botulism, but occurring in adults. In these cases, the patients had surgical alterations of the gastrointestinal tract and/or antibiotic therapy. It is proposed that these procedures may have altered the normal gut flora and allowed *C. botulinum* to colonize the intestinal tract.

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Nature of the Disease: Infective dose - a very small amount (a few nanograms) of toxin can cause illness.

Onset of symptoms in foodborne botulism is usually 18 to 36 hours after ingestion of the food containing the toxin, although cases have varied from 4 hours to 8 days. Early signs of intoxication consist of marked lassitude, weakness and vertigo, usually followed by double vision and progressive difficulty in speaking and swallowing. Difficulty in breathing, weakness of other muscles, abdominal distention, and constipation may also be common symptoms.

Clinical symptoms of infant botulism consist of constipation that occurs after a period of normal development. This is followed by poor feeding, lethargy, weakness, pooled oral secretions, and wail or altered cry. Loss of head control is striking. Recommended treatment is primarily supportive care. Antimicrobial therapy is not recommended. Infant botulism is diagnosed by demonstrating botulinal toxins and the organism in the infants' stools.

Diagnosis of Human Illness: Although botulism can be diagnosed by clinical symptoms alone, differentiation from other diseases may be difficult. The most direct and effective way to confirm the clinical diagnosis of botulism in the laboratory is to demonstrate the presence of toxin in the serum or feces of the patient or in the food which the patient consumed. Currently, the most sensitive and widely used method for detecting toxin is the mouse neutralization test. This test takes 48 hours. Culturing of specimens takes 5-7 days.

Associated Foods: The types of foods involved in botulism vary according to food preservation and eating habits in different regions. Any food that is conducive to outgrowth and toxin production, that when processed allows spore survival, and is not subsequently heated before consumption can be associated with botulism. Almost any type of food that is not very acidic (pH above 4.6) can support growth and toxin production by *C. botulinum*. Botulinal toxin has been demonstrated in a considerable variety of foods, such as canned corn, peppers, green beans, soups, beets, asparagus, mushrooms, ripe olives, spinach, tuna fish, chicken and chicken livers and liver pate', and luncheon meats, ham, sausage, stuffed eggplant, lobster, and smoked and salted fish.

Frequency: The incidence of the disease is low, but the mortality rate is high if not treated immediately and properly. There are generally between 10 to 30 outbreaks a year in the United States. Some cases of botulism may go undiagnosed because symptoms are transient or mild, or misdiagnosed as Guillain-Barre syndrome.

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The Usual Course of Disease and Complications: Botulinum toxin causes flaccid paralysis by blocking motor nerve terminals at the myoneural junction. The flaccid paralysis progresses symmetrically downward, usually starting with the eyes and face, to the throat, chest and

extremities. When the diaphragm and chest muscles become fully involved, respiration is inhibited and death from asphyxia results. Recommended treatment for foodborne botulism includes early administration of botulinal antitoxin (available from CDC) and intensive supportive care (including mechanical breathing and assistance).

Recent Outbreaks: In the last 10 years, two separate outbreaks of botulism have occurred involving commercially canned salmon. Restaurant foods such as sautéed onions, chopped bottled garlic, potato salad made from baked potatoes and baked potatoes themselves have been responsible for a number of outbreaks. Also, smoked fish, both hot and cold-smoke (e.g., Kapchunka) have caused outbreaks of type E botulism.

In October and November, 1987, 8 cases of type E botulism occurred, 2 in New York City and 6 in Israel. All 8 patients had consumed Kapchunka, an uneviscerated dry-salted, air-dried, whole whitefish. The product was made in New York City and some of it was transported by individuals to Israel. All 8 patients with botulism developed symptoms within 36 hours of consuming the Kapchunka. One female died, 2 required breathing assistance, 3 were treated therapeutically with antitoxin, and 3 recovered spontaneously. The Kapchunka involved in this outbreak contained high levels of type E botulinal toxin despite salt levels that exceeded those sufficient to inhibit *C. botulinum* type E outgrowth. One possible explanation was that the fish contained low salt levels when air-dried at room temperature, became toxic, and then were re-brined. Regulations were published to prohibit the processing, distribution and sale of Kapchunka and Kapchunka-type products in the United States.

Most recently, a bottled chopped garlic-in-oil mix was responsible for three cases of botulism in Kingston, New York. Two men and a woman were hospitalized with botulism after consuming a chopped garlic-in-oil mix that had been used in a spread for garlic bread. The bottled chopped garlic relied solely on refrigeration to ensure safety and did not contain any additional antibotulinal additives or barriers. The FDA has ordered companies to stop making the product and to withdraw from the market any garlic-in-oil mix which does not include microbial inhibitors or acidifying agents and does not require refrigeration for safety.

Since botulism is a life-threatening disease, FDA always initiates a Class I recall.

7. NAME OF THE ORGANISM: Clostridium perfringens

Clostridium perfringens is an anaerobic, Gram-positive, sporeforming rod (anaerobic means unable to grow in the presence of free oxygen). It is widely distributed in the environment and

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frequently occurs in the intestines of humans and many domestic and feral animals. Spores of the organism persist in soil, sediments, and areas subject to human or animal fecal pollution.

Name of the Acute Disease: Perfringens food poisoning is the term used to describe the common foodborne illness caused by *C. perfringens*. A more serious but rare illness is also

caused by ingesting food contaminated with Type C strains. The latter illness is known as enteritis necroticans or pig-bel disease.

Nature of the Disease: The common form of perfringens poisoning is characterized by intense abdominal cramps and diarrhea which begin 8-22 hours after consumption of foods containing large numbers of those *C. perfringens* bacteria capable of producing the food poisoning toxin. The illness is usually over within 24 hours but less severe symptoms may persist in some individuals for 1 or 2 weeks. A few deaths have been reported as a result of dehydration and other complications.

Infective Dose: The symptoms are caused by ingestion of large numbers (greater than 10⁸ [100,000,000] vegetative cells. Toxin production in the digestive tract (or in test tubes) is associated with sporulation. This disease is a food infection; only one episode has ever implied the possibility of intoxication (i.e., disease from preformed toxin).

Diagnosis of Human Illness: Perfringens poisoning is diagnosed by its symptoms and the typical delayed onset of illness. Diagnosis is confirmed by detecting the toxin in the feces of patients. Bacteriological confirmation can also be done by finding exceptionally large numbers of the causative bacteria in implicated foods or in the feces of patients.

Associated Foods and Food Handling: In most instances, the actual cause of poisoning by *C. perfringens* is temperature abuse of prepared foods. Small numbers of the organisms are often present after cooking and multiply to food poisoning levels during cool down and storage of prepared foods. Meats, meat products, and gravy are the foods most frequently implicated.

Frequency: Perfringens poisoning is one of the most commonly reported foodborne illnesses in the U.S. There were 1,162 cases in 1981, in 28 separate outbreaks. At least 10-20 outbreaks have been reported annually in the U.S. for the past 2 decades. Typically, dozens or even hundreds of persons are affected. It is probable that many outbreaks go unreported because the implicated foods or patient feces are not tested routinely for *C. perfringens* or its toxin. CDC estimates that about 10,000 actual cases occur annually in the U.S.

Usual Course of Disease and Complications: The disease generally lasts 24 hours. In the elderly or infirm, symptoms may last 1-2 weeks. Complications and/or death only very rarely occur.

Recent Outbreaks: Since December 1981, FDA has investigated 10 outbreaks in 5 states. In two instances, more than one outbreak occurred in the same feeding facility within a 3-week period. One such outbreak occurred on March 19, 1984, involving 77 prison inmates. Roast beef served as a luncheon meat was implicated as the food vehicle and *C. perfringens* was

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confirmed as the cause by examining stools of 24 patients. Most of the patients became ill 8-16 hours after the meal. Eight days later, on March 27, 1984, a second outbreak occurred involving many of the same persons. The food vehicle was ham. Inadequate

refrigeration and insufficient reheating of the implicated foods caused the outbreaks. Most of the other outbreaks occurred in institutional feeding environments: a hospital, nursing home, labor camp, school cafeteria, and at a firehouse luncheon.

In November, 1985, a large outbreak of *C. perfringens* gastroenteritis occurred among factory workers in Connecticut. Forty-four percent of the 1,262 employees were affected. Four main-course foods served at an employee banquet were associated with illness, but gravy was implicated by stratified analysis. The gravy had been prepared 12-24 hours before serving, had been improperly cooled, and was reheated shortly before serving. The longer the reheating period, the less likely the gravy was to cause illness.

8. NAME OF THE ORGANISM: *Cryptosporidium parvum*

Cryptosporidium parvum, a single-celled animal, i.e., a protozoa, is an obligate intracellular parasite. It has been given additional species names when isolated from different hosts. It is currently thought that the form infecting humans is the same species that causes disease in young calves. The forms that infect avian hosts and those that infect mice are not thought capable of infecting humans. *Cryptosporidium* sp. infects many herd animals (cows, goats, sheep among domesticated animals, and deer and elk among wild animals). The infective stage of the organism, the oocyst is 3 μ m in diameter or about half the size of a red blood cell. The sporocysts are resistant to most chemical disinfectants, but are susceptible to drying and the ultraviolet portion of sunlight. Some strains appear to be adapted to certain hosts but cross-strain infectivity occurs and may or may not be associated with illness. The species or strain infecting the respiratory system is not currently distinguished from the form infecting the intestines.

Disease Name: Intestinal, tracheal, or pulmonary cryptosporidiosis.

Nature of Acute Disease: Intestinal cryptosporidiosis is characterized by severe watery diarrhea but may, alternatively, be asymptomatic. Pulmonary and tracheal cryptosporidiosis in humans is associated with coughing and frequently a low-grade fever; these symptoms are often accompanied by several intestinal distress.

Infective Dose: Less than 10 organisms and, presumably, one organism can initiate an infection. The mechanism of disease is not known; however, the intracellular stages of the parasite can cause severe tissue alteration.

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Diagnosis of Human Illness: Oocysts are shed in the infected individual's feces. Sugar flotation is used to concentrate the organisms and acid fast staining is used to identify them. A commercial kit is available that uses fluorescent antibody to stain the organisms isolated from feces. Diagnosis has also been made by staining the trophozoites in intestinal and biopsy specimens. Pulmonary and tracheal cryptosporidiosis are diagnosed by biopsy and staining.

Food Occurrence: *Cryptosporidium* sp. could occur, theoretically, on any food touched by a contaminated food handler. Incidence is higher in child day care centers that serve food. Fertilizing salad vegetables with manure is another possible source of human infection. Large outbreaks are associated with contaminated water supplies.

Relative Frequency of the Disease: Direct human surveys indicate a prevalence of about 2% of the population in North America. Serological surveys indicate that 80% of the population has had cryptosporidiosis. The extent of illness associated with reactive sera is not known.

Usual Course of the Disease and Complications: Intestinal cryptosporidiosis is self-limiting in most healthy individuals, with watery diarrhea lasting 2-4 days. In some outbreaks at day care centers, diarrhea has lasted 1 to 4 weeks. To date, there is no known effective drug for the treatment of cryptosporidiosis. Immunodeficient individuals, especially AIDS patients, may have the disease for life, with the severe watery diarrhea contributing to death. Invasion of the pulmonary system may also be fatal.

Outbreaks: Since 1984, cryptosporidiosis has been associated with outbreaks of diarrheal illness in child day care centers throughout the United States and Canada. During 1987 a waterborne outbreak in Georgia produced illness in an estimated 13,000 individuals, and exposure to contaminated drinking water was the major distinction between those that were ill and those that were not. This was the first report of disease transmission by a municipal water system that was in compliance with all state and federal standards for drinking water.

9. NAME OF THE ORGANISM: Enteroinvasive Escherichia coli or (EIEC)

Currently, there are four recognized classes of enterovirulent *E. coli* (collectively referred to as the EEC group) that cause gastroenteritis in humans. *E. coli* is part of the normal intestinal flora of humans and other primates. A minority of *E. coli* strains are capable of causing human illness by several different mechanisms. Among these are the enteroinvasive (EIEC) strains. It is unknown what foods may harbor these pathogenic enteroinvasive (EIEC) strains responsible for a form of bacillary dysentery.

Name of the Disease: Enteroinvasive *E. coli* (EIEC) may produce an illness known as bacillary dysentery. The EIEC strains responsible for this syndrome are closely related to *Shigella* spp.

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Nature of the Disease: Following the ingestion of EIEC, the organism invades the epithelial cells of the intestine, resulting in a mild form of dysentery, often mistaken for dysentery caused by *Shigella* species. The illness is characterized by the appearance of blood and mucus in the stools of infected individuals.

Infective Dose: The infectious dose of EIEC is thought to be as few as 10 organisms (same as *Shigella*).

Diagnosis of Human Illness: The culturing of the organism from the stools of infected individuals and the demonstration of invasiveness of isolates in tissue culture or in a suitable animal model is necessary to diagnose dysentery caused by this organism.

More recently, genetic probes for the invasiveness genes of both EIEC and *Shigella* spp. have been developed.

Associated Foods: It is currently unknown what foods may harbor EIEC, but any food contaminated with human feces from an ill individual, either directly or via contaminated water, could cause disease in others. Outbreaks have been associated with hamburger meat and unpasteurized milk.

Relative Frequency of Disease: One major foodborne outbreak attributed to enteroinvasive *E. coli* in the U.S. occurred in 1973. It was due to the consumption of imported cheese from France. The disease caused by EIEC is uncommon, but it may be confused with shigellosis and its prevalence may be underestimated.

The Usual Course of Disease and Some Complications: Dysentery caused by EIEC usually occurs within 12 to 72 hours following the ingestion of contaminated food. The illness is characterized by abdominal cramps, diarrhea, vomiting, fever, chills, and a generalized malaise. Dysentery caused by this organism is generally self-limiting with no known complications. A common sequel associated with infection, especially in pediatric cases, is hemolytic uremic syndrome (HUS).

Outbreaks: Several outbreaks in the U.S. have been attributed to this organism. One outbreak occurred in 1973 and was due to the consumption of imported cheese. More recently, a cruise ship outbreak was attributed to potato salad, and an outbreak occurred in a home for the mentally retarded where subsequent person-to-person transmission occurred.

10. NAME OF THE ORGANISM: Enteropathogenic Escherichia coli (EPEC)

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Currently, there are four recognized classes of enterovirulent *E. coli* (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these are the enteropathogenic (EPEC) strains. EPEC are defined as *E. coli* belonging to serogroups epidemiologically implicated as pathogens but whose virulence mechanism is unrelated to the excretion of typical *E. coli* enterotoxins. *E. coli* are Gram-positive, rod-shaped bacteria belonging to the family Enterobacteriaceae. Source(s) and prevalence of EPEC are

controversial because foodborne outbreaks are sporadic. Humans, bovines, and swine can be infected, and the latter often serve as common experimental animal models. *E. coli* are present in the normal gut flora of these mammals. The proportion of pathogenic to nonpathogenic strains, although the subject of intense research, is unknown.

Name of the Acute Disease: Infantile diarrhea is the name of the disease usually associated with EPEC.

Nature of the Disease: EPEC cause either a watery or bloody diarrhea, the former associated with the attachment to, and physical alteration of, the integrity of the intestine. Bloody diarrhea is associated with attachment and an acute tissue-destructive process, perhaps caused by a toxin similar to that of *Shigella dysenteriae*, also called verotoxin. In most of these strains the shiga-like toxin is cell-associated rather than excreted.

Infective Dose: EPEC are highly infectious for infants and the dose is presumably very low. In the few documented cases of adult diseases, the dose is presumably similar to other colonizers (greater than 10⁶ total dose).

Diagnosis of Human Illness: The distinction of EPEC from other groups of pathogenic *E. coli* isolated from patients' stools involves serological and cell culture assays. Serotyping, although useful, is not strict for EPEC.

Associated Foods: Common foods implicated in EPEC outbreaks are raw beef and chicken, although any food exposed to fecal contamination is strongly suspect.

Relative Frequency of Disease: Outbreaks of EPEC are sporadic. Incidence varies on a worldwide basis; countries with poor sanitation practices have the most frequent outbreaks.

Usual Course of Disease and Some Complications: Occasionally, diarrhea in infants is prolonged, leading to dehydration, electrolyte imbalance and death (50% mortality rates have been reported in third world countries).

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History of Recent Outbreaks: Sporadic outbreaks of EPEC diarrhea have occurred for half a century in infant nurseries, presumably derived from the hospital environment or contaminated infant formula. Common-source outbreaks of EPEC diarrhea involving healthy young adults were reported in the late 1960s. Presumably a large inoculum was ingested.

11. NAME OF THE ORGANISM: Enterotoxigenic Escherichia coli (ETEC)

Currently there are four recognized classes of enterovirulent *E. coli* (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these are the enterotoxigenic

(ETEC) strains. They comprise a relatively small proportion of the species and have been etiologically associated with diarrheal illness of all age groups from diverse global locations. The organism frequently causes diarrhea in infants in less developed countries and in visitors there from industrialized countries. The etiology of this cholera-like illness has been recognized for about 20 years.

Name of the Acute Disease: Gastroenteritis is the common name of the illness caused by ETEC, although travelers' diarrhea is a frequent sobriquet.

Nature of the Disease: The most frequent clinical syndrome of infection includes watery diarrhea, abdominal cramps, low-grade fever, nausea and malaise.

Infective Dose: Volunteer feeding studies indicate that a relatively large dose (100 million to 10 billion bacteria) of enterotoxigenic *E. coli* is probably necessary to establish colonization of the small intestine, where these organisms proliferate and produce toxins which induce fluid secretion. With high infective dose, diarrhea can be induced within 24 hours. Infants may require fewer organisms for infection to be established.

Diagnosis of Human Illness: During the acute phase of infection, large numbers of enterotoxigenic cells are excreted in feces. These strains are differentiated from nontoxigenic *E. coli* present in the bowel by a variety of in vitro immunochemical, tissue culture, or gene probe tests designed to detect either the toxins or genes that encode for these toxins. The diagnosis can be completed in about 3 days.

Associated Foods: ETEC is not considered a serious foodborne disease hazard in countries having high sanitary standards and practices. Contamination of water with human sewage may lead to contamination of foods. Infected food handlers may also contaminate foods. These organisms are infrequently isolated from dairy products such as semi-soft cheeses.

Relative Frequency of Disease: Only four outbreaks in the U.S. have been documented, one resulting from consumption of water contaminated with human sewage, another from

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consumption of Mexican food prepared by an infected food handler. In two others, one in a hospital cafeteria and one aboard a cruise ship, food was the probable cause. The disease among travelers to foreign countries, however, is common.

History of Recent Major Outbreaks: In the last decade, four major common-source outbreaks of ETEC gastroenteritis occurred in the U.S. In late 1975 one-third of the passengers on two successive cruises of a Miami-based ship experienced diarrheal illness. A CDC investigation found ETEC to be the cause, presumably linked to consumption of crabmeat cocktail. In early 1980, 415 persons eating at a Mexican restaurant experienced diarrhea. The source of the causative organism was an ill food handler. In 1981, 282 of

3,000 personnel at a Texas hospital acquired ETEC gastroenteritis after eating in the hospital cafeteria. No single food was identified by CDC.

12. NAME OF THE ORGANISM: Escherichia coli 0157:H7 (enterohemorrhagic E. coli or EHEC)

Currently, there are four recognized classes of enterovirulent E. coli (collectively referred to as the EEC group) that cause gastroenteritis in humans. Among these is the enterohemorrhagic (EHEC) strain designated E. coli 0157:H7. E. coli is a normal inhabitant of the intestines of all animals, including humans. When aerobic culture methods are used, E. coli is the dominant species found in feces. Normally E. coli serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. A minority of E. coli strains are capable of causing human illness by several different mechanisms. E. coli serotype 0157:H7 is a rare variety of E. coli that produces large quantities of one or more related, potent toxins that cause severe damage to the lining of the intestine. These toxins [verotoxin (VT), shiga-like toxin] are closely related or identical to the toxin produced by Shigella dysenteriae.

Name of the Acute Disease: Hemorrhagic colitis is the name of the acute disease caused by E. coli 0157:H7.

Nature of the Disease: The illness is characterized by severe cramping (abdominal pain) and diarrhea which is initially watery but becomes grossly bloody. Occasionally vomiting occurs. Fever is either low-grade or absent. The illness is usually self-limited and lasts for an average of 8 days. Some individuals exhibit watery diarrhea only.

Infective Dose: Unknown, but from a compilation of outbreak data, including the organism's ability to be passed person-to-person in the day-care setting and nursing homes, the dose may be similar to that of Shigella spp. (10 organisms).

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Diagnosis of Human Illness: Hemorrhagic colitis is diagnosed by isolation of *E. coli* of serotype 0157:H7 or other verotoxin-producing *E. coli* from diarrheal stools. Alternatively, the stools can be tested directly for the presence of verotoxin. Confirmation can be obtained by isolation of *E. coli* of the same serotype from the incriminated food.

Associated Foods: Undercooked or raw hamburger (ground beef) has been implicated in nearly all documented outbreaks and in other sporadic cases. Raw milk was the vehicle in a school outbreak in Canada. In recent years unpasteurized apple cider has been epidemiologically implicated.

Relative Frequency of Disease: Hemorrhagic colitis infections are not too common, but this is probably not reflective of the true frequency. In the Pacific Northwest, *E. coli* 0157:H7 is thought to be second only to *Salmonella* as a cause of bacterial diarrhea. Because of the unmistakable symptoms of profuse, visible blood in severe cases, those victims probably seek medical attention, but less severe cases are probably more numerous.

Usual Course of Disease and Some Complications: Some victims, particularly the very young, have developed the hemolytic uremic syndrome (HUS), characterized by renal failure and hemolytic anemia. From 0 to 15% of hemorrhagic colitis victims may develop HUS. The disease can lead to permanent loss of kidney function.

In the elderly, HUS, plus two other symptoms, fever and neurologic symptoms, constitutes thrombotic thrombocytopenic purpura (TTP). This illness can have a mortality rate in the elderly as high as 50%.

History of Recent Outbreaks: Three outbreaks occurred in 1982. Two of them, one in Michigan and one in Oregon, involved hamburgers from a national fast-food chain. The third occurred in a home for the aged in Ottawa, Ontario; club sandwiches were implicated, and 19 people died. More recently, several outbreaks in nursing homes and a day-care center have been investigated. Two large outbreaks occurred in 1984, one in 1985, three in 1986. Larger outbreaks have occurred in the Northwest U.S. and Canada.

In October-November, 1986, an outbreak of hemorrhagic colitis caused by *E. coli* 0157:H7 occurred in Walla Walla, Washington. Thirty-seven people, aged 11 months to 78 years developed diarrhea caused by the organism. All isolates from patients (14) had a unique plasmid profile and produced Shiga-like toxin II. In addition to diarrhea, 36 persons reported grossly bloody stools and 36 of the 37 reported abdominal cramps. Seventeen patients were hospitalized. One patient developed HUS (4 years old) and three developed TTP (70, 78, and 78 years old). Two patients with TTP died. Ground beef was the implicated food vehicle.

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In August, 1999, the largest U.S. outbreak of hemorrhagic colitis caused by *E. coli* 0157:H7 occurred at the Washington County Fair in Greenwich, New York. Over 1,000 individuals became ill, of which hundreds were hospitalized and two deaths (a 3-year old and a 70-year old). The outbreak was traced to an untreated private water supply on the fair grounds which appears to have become contaminated by runoff from a rain storm. The aquifer was located near a dairy animal barn which had manure stored outside. The water from this aquifer was used to supply various food vendors and restroom facilities at the fair.

13. NAME OF THE ORGANISM: *Giardia lamblia*

Giardia lamblia (intestinalis) is a single celled animal, i.e., a protozoa, that moves with the aid of five flagella. In Europe, it is sometimes referred to as *Lamblia intestinalis*.

Name of the Disease: Giardiasis is the most frequent cause of non-bacterial diarrhea in North America.

Nature of the Disease: Organisms that appear identical to those that cause human illness have been isolated from domestic animals (dogs and cats) and wild animals (beavers and bears). A related but morphologically distinct organism infects rodents, although rodents may be infected with human isolates in the laboratory. Human giardiasis may involve diarrhea within 1 week of ingestion of the cyst, which is the environmental survival form and infective stage of the organism. Normally illness lasts for 1 to 2 weeks, but there are cases of chronic infections lasting months to years. Chronic cases, both those with defined immune deficiencies and those without, are difficult to treat. The disease mechanism is unknown, with some investigators reporting that the organism produces a toxin while others are unable to confirm its existence. The organism has been demonstrated inside host cells in the duodenum, but most investigators think this is such an infrequent occurrence that it is not responsible for disease symptoms. Mechanical obstruction of the absorptive surface of the intestine has been proposed as a possible pathogenic mechanism, as has a synergistic relationship with some of the intestinal flora. *Giardia* can be excysted, cultured and encysted in vitro; new isolates have bacterial, fungal, and viral symbionts. Classically the disease was diagnosed by demonstration of the organism in stained fecal smears. Several strains of *G. lamblia* have been isolated and described through analysis of their proteins and DNA; type of strain, however, is not consistently associated with disease severity. Different individuals show various degrees of symptoms when infected with the same strain, and the symptoms of an individual may vary during the course of the disease.

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Infective Dose: Ingestion of one or more cysts may cause disease, as contrasted to most bacterial illnesses where hundreds to thousands of organisms must be consumed to produce illness.

Diagnosis of Human Illness: *Giardia lamblia* is frequently diagnosed by visualizing the organism, either the trophozoite (active reproducing form) or the cyst (the resting stage that is resistant to adverse environmental conditions) in stained preparations or unstained wet mounts with the aid of a microscope. A commercial fluorescent antibody kit is available to stain the organism. Organisms may be concentrated by sedimentation or flotation; however, these procedures reduce the number of recognizable organisms in the sample. An enzyme linked immunosorbant assay (ELISA) that detects excretory secretory products of the

organism is also available. So far, the increased sensitivity of indirect serological detection has not been consistently demonstrated.

Associated Foods: Giardiasis is most frequently associated with the consumption of contaminated water. Five outbreaks have been traced to food contamination by infected or infested food handlers, and the possibility of infections from contaminated vegetables that are eaten raw cannot be excluded. Cool moist conditions favor the survival of the organism.

Relative Frequency of Disease: Giardiasis is more prevalent in children than in adults, possibly because many individuals seem to have a lasting immunity after infection. This organism is implicated in 25% of the cases of gastrointestinal disease and may be present asymptotically. The overall incidence of infection in the United States is estimated at 2% of the population. This disease afflicts many homosexual men, both HIV-positive and HIV-negative individuals. This is presumed to be due to sexual transmission. The disease is also common in child day care centers, especially those in which diapering is done.

Major Outbreaks: Major outbreaks are associated with contaminated water systems that do not use sand filtration or have a defect in the filtration system. The largest reported foodborne outbreak involved 24 to 36 persons who consumed macaroni salad at a picnic.

14. NAME OF THE ORGANISM: Hepatitis A Virus

Hepatitis A. virus (HAV) is classified with the enterovirus group of the Picornaviridae family. HAV has a single molecule of RNA surrounded by a small (27 nm diameter) protein capsid and a buoyant density in CsCl of 1.22 g/ml. Many other picornaviruses cause human disease, including polioviruses, coxsackieviruses, echoviruses, and rhinoviruses (cold viruses).

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Name of the Acute Disease: The term hepatitis A (HA) or type A viral hepatitis has replaced all previous designations: Infectious hepatitis, epidemic hepatitis, epidemic jaundice, catarrhal jaundice, infectious icterus, Botkins disease, and MS-1 hepatitis.

Name of the Disease: Hepatitis A is usually a mild illness characterized by sudden onset of fever, malaise, nausea, anorexia, and abdominal discomfort, followed in several days by jaundice. The infectious dose is unknown but presumably is 10-100 virus particles.

Diagnosis of Human Illness: Hepatitis A is diagnosed by finding IgM-class anti-HAV in serum collected during the acute or early convalescent phase of disease. Commercial kits are available.

Associated Foods: HAV is excreted in feces of infected people and can produce clinical disease when susceptible individuals consume contaminated water or foods. Cold cuts and

sandwiches, fruits and fruit juices, milk and milk products, vegetables, salads, shellfish, and iced drinks are commonly implicated in outbreaks. Water, shellfish, and salads are the most frequent sources. Contamination of foods by infected workers in food processing plants and restaurants is common.

15. NAME OF THE ORGANISM: *Listeria monocytogenes*

This is a Gram-positive bacterium, motile by means of flagella. Some studies suggest that 1-10% of humans may be intestinal carriers of *L. monocytogenes*. It has been found in at least 37 mammalian species, both domestic and feral, as well as at least 17 species of birds and possibly some species of fish and shellfish. It can be isolated from soil, silage, and other environmental sources. *L. monocytogenes* is quite hardy and resists the deleterious effects of freezing, drying and heat remarkably well for a bacterium that does not form spores. Most *L. monocytogenes* are pathogenic to some degree.

Name of the Acute Disease: Listeriosis is the name of the general group of disorders caused by *L. monocytogenes*.

Nature of the Disease: Listeriosis is clinically defined when the organism is isolated from blood, cerebrospinal fluid, or an otherwise normally sterile site (e.g. placenta, fetus).

The manifestations of listeriosis include septicemia, meningitis (or meningoencephalitis), encephalitis, and intrauterine or cervical infections in pregnant women, which may result in spontaneous abortion (2nd/3rd trimester) or stillbirth. The onset of the aforementioned disorders is usually preceded by influenza-like symptoms including persistent fever. It was recently reported that gastrointestinal symptoms such as nausea, vomiting, and diarrhea may

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precede more serious forms of listeriosis or may be the only symptoms expressed. Gastrointestinal symptoms were epidemiologically associated with use of antacids or cimetidine. The onset time to serious forms of listeriosis is unknown but may range from a few days to three weeks. The onset time to gastrointestinal symptoms is unknown but is probably greater than 12 hours.

Infective Dose: Unknown, but is believed to vary with the strain and susceptibility of the victim. From cases contracted through raw or supposedly pasteurized milk, it is safe to assume that in susceptible persons, fewer than 1,000 total organisms may cause disease. *L. monocytogenes* may invade the gastrointestinal epithelium. Once the bacterium enters the host's monocytes, macrophages, or polymorphonuclear leukocytes, it is bloodborne (septicemic) and can grow. Its presence intracellularly in phagocytic cells also permits access to the brain and probably transplacental migration to the fetus in pregnant women. The

pathogenesis of *L. monocytogenes* centers on its ability to survive and multiply in phagocytic host cells.

Diagnosis of Human Illness: Listeriosis can only be positively diagnosed by culturing the organism from blood, cerebrospinal fluid, or stool (although the latter is difficult and of limited value).

Associated Foods: *L. monocytogenes* has been associated with such foods as raw milk, supposedly pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish. Its ability to grow at temperatures as low as 3°C (37.4°F) permits multiplication in refrigerated foods.

Frequency of the Disease: The 1987 incidence data prospectively collected by CDC suggests that there are at least 1,600 cases of listeriosis with 415 deaths per year in the U.S. The vast majority of cases are sporadic, making epidemiological links to food very difficult.

Recent Outbreaks: Recent outbreaks include the California episode in 1985, which was due to Mexican-style cheese and led to numerous stillbirths. As a result of this episode, FDA has been monitoring domestic and imported cheeses and has taken numerous actions to remove these products from the market when *L. monocytogenes* is found.

There have been other clustered cases, such as in Philadelphia, Pennsylvania, in 1987. Specific food linkages were only made epidemiologically in this cluster.

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CDC has established an epidemiological link between consumption of raw hot dogs or undercooked chicken and approximately 20% of the sporadic cases under prospective study.

16. NAME OF THE ORGANISM: The Norwalk virus family

Norwalk virus is the prototype of a family of unclassified small round structured viruses (SRSVs) which may be related to the caliciviruses. They contain a positive strand RNA genome of 7.5 kb and a single structural protein of about 60 kDa. The 27-32 nm viral particles have a buoyant density of 1.39-1.40 g/ml in CsCl. The family consists of several serologically distinct groups of viruses that have been named after the places where the outbreaks occurred. In the U.S., the Norwalk and Montgomery County agents are serologically related but distinct from the Hawaii and Snow Mountain agents. The Taunton, Moorcroft, Barnett, and Amulree agents were identified in the U.K., and the Sapporo and Otofuke agents in Japan. Their serological relationships remain to be determined.

Name of the Acute Disease: Common names of the illness caused by the Norwalk and Norwalk-like viruses are viral gastroenteritis, acute nonbacterial gastroenteritis, food poisoning, and food infection.

Nature of the Disease: The disease is self-limiting, mild, and characterized by nausea, vomiting, diarrhea and abdominal pain. Headache and low-grade fever may occur. The infectious dose is unknown but presumed to be low.

Diagnosis of Human Illness: Specific diagnosis of the disease can only be made by a few laboratories possessing reagents from human volunteer studies. Identification of the virus can be made on early stool specimens using immune electron microscopy and various immunoassays. Confirmation often requires demonstration of seroconversion, the presence of specific IgM antibody, or a four-fold rise in antibody titer to Norwalk virus on paired acute-convalescent sera.

Associated Foods: Norwalk gastroenteritis is transmitted by the fecal-oral route via contaminated water and foods. Secondary person-to-person transmission has been documented. Water is the most common source of outbreaks and may include water from municipal supplies, well, recreational lakes, swimming pools and water stored aboard cruise ships.

Shellfish and salad ingredients are the foods most often implicated in Norwalk outbreaks. Ingestion of raw or insufficiently steamed clams and oysters poses a high risk for infection with Norwalk virus. Foods other than shellfish are contaminated by ill food handlers.

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History of Recent Outbreaks: Foodborne outbreaks of gastroenteritis caused by Norwalk virus are often related to consumption of raw shellfish. Frequent and widespread outbreaks, reaching epidemic proportions, occurred in Australia (1978) and in the state of New York (1982) among consumers of raw clams and oysters. From 1983 to 1987, ten well documented outbreaks caused by Norwalk virus were reported in the U.S., involving a variety of foods: fruits, salads, eggs, clams, and bakery items.

Preliminary evidence suggests that large outbreaks of gastroenteritis which occurred in Pennsylvania and Delaware in September, 1987, were caused by Norwalk virus. The source of both outbreaks was traced to ice made with water from a contaminated well. In Pennsylvania, the ice was consumed at a football game, and in Delaware, at a cocktail party. Norwalk virus is also suspected to have caused an outbreak aboard a cruise ship in Hawaii in 1990. Fresh fruits were the probable vehicle of contamination.

Snow Mountain virus was implicated in an outbreak in a retirement community in California (1988) which resulted in two deaths. Illness was associated with consumption of shrimp probably contaminated by food handlers.

17. NAME OF THE ORGANISM: Other Viruses Associated with Gastroenteritis

Although the rotavirus and the Norwalk family of viruses are the leading causes of viral gastroenteritis, a number of other viruses have been implicated in outbreaks, including astroviruses, caliciviruses, enteric adenoviruses and parvovirus. Astroviruses, caliciviruses, and the Norwalk family of viruses possess well-defined surface structures and are sometimes identified as “small round structured viruses” or SRSVs. Viruses with smooth edge and no discernible surface structure are designated “featureless viruses” or “small round viruses” (SRVs). These agents resemble enterovirus or parvovirus, and may be related to them.

Name of the Acute Disease: Common names of the illness caused by these viruses are acute nonbacterial infectious gastroenteritis and viral gastroenteritis.

Nature of the Disease: Viral gastroenteritis is usually a mild illness characterized by nausea, vomiting, diarrhea, malaise, abdominal pain, headache, and fever.

Infective Dose: Not known, but is presumed to be low.

Diagnosis of Human Illness: Specific diagnosis of the disease can be made by some laboratories possessing appropriate reagents. Identification of the virus present in early acute stool samples is made by immune electron microscopy and various enzyme immunoassays. Confirmation often requires demonstration of seroconversion to the agent by serological tests on acute and convalescent serum pairs.

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Associated Foods: Viral gastroenteritis is transmitted by the fecal-oral route via person-to-person contact or ingestion of contaminated foods and water. Ill food handlers may contaminate foods that are not further cooked before consumption.

History of Recent Outbreaks: Outbreaks of astrovirus and calicivirus occur mainly in child care settings and nursing homes.

Outbreaks of adenovirus have been reported in England and Japan, all involving children in hospitals or day care centers.

The small featureless parvo-like viruses caused outbreaks of gastroenteritis in primary and secondary schools in England and Australia. The cockle agent caused a large community-wide outbreak in England (1977) associated with consumption of contaminated seafood. Parvo-like viruses were also implicated in several outbreaks which occurred in the States of New York and Louisiana in 1982-1983.

18. NAME OF THE ORGANISM: Salmonella spp.

Salmonella is a rod-shaped, motile bacterium (nonmotile exceptions *S. gallinarum* and *S. pullorum*), nonsporeforming and Gram-negative. There is a widespread occurrence in animals, especially in poultry and swine. Environmental sources of the organism include water, soil, insects, factory surfaces, kitchen surfaces, animal feces, raw meats, raw poultry, and raw seafoods, to name only a few.

Nature of the Acute Disease: *S. typhi* and the paratyphoid bacteria are normally septicemic and produce typhoid or typhoid-like fever in humans. Other forms of salmonellosis generally produce milder symptoms.

Nature of the Disease: Acute symptoms - Nausea, vomiting, abdominal cramps, diarrhea, fever and headache. Chronic consequences - arthritic symptoms may follow 3-4 weeks after onset of acute symptoms.

Onset Time: 6-48 hours

Infective Dose: As few as 15-20 cells; depends upon age and health of host, and strain differences among the members of the genus.

Duration of Symptoms: Acute symptoms may last for 1 to 2 days or may be prolonged, again depending on host factors, ingested dose, and strain characteristics.

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Cause of Disease: Penetration and passage of Salmonella organisms from gut lumen into epithelium of small intestine where inflammation occurs; there is evidence that an enterotoxin may be produced, perhaps within the enterocyte.

Diagnosis of Human Illness: Serological identification of culture isolated from stool.

Associated Foods: Raw meats, poultry, eggs, milk and dairy products, fish, shrimp, frog legs, yeast, coconut, sauces and salad dressing, cake mixes, cream-filled desserts and toppings, dried gelatin, peanut butter, cocoa and chocolate. Various Salmonella species have long been isolated from the outside of egg shells. The present situation with *S. enteritidis* is complicated by the presence of the organism inside the egg, in the yolk. This and other information strongly suggest vertical transmission, i.e., deposition of the organism in the yolk by an infected layer hen prior to shell deposition. Foods other than eggs have also caused outbreaks of *S. enteritidis* disease.

Relative Frequency of Disease: It is estimated that from 2 to 4 million cases of salmonellosis occur in the U.S. annually.

The incidence of salmonellosis appears to be rising both in the U.S. and in other industrialized nations. *S. enteritidis* isolations from humans have shown a dramatic rise in the past decade, particularly in the northeast United States (6-fold or more), and the increase in human infections is spreading south and west, with sporadic outbreaks in other regions.

Major Outbreaks: Salmonellosis outbreaks of varying size caused by all *Salmonella* spp. occur rather regularly throughout the U.S.

In 1985, a salmonellosis outbreak involving 16,000 confirmed cases in 6 states was caused by low fat and whole milk from one Chicago dairy. This was the largest outbreak of foodborne salmonellosis in the U.S. FDA inspectors discovered that the pasteurization equipment had been modified to facilitate the running off of raw milk, resulting in the pasteurized milk being contaminated with raw milk under certain conditions. The dairy has subsequently disconnected the cross-linking line. Persons on antibiotic therapy were more apt to be affected in this outbreak.

In August and September, 1985, *S. enteritidis* was isolated from employees and patrons of three restaurants of a chain in Maryland. The outbreak in one restaurant had at least 71 illnesses resulting in 17 hospitalizations. Scrambled eggs from a breakfast bar were epidemiologically implicated in this outbreak and in possibly one other of the three restaurants. The plasmid profiles of isolates from patients all three restaurants matched.

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The Centers for Disease Control (CDC) has recorded >120 outbreaks of *S. enteritidis* to date, many occurring in restaurants, and some in nursing homes, hospitals and prisons. In 1984, 186 cases of salmonellosis (*S. enteritidis*) were reported on 29 flights to the United States on a single international airline. An estimated 2,747 passengers were affected overall. No specific food item was implicated, but food ordered from the first class menu was strongly associated with disease.

S. enteritidis outbreaks continue to occur in the U.S. The CDC estimates that 75% of those outbreaks are associated with the consumption of raw or inadequately cooked Grade A whole shell eggs. The U.S. Department of Agriculture published Regulations on February 16, 1990, in the Federal Register establishing a mandatory testing program for egg-producing breeder flocks and commercial flocks implicated in causing human illnesses. This testing should lead to a reduction in cases of gastroenteritis caused by the consumption of Grade A whole shell eggs.

19. NAME OF TOXIN: Scombrototoxin

Name of Acute Disease: Scombroid Poisoning (also called Histamine Poisoning)

Scombroid poisoning is caused by the ingestion of foods that contain high levels of histamine and possibly other vasoactive amines and compounds. Histamine and other amines are formed by the growth of certain bacteria and the subsequent action of their decarboxylase enzymes on histidine and other amino acids in food, either during the production of a product such as Swiss cheese or by spoilage of foods such as fishery products, particularly tuna or mahi mahi. However, any food that contains the appropriate amino acids and is subjected to certain bacterial contamination and growth may lead to scombroid poisoning when ingested.

Nature of the Disease: Initial symptoms may include a tingling or burning sensation in the mouth, a rash on the upper body and a drop in blood pressure. Frequently, headaches and itching of the skin are encountered. The symptoms may progress to nausea, vomiting, and diarrhea and may require hospitalization, particularly in the case of elderly or impaired patients.

Normal Course of Disease: The onset of intoxication symptoms is rapid, ranging from immediate to 30 minutes. The duration of the illness is usually 3 hours, but may last several days.

Diagnosis of Human Illness: Diagnosis of the illness is usually based on the patient's symptoms, time of onset, and the effect of treatment with antihistamine medication. The suspected food must be analyzed within a few hours for elevated levels of histamine to confirm a diagnosis.

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Associated Foods: Fishery products that have been implicated in scombroid poisoning include the tunas (e.g., skipjack and yellowfin), mahi mahi, bluefish, sardines, mackerel, amberjack, and abalone. Many other products also have caused the toxic effects. The primary cheese involved in intoxications has been Swiss cheese. The toxin forms in a food when certain bacteria are present and time and temperature permit their growth. Distribution of the toxin within an individual fish fillet or between cans in a case lot can be uneven, with some sections of a product causing illnesses and others not. Neither cooking, canning, or freezing reduces the toxic effect. Common sensory examination by the consumer cannot ensure the absence or presence of the toxin. Chemical testing is the only reliable test for evaluation of a product.

Relative Frequency of Disease: Scombroid poisoning remains one of the most common forms of fish poisoning in the United States. Even so, incidents of poisoning often go unreported because of the lack of required reporting, a lack of information by some medical personnel, and confusion with the symptoms of other illnesses. Difficulties with underreporting are a worldwide problem. In the United States from 1968 to 1980, 103 incidents of intoxication involving 827 people were reported. For the same period in Japan, where the quality of fish is a national priority, 42 incidents involving 4,122 people were recorded. Since 1978, 2 actions by FDA have reduced the frequency of intoxications caused by specific products. A defect action level for histamine in canned tuna resulted in increased industry quality control. Secondly, blacklisting of mahi mahi reduced the level of fish imported to the United States.

History of Recent Outbreaks: Several large outbreaks of scombroid poisoning have been reported. In 1970, some 40 children in a school lunch program became ill from imported canned tuna. In 1973, more than 200 consumers across the United States were affected by domestic canned tuna. In 1979-1980 more than 200 individuals became ill after consuming imported frozen mahi mahi. Symptoms varied with each incident. In the 1973 situation, of the interviewed patients, 86% experienced nausea, 55% diarrhea, 44% headaches and 32% rashes.

More recent incidents of intoxication have resulted from the consumption of canned abalone-like products, canned anchovies, and fresh and frozen amberjack, bluefish sole, and scallops. In particular, shipments of unfrozen fish packed in refrigerated containers have posed a significant problem because of inadequate temperature control.

20. NAME OF THE ORGANISM: *Shigella* spp. (*Shigella* *sonei*, *S. boydii*, *S. flexneri*, and *S. dysenteriae*)

Shigella are Gram-negative, nonmotile, non sporeforming rod-shaped bacteria. The illness caused by *Shigella* (shigellosis) accounts for less than 10% of the reported outbreaks of foodborne illness in this country. *Shigella* rarely occurs in animals; principally a disease of

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humans except other primates such as monkeys and chimpanzees. The organism is frequently found in water polluted with human feces.

Name of the Disease: Shigellosis (bacillary dysentery).

Nature of the Disease: Symptoms - Abdominal pain; cramps; diarrhea; fever; vomiting; blood, pus, or mucus in stools; tenesmus.

Onset time - 12 to 50 hours.

Infective Dose: As few as 10 cells depending on age and condition of host. The *Shigella* spp. are highly infectious agents that are transmitted by the fecal-oral route.

The disease is caused when virulent *Shigella* organisms attach to, and penetrate, epithelial cells of the intestinal mucosa. After invasion, they multiply intracellularly, and spread to contiguous epithelial cells resulting in tissue destruction. Some strains produce enterotoxin and Shiga toxin (very much like the verotoxin of *E. coli* 0157:H7).

Diagnosis of Human Illness: Serological identification of culture isolated from stool.

Associated Foods: Salads (potato, tuna, shrimp, macaroni and chicken) raw vegetables, milk and dairy products, and poultry. Contamination of these foods is usually through the fecal-oral route. Fecally contaminated water and unsanitary handling by food handlers are the most common causes of contamination.

Relative Frequency of Disease: An estimated 300,000 cases of shigellosis occur annually in the U.S. The number attributable to food is unknown, but given the low infectious dose, it is probably substantial.

Recent Outbreaks: In the U.S., foodborne outbreaks of shigellosis have occurred in several documented instances.

In 1985, a huge outbreak of foodborne shigellosis occurred in Midland-Odessa, Texas, involving perhaps as many as 5,000 persons. The implicated food was chopped, bagged lettuce, prepared in a central location for a Mexican restaurant chain. FDA research subsequently showed that *S. sonnei*, the isolate from the lettuce, could survive in chopped lettuce under refrigeration, and the lettuce remained fresh and appeared to be quite edible.

In 1985-86, several outbreaks of shigellosis occurred on college campuses, usually associated with fresh vegetables from the salad bar. Usually an ill food service worker was shown to be

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the cause. In 1987, several very large outbreaks of shigellosis (*S. sonnei*) occurred involving thousands of persons, but no specific food vector could be proven.

In 1988, numerous individuals contracted shigellosis from food consumed aboard Northwest Airlines flights; food on these flights had been prepared in one central commissary. No specific food item was implicated but various sandwiches were suspected.

Note: Although all *Shigella* spp. have been implicated in foodborne outbreaks at some time, *S. sonnei* is clearly the leading cause of shigellosis from food. The other species are more

closely associated with contaminated water. One in particular, *S. flexneri*, is now thought to be in large part sexually transmitted.

21. NAME OF THE ORGANISM: *Staphylococcus aureus*

S. aureus is a spherical bacterium (coccus) which on microscopic examination appears in pairs, short chains, or bunched, grape-like clusters. These organisms are Gram-positive. Some strains are capable of producing a highly heat-stable protein toxin that causes illness in humans.

Name of the Acute Disease: Staphylococcal food poisoning (staphyloenterotoxigenosis; staphyloenterotoxemia) is the name of the condition caused by the enterotoxins which some strains of *S. aureus* produce.

Nature of the Disease: The onset of symptoms in staphylococcal food poisoning is usually rapid and in many cases acute, depending on individual susceptibility to the toxin, the amount of contaminated food eaten, the amount of toxin in the food ingested, and the general health of the victim. The most common symptoms are nausea, vomiting, retching, abdominal cramping, and prostration. Some individuals may not always demonstrate all the symptoms associated with the illness. In more severe cases, headache, muscle cramping, and transient changes in blood pressure and pulse rate may occur. Recovery generally takes two days, however, it is not unusual for complete recovery to take three days and sometimes longer in severe cases.

Infective Dose: A toxin dose of less than 1.0 microgram in contaminated food will produce symptoms of staphylococcal intoxication. This toxin level is reached when *S. aureus* populations exceed 10^5 [100,000] per gram.

Diagnosis of Human Illness: In the diagnosis of staphylococcal foodborne illness, proper interviews with the victims and gathering and analyzing epidemiologic data are essential. Incriminated foods should be collected and examined for staphylococci. The presence of relatively large numbers of enterotoxigenic staphylococci is good circumstantial evidence that the food contains toxin. The most conclusive test is the linking of an illness with a specific

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food or in cases where multiple vehicles exist, the detection of the toxin in the food sample(s). In cases where the food may have been treated to kill the staphylococci, as in pasteurization or heating, direct microscopic observation of the food may be an aid in the diagnosis. A number of serological methods for determining the enterotoxigenicity of *S. aureus* isolated from foods as well as methods for the separation and detection of toxins in foods have been developed and used successfully to aid in the diagnosis of the illness. Phage typing may also be useful when viable staphylococci can be isolated from the incriminated food, from victims, and from suspected carrier such as food handlers.

Foods Incriminated: Foods that are frequently incriminated in staphylococcal food poisoning include meat and meat products; poultry and egg products; salads such as egg, tuna, chicken, potato, and macaroni; bakery products such as cream-filled pastries, cream pies, and chocolate eclairs; sandwich fillings; and milk and dairy products. Foods that require considerable handling during preparation and that are kept at slightly elevated temperatures after preparation are frequently involved in staphylococcal food poisoning.

Staphylococci exist in air, dust, sewage, water, milk, and food or on food equipment, environmental surfaces, humans and animals. Humans and animals are the primary reservoirs. Staphylococci are present in the nasal passages and throats and on the hair and skin of 50 percent or more of healthy individuals. This incidence is even higher for those who associate with or who come in contact with sick individuals and hospital environments. Although food handlers are usually the main source of food contamination in food poisoning outbreaks, equipment and environmental surfaces can also be sources of contamination with *S. aureus*. Human intoxication is caused by ingesting enterotoxins produced in food by some strains of *S. aureus*, usually because the food has not been kept hot enough (60°C, 140°F, or above) or cold enough (7.2°C, 45°F, or below).

Frequency of Illness: The true incidence of staphylococcal food poisoning is unknown for a number of reasons including poor responses from victims during interviews with health officials; misdiagnosis of the illness, which may be symptomatically similar to other types of food poisoning (such as vomiting caused by *Bacillus cereus* toxin); inadequate collection of samples for laboratory analyses; and improper laboratory examination. Of the bacterial pathogens causing foodborne illnesses in the U.S. (127 outbreaks, 7,082 cases recorded in 1983), 14 outbreaks involving 1,257 cases were caused by *S. aureus*. These outbreaks were followed by 11 outbreaks (1,153 cases) in 1984, 14 outbreaks (421 cases) in 1985, 7 outbreaks (250 cases) in 1986 and one reported outbreak (100 cases) in 1987.

Typical Outbreak: Recently, 1,364 children became ill out of a total of 5,824 who had eaten lunch served at 16 elementary schools in Texas. The lunches were prepared in a central kitchen and transported to the schools by truck. Epidemiological studies revealed that 95% of the children who became ill had eaten a chicken salad. The afternoon of the day preceding the

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lunch, frozen chickens were boiled for 3 hours. After cooking, the chickens were deboned, cooled to room temperature with a fan, ground into small pieces, placed into 12-inch-deep aluminum pans and stored overnight in a walk-in refrigerator at 42-45°F. The following morning, the remaining ingredients of the salad were added and the mixture was blended with an electric mixer. The food was placed in thermal containers and transported to the various schools at 9:30 a.m. to 10:30 a.m., where it was kept at room temperature until served between 11:30 a.m. and Noon. Bacteriological examination of the chicken salad revealed the presence of large numbers of *S. aureus*.

Contamination of the chicken probably occurred when it was deboned. The chicken was not cooled rapidly enough because it was stored in 12-inch-deep layers. Growth of the staphylococcus probably occurred also during the period when the food was kept in the warm classrooms. Prevention of this incident would have entailed screening the individuals who deboned the chicken for carriers of the staphylococcus, more rapid cooling of the chicken, and adequate refrigeration of the salad from the time of preparation to its consumption.

22. **NAME OF TOXINS: Tetrodotoxin (anhydrotetrodotoxin, 4-epitetrodotoxin, tetrodonic acid)**

Name of the Acute Disease: Pufferfish Poisoning, Tetradon Poisoning, Fugu Poisoning

Nature of the Disease: Fish poisoning by consumption of members of the order Tetraodontiformes is one of the most violent intoxications from marine species. The gonads, liver, intestines, and skin of pufferfish can contain levels of tetrodotoxin sufficient to produce rapid and violent death. The flesh of many pufferfish may not usually be dangerously toxic. Tetrodotoxin has also been isolated from widely differing animal species, including the California newt, parrotfish, frogs of the genus *Atelopus*, the blue-ringed octopus, starfish, angelfish, and xanthid crabs. The metabolic source of tetrodotoxin is uncertain. No algal source has been identified, and until recently tetrodotoxin was assumed to be a metabolic product of the host. However, recent reports of the production of tetrodotoxin/anhydrotetrodotoxin by several bacterial species, including strains of the family Vibrionaceae, *Pseudomonas* sp., and *Photobacterium phosphoreum*, point toward a bacterial origin of this family of toxins. These are relatively common marine bacteria that are often associated with marine animals. If confirmed, these findings may have some significance in toxicoses that have been more directly related to these bacterial species.

Normal Course of the Disease: The first symptom of intoxication is a slight numbness of the lips and tongue, appearing between 20 minutes to three hours after eating poisonous pufferfish. The next symptom is increasing paraesthesia in the face and extremities, which may be followed by sensations of lightness or floating. Headache, epigastric pain, nausea, diarrhea, and/or vomiting may occur. Occasionally, some reeling or difficulty in walking may occur.

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The second stage of the intoxication is increasing paralysis. Many victims are unable to move; even sitting may be difficult. There is increasing respiratory distress. Speech is affected, and the victim usually exhibits dyspnea, cyanosis, and hypotension. Paralysis increases and convulsions, mental impairment and cardiac arrhythmia may occur. The victim, although completely paralyzed, may be conscious and in some cases completely lucid until shortly before death. Death usually occurs within 4 to 6 hours, with a known range of about 20 minutes to 8 hours.

Diagnosis of Human Illness: The diagnosis of pufferfish poisoning is based on the observed symptomology and recent dietary history.

Associated Foods: Poisonings from tetrodotoxin have been almost exclusively associated with the consumption of pufferfish from waters of the Indo-Pacific ocean regions. Several reported cases of poisonings, including fatalities, involved pufferfish from the Atlantic Ocean, Gulf of Mexico, and Gulf of California. There have been no confirmed cases of poisoning from the Atlantic pufferfish, *Spherooides maculatus*. However, in one study, extracts from fish of this species were highly toxic in mice. The trumpet shell *Charonia sauliae* has been implicated in food poisonings, and evidence suggests that it contains a tetrodotoxin derivative. There have been several reported poisonings from mislabeled pufferfish and at least one report of a fatal episode when an individual swallowed a California newt.

Relative Frequency of the Disease: From 1974 through 1983 there were 646 reported cases of pufferfish poisoning in Japan, with 179 fatalities. Estimates as high as 200 cases per year with mortality approaching 50% have been reported. Only a few cases have been reported in the United States, and outbreaks in countries outside the Indo-Pacific area are rare.

History of Recent Outbreaks: Pufferfish poisoning is a continuing problem in Japan, affecting 30-100 persons a year. Most of these poisoning episodes occur from home preparation and consumption and not from commercial sources of the pufferfish. Three deaths were reported in Italy in 1977 following the consumption of frozen pufferfish imported from Taiwan and mislabeled as angler fish.

23. NAME OF TOXINS: Various Shellfish-Associated

Shellfish poisoning is caused by a group of toxins elaborated by planktonic algae (dinoflagellates, in most cases) upon which the shellfish feed. The toxins are accumulated and sometimes metabolized by the shellfish. The 20 toxins responsible for paralytic shellfish poisonings (PSP) are all derivatives of saxitoxin. Diarrheic shellfish poisoning (DSP) is presumably caused by a group of high molecular weight polyethers, including okadaic acid, the dinophysins, the pectenotoxins, and yessotoxin. Neurotoxic shellfish poisoning (NSP) is

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the result of exposure to a group of polyethers called brevetoxins. Amnesic shellfish poisoning (ASP) is caused by the unusual amino acid, domoic acid, as the contaminant of shellfish.

Name of the Acute Diseases: Shellfish Poisoning: Paralytic Shellfish Poisoning (PSP), Diarrheic Shellfish Poisoning (DSP), Neurotoxic Shellfish Poisoning (NSP), Amnesic Shellfish Poisoning (ASP).

Nature of the Diseases: Ingestion of contaminated shellfish results in a wide variety of symptoms, depending upon the toxin(s) present, their concentrations in the shellfish and the amount of contaminated shellfish consumed. In the case of PSP, the effects are predominantly neurological and include tingling, burning, numbness, drowsiness, incoherent speech, and respiratory paralysis. Less well characterized are the symptoms associated with DSP, NSP, and ASP. DSP is primarily observed as a generally mild gastrointestinal disorder, i.e., nausea, vomiting, diarrhea, and abdominal pain accompanied by chills, headache, and fever. Both gastrointestinal and neurological symptoms characterize NSP, including tingling and numbness of lips, tongue, and throat, muscular aches, dizziness, reversal of the sensations of hot and cold, diarrhea, and vomiting. ASP is characterized by gastrointestinal disorders (vomiting, diarrhea, abdominal pain) and neurological problems (confusion, memory loss, disorientation, seizure, coma).

Normal Course of the Disease:

PSP: Symptoms of the disease develop fairly rapidly, within 0.5 to 2 hours after ingestion of the shellfish, depending on the amount of toxin consumed. In severe cases respiratory paralysis is common, and death may occur if respiratory support is not provided. When such support is applied within 12 hours of exposure, recovery usually is complete, with no lasting side effects. In unusual cases, because of the weak hypotensive action of the toxin, death may occur from cardiovascular collapse despite respiratory support.

NSP: Onset of this disease occurs within a few minutes to a few hours; duration is fairly short, from a few hours to several days. Recovery is complete with few after effects; no fatalities have been reported.

DSP: Onset of the disease, depending on the dose of toxin ingested, may be as little as 30 minutes to 2 to 3 hours, with symptoms of the illness lasting as long as 2 to 3 days. Recovery is complete with no after effects; the disease is generally not life threatening.

ASP: The toxicosis is characterized by the onset of gastrointestinal symptoms within 24 hours; neurological symptoms occur with 48 hours. The toxicosis is particularly serious in elderly patients, and includes symptoms reminiscent of Alzheimer's disease. All fatalities to date have involved elderly patients.

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Diagnosis of Human Illnesses: Diagnosis of shellfish poisoning is based entirely on observed symptomatology and recent dietary history.

Associated Foods: All shellfish (filter-feeding molluscs) are potentially toxic. However, PSP is generally associated with mussels, clams, cockles, and scallops; NSP with shellfish harvested along the Florida coast and the Gulf of Mexico; DSP with mussels, oysters, and scallops, and ASP with mussels.

History of Recent Outbreaks: PSP is associated with relatively few outbreaks, most likely because of the strong control programs in the United States that prevent human exposure to toxic shellfish. That PSP can be a serious public health problem, however, was demonstrated in Guatemala, where an outbreak of 187 cases with 26 deaths, recorded in 1987, resulted from ingestion of a clam soup. The outbreak led to the establishment of a control program over shellfish harvested in Guatemala.

ASP first came to the attention of public health authorities in 1987 when 156 cases of acute intoxication occurred as a result of ingestion of cultured blue mussels (*Mytilus edulis*) harvested off Prince Edward Island, in eastern Canada; 22 individuals were hospitalized and three elderly patients eventually died.

The occurrence of DSP in Europe is sporadic, continuous and presumably widespread (anecdotal). DSP poisoning has not been confirmed in U.S. seafood, but the organisms that produce DSP are present in U.S. waters. An outbreak of DSP was recently confirmed in Eastern Canada. Outbreaks of NSP are sporadic and continuous along the Gulf coast of Florida and were recently reported in North Carolina and Texas.

24. NAME OF THE ORGANISM: *Vibrio parahaemolyticus* (and other marine *Vibrio* spp.)**

This bacterium is frequently isolated from the estuarine and marine environment of the United States. Both pathogenic and non-pathogenic forms of the organism can be isolated from marine and estuarine environments and from fish and shellfish dwelling in these environments.

Name of the Acute Disease: *V. parahaemolyticus*-associated gastroenteritis is the name of the infection caused by this organism.

Nature of the Disease: Diarrhea, abdominal cramps, nausea, vomiting, headache, fever, and chills may be associated with infections caused by this organism. The illness is usually mild or moderate, although some cases may require hospitalization. The median duration of the illness is 2.5 days. The incubation period is 4-96 hours after the ingestion of the organism, with a

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mean of 15 hours. Disease is caused when the organism attaches itself to an individual's small intestine and excretes an as-yet unidentified toxin.

Infective Dose: A total dose of greater than one million organisms may cause disease; this is markedly lowered by antacids (or presumably by food with buffering capability).

Diagnosis of Human Illness: Diagnosis of gastroenteritis caused by this organism is made by culturing the organism from the diarrheic stools of an individual.

Associated Foods: Infections with this organism have been associated with the consumption of raw, improperly cooked, or cooked, recontaminated fish and shellfish. A correlation exists between the probability of infection and warmer months of the year. Improper refrigeration of seafoods contaminated with this organism will allow its proliferation, which increases the possibility of infection.

Relative Frequency of Disease: Major outbreaks have occurred in the U.S. during the warmer months of the year. Sporadic cases occur frequently along all coasts of the U.S.

The Usual Course of the Disease: Diarrhea caused by this organism is usually self-limiting, with few cases requiring hospitalization and/or antibiotic treatment.

Outbreaks: Sporadic outbreaks of gastroenteritis caused by this organism have occurred in the U.S. and cases are more common during the warmer months. It is very common in Japan, where large outbreaks occur with regularity.

****OTHER MARINE VIBRIOS IMPLICATED IN FOODBORNE DISEASE:**

Several other marine vibrios have been implicated in human disease. Some may cause wound or ear infections and others, gastroenteritis. The amount of evidence for certain of these organisms as being causative of human gastroenteritis is small. Nonetheless, several have been isolated from human feces from diarrhea patients from which no other pathogens could be isolated. Methods for recovery of these organisms from foods are similar to those used for recovery of *V. parahaemolyticus*. The species implicated in human disease include:

<i>Vibrio alginolyticus</i>	<i>Vibrio furnissii</i>
<i>Vibrio carchariae</i>	<i>Vibrio hollisae</i>
<i>Vibrio cincinnatiensis</i>	<i>Vibrio metschnikovii</i>
<i>Vibrio damsela</i>	<i>Vibrio mimicus</i>
<i>Vibrio fluvialis</i>	

25. NAME OF THE ORGANISM: *Vibrio vulnificus*

This bacterium infects only humans and other primates. It has been isolated from a wide range of environmental sources, including water, sediment, plankton, and shellfish (oysters, clams

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and crabs) and a variety of locations, including the Gulf of Mexico, the Atlantic Coast as far north as Cape Cod, and the entire U.S. west coast. Cases of illness have also been associated with brackish lakes in New Mexico and Oklahoma.

Name of the Acute Disease: This organism causes wound infections, gastroenteritis, or a syndrome known as “primary septicemia.”

Nature of the Disease: Wound infections result either from contaminating an open wound with sea water harboring the organism, or by lacerating part of the body on coral, fish, etc., followed by contamination with the organism. The ingestion of *V. vulnificus* by healthy individuals can result in gastroenteritis. The “primary septicemia” form of the disease follows consumption of raw seafood containing the organism by individuals with underlying chronic disease, particularly liver disease (see below). In these individuals the microorganism enters the blood stream, resulting in septic shock, rapidly followed by death in many cases (about 50%). Over 70% of infected individuals have distinctive bulbous skin lesions.

Infective Dose: The infective dose for gastrointestinal symptoms in healthy individuals is unknown but for predisposed persons, septicemia can presumably occur with doses of less than 100 total organisms.

Diagnosis of Human Illness: The culturing of the organism from wounds, diarrhetic stools, or blood is diagnostic of this illness.

Associated Foods: This organism has been isolated from oysters, clams, and crabs. Consumption of these products raw or recontaminated may result in illness.

The Usual Course of Disease and Some Complications: In healthy individuals, gastroenteritis usually occurs within 16 hours of ingesting the organism. Ingestion of the organism by individuals with some type of chronic underlying disease [such as diabetes, cirrhosis, leukemia, lung carcinoma, acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), or asthma requiring the use of steroids] may cause the “primary septicemia” form of illness. The mortality rate for individuals with this form of the disease is over 50%.

Outbreaks: No large outbreaks of illness in the U.S. have been attributed to this organism. Sporadic cases continue to occur all year, increasing in frequency during the warmer months.

26. NAME OF THE ORGANISM: *Yersinia enterocolitica* (and *Yersinia pseudotuberculosis*)

Y. enterocolitica, a small rod-shaped, Gram-negative bacterium, is often isolated from clinical specimens such as wounds, feces, sputum and mesenteric lymph nodes. However, it is not part of the normal human flora. *Y. pseudotuberculosis* has been isolated from the diseased appendix of humans.

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Both organisms have often been isolated from such animals as pigs, birds, beavers, cats and dogs. Only *Y. enterocolitica* has been detected in environmental and food sources, such as ponds, lakes, meats, ice cream and milk. Most isolates have been found not to be pathogenic.

Name of the Disease: Yersiniosis - There are 3 pathogenic species in the genus *Yersinia*, but only *Y. enterocolitica* and *Y. pseudotuberculosis* cause gastroenteritis. To date, no foodborne outbreaks caused by *Y. pseudotuberculosis* have been reported in the United States, but human infections transmitted via contaminated water and foods have been reported in Japan. *Y. pestis*, the causative agent of “the plague,” is genetically very similar to *Y. pseudotuberculosis* but infects humans by routes other than food.

Nature of the Disease: Yersiniosis is frequently characterized by such symptoms as gastroenteritis with diarrhea and/or vomiting; however, fever and abdominal pain are the hallmark symptoms. *Yersinia* infections mimic appendicitis and mesenteric lymphadenitis, but the bacteria may also cause infections of other sites such as wounds, joints and the urinary tract.

Infective Dose: Unknown - Illness onset is usually between 24 and 48 hours after ingestion, which (with food or drink as vehicle) is the usual route of infection.

Diagnosis of Human Illness: Diagnosis of yersiniosis begins with isolation of the organisms from the human host’s feces, blood, or vomit, and sometimes at the time of appendectomy. Confirmation occurs with the isolation, as well as biochemical and serological identification, of *Y. enterocolitica* from both the human host and the ingested foodstuff. Diarrhea is reported to occur in about 80% of cases; abdominal pain and fever are the most reliable symptoms.

Because of the difficulties in isolating yersiniae from feces, several countries rely on serology. Acute and convalescent patient sera are titrated against the suspect serotype of *Yersinia* spp.

Yersiniosis has been misdiagnosed as Crohn’s disease (regional enteritis) as well as appendicitis.

Associated Foods: Strains of *Y. enterocolitica* can be found in meats (pork, beef, lamb, etc.), oysters, fish, and raw milk. The exact cause of the food contamination is unknown. However, the prevalence of this organism in the soil and water and in animals such as beavers, pigs, and squirrels, offers ample opportunities for it to enter our food supply. Poor sanitation and improper sterilization techniques by food handlers, including improper storage, cannot be overlooked as contributing to contamination.

Frequency of the Disease: Yersiniosis does not occur frequently. It is rare unless a breakdown occurs in food processing techniques. CDC estimates that about 17,000 cases occur

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annually in the USA. Yersiniosis is a far more common disease in Northern Europe, Scandinavia, and Japan.

Recent Major Outbreaks in the USA:

- A. 1976 - A chocolate milk outbreak in Oneida County, New York, involving school children (first reported yersiniosis incident in the United States in which a food vehicle was identified). A research laboratory was set up by FDA to investigate and study *Y. enterocolitica* and *Y. pseudotuberculosis* in the human food supply.
- B. December 1981 - February, 1982 - *Y. enterocolitica* enteritis in King County, Washington, caused by ingestion of tofu, a soybean curd. FDA investigators and researchers determined the source of the infection to be a non-chlorinated water supply. Manufacturing was halted until uncontaminated product was produced.
- C. June 11 to July 21, 1982 - *Y. enterocolitica* outbreak in Arkansas, Tennessee, and Mississippi associated with the consumption of pasteurized milk. FDA personnel participated in the investigation, and presumptively identified the infection source to be externally contaminated milk containers.

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VERMIN CONTROL

We are interested in the control of all insects and rodents that destroy or contaminate our food supply. We are primarily concerned with the relatively few insects and rodents which spread disease through food. Another concern is the insects, which cause damage to stored food. These include the rat, the housefly, the cockroach and some small moths and beetles. Insects and rats carry disease bacteria internally and on their hairy bodies. A fly is known to carry as many as six million microorganisms on its body, and many more internally, which may be deposited on food and food surfaces by excreta. We know that in order to prevent outbreaks of foodborne illness we must break the chain of infection or contamination. The good practices of washing and sanitizing hands by employees; the proper cleaning and sanitizing of utensils and food contact surfaces; the proper storage of dishes and utensils and good refrigeration practices as well as time and temperature controls in food handling, can all be wasted if insects and rats are allowed to contaminate food and food contact surfaces.

INSECTS, AN OVERVIEW

FLIES

There are many kinds of flies, and it is possible to spend a lifetime learning about them. Fortunately there are only a few, commonly found around food establishments. These are the ones we are really interested in, certain blowflies and most of the entire house fly (*Musca Domestica*).

The housefly is the one most likely to spread human disease as it breeds in human or animal waste as well as garbage and then enters food establishments where it may contaminate food. When a fly walks over filth, some of the filth material sticks to its hairy body. If disease bacteria are in the material they too stick to its body and leg hairs. When it feeds on the waste material it takes some of the bacterial into its intestines. The rest of the story you are familiar with. The fly goes into the dining area or kitchen where it walks on the food, utensils and food surface areas. More sickening is the fact that the housefly has to vomit on solid food to soften it before it can eat it. This is because a housefly cannot chew, but has sponging, sucking mouthparts. In vomiting, some bacteria are spread on food and can cause intestinal infections (worms, amoebic organisms, etc.). Bacteria are also present in the fly excreta, called flyspecks.

Blowflies are usually larger than the housefly and are often a shiny blue, green, or bronze color. Because of their keen sense of smell they are particularly attracted to garbage dumps, stockyards and meat processing plants but also are attracted to restaurants and food processing plants. Of the other flies, the one that is the biggest nuisance is the stable fly (biting housefly). It looks like a housefly but has a sharp beak (Proboscis) and bites or stings, usually around the ankles. A single fly may carry up to approximately six million bacteria on its outside body and 25 million in its intestine.

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The housefly is typical of flies as a whole, and will be discussed as an example. The female fly lays up to 150 eggs at a time in garbage, human or animal waste, or other moist food. The small white, oval eggs (about 1/25 inch long) are deposited in batches of 75 to 150, with the average female laying 5 or 6 batches during her lifetime. Hatching of larvae (maggot) occurs 12-24 hours after laying, during the summer months. The active young larva burrow into the breeding material using its two mouth hooks for tearing and loosening food material. When the larva (maggot) is fully-grown (4-7 days in warm weather) it crawls into the soft ground nearby where it forms a brown shell (puparium) which encloses the true pupa. The pupa is immobile and takes no food. The pupal stage normally takes about 4-5 days. At warm temperatures pupation may take as short a time as 3 days or several weeks at low temperatures. When the pupal period is complete, the fly breaks open the end of the puparium and surfaces to the ground where it crawls about rapidly while its wings unfold and its body expands, dries and hardens. This takes about one hour in warm temperatures. Complete activity is reached in about 15 hours at which time mating can take place. The female begins laying eggs within 4-20 days after hatching. The adult is a very active two-winged, six-legged insect. During daylight hours it moves from one attractant to another; it is strongly attracted to excrement, decaying organic matter as well as milk and food products. When not feeding, it rests on floors, walls, ceilings, fences, steps, tall weeds, etc.

COCKROACHES

There are four common types of roaches. The American, Oriental, German and Brown Banded. There are others common to certain areas such as the Australian Roach found in Southern Florida and California and the Brown Roach found in the Southern United States. Cockroaches have been in existence for 300 million years. Similar to flies, the cockroaches are capable of carrying disease organisms on their body. They crawl from toilets and sewers into kitchens, running over utensils, food preparation areas and unprotected food. They carry bacteria on their hairy legs and body as well as in their intestinal tract. Roaches harbor in cracks and crevices and are nocturnal (avoid light). It is possible to have a number of roaches around without realizing they are there until they are caught by surprise when a light is suddenly turned on.

American Roach (*Periplaneta Americana*) - One of the larger roaches and is found in boiler rooms, basements and sewerage systems. It is capable of flights of a gliding nature. Adult is 1 1/2 inches in length.

Oriental Roach (*Blatta Orientalis*) - Found in garbage and refuse, sewer lines, under refrigerators, etc. It does not fly and is less domestic than most others. It grows to about one inch in length.

German Roach (*Blatella Germanica*) - Found in kitchens, food storage areas, and toilets and is the most common roach found in restaurants. It does not fly. It grows to about 3/4 of an inch in length. Is the only domestic roach where egg cases are carried by the female until ready to hatch.

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Brown Banded Roach (*Supella Supellectum*) - Found throughout restaurants and not in any one particular place. The adults will fly readily. Favorite place for depositing egg cases is in furniture. Grows to about 3/4 inch in length.

Cockroaches do not develop as flies do. The fly, as you recall, has four stages- egg, larva, pupae and adult. The roach has only three stages- egg, nymph and adult. The eggs are laid in a case or capsule called ootheca. When the eggs hatch, tiny nymphs (which resemble the adult, but have no wings and are much smaller) emerge and go through a succession of molts before becoming a mature adult. The egg cases are deposited almost anywhere, and are very often glued to some object like a shelf or curtain. The newly molted (nymph) roaches are white or cream colored before it's tissues harden, which accounts for reports of albino roaches. Life cycle takes from 3 months to a year. Roaches love to live where there is plenty of food to eat. They are capable of getting into food establishments by crawling in through cracks and along pipes as well as coming in on food and supplies.

STORED FOOD INSECTS INFESTING WHOLE GRAIN

There are many other insects that bother us by invading foods. Most of these are small moths or beetles, which create problems of wasted food and nuisance rather than disease.

Rice Weevil (*Sitophilus oryza*) - Worldwide in distribution, is probably the most important grain pest. This small, reddish-brown to black snout beetle, 1/8 to 1/6 inch long, has small, round pits on the thorax and two reddish or yellowish spots on each wing cover. The larva is short, fat and whitish. The adult is a strong flier. The larva and pupa develop within a single grain of rice or kernel of corn, from which the adult weevil emerges about 30 days after the egg is laid. The adult female live 4 to 5 months, depositing 300 to 400 eggs in small opening bored into grain. The rice weevil feeds upon corn, rice, wheat, barley and other grains.

Granary Weevil (*Sitophilus granarius*) - Similar to the rice weevil in appearance, but with oval pits on the thorax, and with the wing covers uniformly dark brown. This insect has become thoroughly domesticated, losing its power of flight and forsaking wild and cultivated grain fields for the grain storehouses of man. This snout beetle is slightly larger than the rice weevil and lives from 7 to 8 months. Whereas the rice weevil is a major pest in the South, the granary weevil more often frequents the Northern States.

Cadelle (*Tenebroides mauritanicus*) - A black beetle 1/3 to 1/2 inch long, with the head and pronotum distinctly separated from the forewings by a loose joint. The large, whitish, fleshy larvae are about 3/4 inch long when fully grown and may be recognized by their prominent black heads, the paired black spots on the three segments of the thorax, and two short dark hooks, at the posterior end of the abdomen. Larvae burrow into the woodwork of grain bins, and a seemingly clean bin may harbor thousands of larvae, pupae, and adults. The life cycle requires from 2 to 14 months, many adults living more than a year. The females lay about 1,000 eggs in protected situations, such as in cracks near

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food. The cadelle feeds upon grain and grain products and does much damage to bolting silk in flourmills. It is especially injurious in poorly sanitized mills.

Lesser Grain Borer (*Rhyzopertha dominica*) - A brown or black, slender, cylindrical beetle with numerous coarse elevations on the pronotum, is about 1/8 inch long and is most common in the Gulf States but may occur anywhere in the country. Both larvae and adults attack and destroy wheat kernels. The females lay up to 500 eggs each, dropping them in the loose grain. In warm weather the life cycle is completed in about 1 month.

Angoumois Grain Moth (*Sitotroga cerealella*) - A light grayish-brown or straw-colored moth with a satiny luster and wing expanse of 1/2 to 2/3 inch. The hind wings are fringed with long, dark setae, and have a point at the tip like a finger, which distinguishes the insect from the clothes moth. The larva is white, with a brown head. It is only 1/5 inch long and lives within the individual grain of wheat, corn, or other grain. The winter is passed in the larval stage in stored grain. The adult emerges and infests cereal crops either in the field or in storage, depositing about 400 eggs. The entire life cycle may be completed in 5 weeks. The Angoumois Grain Moth is second in importance to the rice granary weevils as a pest of stored grain. It is of greatest importance in the South and in the soft red-winter-wheat region of the Eastern and Central States.

STORED FOOD INSECTS INFESTING BROKEN GRAIN

Confused Flour Beetle (*Tribolium confusum*) and the **Red Flour Beetle** (*Tribolium castaneum*) - Similar in appearance and habits, adult Confused Flour Beetles have the antennae gradually enlarged toward the tip, whereas the antennae of the Red Flour Beetle have the last three segments abruptly enlarged. The *T. confusum* cannot fly, whereas, *T. castaneum* may fly. The elongate, reddish-brown beetles are about 1/7 inch long, with a distinct joint between the thorax and abdomen. The adult female may live for as long as 2 years, depositing 300 to 400 eggs. The mature larva is brownish-white with six legs, and is up to 1/2 inch long. The life cycle requires 2 to 4 months when temperatures are favorable. These beetles are very important pests of flour, infesting many flour mills, warehouses, and grocery stores. They also feed upon grain, dried fruits, nuts, chocolate, and other foods.

Flat Grain Beetle (*Cryptolestes pusillus*) - One of the smallest beetles found in stored grain. It is a tiny, reddish-brown beetle about 1/16 inch long with antennae nearly as long as the insect. It is usually found with other grain pests.

Indian Meal Moth (*Plodia interpunctella*) - Has a wing expanse of 1/2 to 3/4 inch, with the basal one-third of each forewing dull white to cream and the outer two-thirds, brown to copper. The females lay about 200 eggs, and the tiny whitish, brown-headed larvae emerge in 2-14 days. The life cycle is 50-305 days. Full-grown larvae (1/3 to 1/2 inch long) produce silk, which webs together flour, graham crackers, nuts, dried fruit, powdered milk and other foods.

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BEETLES INFESTING DRIED PEAS AND BEANS

Bean Weevil (*Acanthoscelides obtectus*) - A short snout beetle that feeds upon stored beans and peas. The adult is 1/8 inches long with reddish legs and a light olive-brown color, mottled with darker brown and gray. The body narrows evenly toward the head. The tiny, legless larva and pupa live within the bean, whereas the adult emerges from the bean and feeds upon other materials. The female deposits eggs in beans, both in the field and in storage, and six or seven generations may be completed in a year. As many as 28 weevils have been known to develop in 1 bean. The use of tight sacks has been found to afford considerable protection. Bean vines and other refuse should be burned in the field or plowed under to prevent propagation of this insect. The adults hibernate in fields and warehouses.

Pea Weevil (*Bruchus pisorum*) - Appears similar to the bean weevil, but is larger (1/5 inch long), brownish, flecked with white, and with black to gray patches or scales. There is one generation per year, the adults overwintering in peas in the field or in storage. Egg deposition occurs only in the field. House mice eat pea weevils by cracking open the infested pea, eating the weevil, and discarding the pea.

BEETLES AND FLIES INFESTING MEATS AND CHEESE

Larder Beetle (*Dermestes lardarius*) - About 1/3 inch long, dark brown, with a wide yellow band across the front part of the wing cover. The larva is brown, very hairy, tapering towards the ends of the body. This insect is worldwide in distribution. The eggs are laid on or near animal products such as feathers, horns, skins, hair, ham, bacon, dried beef, and like products. The life cycle requires 40 to 50 days. This insect may be found in dog biscuits, cheese, museum specimens, dried fish, and stored tobacco. It is also known to penetrate lead. Control consists chiefly of protection from attack, such as wrapping hams in paper and cloth immediately after smoking, and the use of cold storage lockers. Skins and hides are protected by dusting or spraying with 1 percent Lindane.

BEETLES THAT ARE FEEDERS ON STORED FOOD

Saw-toothed Grain Beetle (*Oryzaephilus surinamensis*) - An important pest known throughout most of the world. A closely related species, *Oryzaephilus mercator*, is also important and is often mistaken for the saw-tooth grain beetle. The adult is a small active, brown beetle 1/10-inch long, with a flattened body and six saw-toothed projections on each side of the thorax. The larva is yellowish-white, less than 1/8 inch long, with a brown head, and abdomen tapering toward the tip. The female lives for 6 to 10 months, depositing 45 to 285 eggs in foodstuffs. Several generations may occur each year, as the life cycle requires only 3 to 4 weeks during the summer. The saw-toothed grain beetle is an important pest in grocery stores, food warehouses, and grain storage. It readily penetrates packaged cereals, dries fruits, and candies. It also attacks flour, meal, sugar, drugs, dried meat, and tobacco.

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RODENTS, AN OVERVIEW

Man's continual battle to eliminate or reduce rodent populations has been going on for centuries, ever since the cave dwelling paleolithic man began to store the product of his hunt. Historically, rodents have been responsible for more human illness and deaths than any other group of mammals. It is estimated that each rat damages \$5.00 worth of food and other materials per year by gnawing and feeding, and contaminates 5 to 10 times more, (by discharged body wastes and body contact). Rats may carry a number of diseases such as salmonellosis, leptospirosis, plague, and murine typhus. In addition rat bites create a serious health problem. The national average is around 30 bites per thousand population. Children and a few derelicts are the most common victims. Rodent populations are like a cork floating in water. Pressure keeps the cork down, release the pressure and the cork surfaces. Man must keep the pressure on in order to control rodent populations.

TYPES OF SIGNIFICANT RODENTS

The term domestic rodent includes Norway rats, Roof rats, and House mice. These rodents are best characterized by having a single pair of incisor teeth on each jaw and by the absence of canine teeth. These incisors grow about 6 inches in length a year, which accounts for the rat's tendency to gnaw and chew to wear the teeth down. They can chew through plastic, wood, lead pipe and aluminum.

Norway Rat - The most important and predominant rat in the US, except for some coastal areas. The Norway rat being the larger and more aggressive will many times fight off and even kill the Roof rat. Common names for the Norway rat are Sewer rat, Wharf rat, Brown rat, House rat, and Barn rat. The Norway rat is predominately a burrowing rat, and therefore it harbors in burrows in ground, around dumps, sewers, and buildings close to food and water. It will eat almost any food, but prefers garbage, meat, fish and cereal. The range of travel is usually no more than 100-150 feet.

House Mouse - The smallest of the domestic rodents. It has the widest distribution of the three rodents throughout the US. It is found primarily in and around buildings, nesting in walls, cabinets, furniture, and stored goods. It prefers food similar to the Roof rat such as cereal, grain, etc. The House mouse is a nibbler, taking a bite here and a bite there. Range of travel 10-30 feet.

RECOGNITION OF RODENT SIGNS

It is unusual to see rats or mice during the daytime as they are nocturnal by habit. It is therefore necessary to interpret signs of their activities. From rodent signs one can determine the species or type of rodent, whether it is old or new and whether there is a light or heavy infestation.

Droppings - The presence of rat or mouse feces is one of the best indications of an infestation. Fresh droppings are usually moist, soft and shiny while old droppings become dry and hard and have a dull grayish appearance and crumble when pressed with a stick. Norway rat droppings are largest, 1/2 to 3/4 inch long, and have bluntly rounded ends, which give it a spindle-shaped appearance. Roof rat droppings are smaller (1/3 to 1/2 inch long) and more regular in form. The ends are usually quite blunt. House mouse droppings are very small (3/16 to 1/2 inch), pointed at each end. American cockroach droppings are smaller than mice and have blunt, almost squared off ends.

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Runways - Rats occupy only a limited area and use the same paths and odor trails that they are familiar with, as they are very cautious and suspicious. Outdoors in vegetation, such as grass, or weeds, you can see paths worn down which are between 2 to 3 inches wide. On earthen floors (outdoors) the runways appear as clean-swept, well packed earth paths.

Rubmarks - Rats prefer to follow closely to walls where their highly sensitive whiskers (vibrissae) and guard (body) hairs can keep in contact with side surfaces. By using the same runs their oily bodies, rub against a wall or baseboard, creating a rubmark. Rubmarks of the Roof rat are commonly beneath beams or rafters at the point where they connect to the walls. Fresh marks are soft and will smear when rubbed. Mice do not leave rubmarks that are detectable except when the infestation is heavy.

Burrows - The Norway rat prefers to burrow for nesting and harborage while the Roof rat burrows only occasionally. Burrows are found in earth banks, hedgerows, along walls, under rubbish or concrete slabs, and near doghouses. Rat holes are about 3 inches in diameter while mice holes are only about 1 inch in diameter. If a burrow is active it will be free of cobwebs and dust. Fresh rubmarks on hard-packed soil at the opening indicate a well-established and active burrow. The presence of fresh fragments of food or freshly dug earth at burrow entrance also indicates an active burrow.

Gnawings - Since the incisor teeth of rats grow 4-6 inches a year they have to do some gnawing each day in order to keep their teeth short enough to use. Gnawings in wood are fresh if they are light colored and show distinct teeth marks. Small chips of wood or other materials indicate recent gnawing. Old wood gnawings become dark and smooth.

Tracks - These may be observed anywhere along rat or mouse runs both indoors and outdoors. Tracks are more clearly seen by side illumination from a flashlight than by direct illumination from above. Dust in little-used rooms and in mud around outdoor puddles are especially good places to look for tracks. Rat tracks may be 1 1/2 inches long. The rear paws of rats have 5 toes while the front paws have 4. Tail marks are also often visible in dust or tracking patches.

Live or Dead Rats - Positive proof of a rodent infestation is to see a live or dead rat or mouse. As a rule, only a very heavy infestation will you see a live rat. Dead animals may either indicate a current or past infestation.

Miscellaneous Signs - Urine stains can be seen with an ultraviolet light. The rat leaves a distinct pattern from that of mice. Rat and mouse hairs may be found along walls etc., and when examined under a microscope can be distinguished from hair of other animals.

CONTROL OF RODENTS

Environmental Sanitation - Get rid of all unwanted materials that might provide food or shelter. This means storing garbage and rubbish in approved type containers with tight fitting lids (plastic bags

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won't keep out rats). Lumber and other materials should be stacked 18 inches off the ground. Food set out for dogs, rabbits, pigeons or chickens is often a source of food for rats or mice and should be policed by picking up scraps of leftover food, and keeping dog dishes clean. Keep animal droppings cleaned up around dog pens.

Rat Proofing - This consists of changing structural details to eliminate any openings 1/2 inch or larger that would admit rats, and 1/4 inch or larger for mice. Where only Norway rats are found, usually only first floor stoppage work is economically feasible and then at the likely points of entry and not every possible opening; e.g., around doors, windows, where pipes and conduits enter building, floor drains, transoms, letter drops, fan openings, and foundations. Concrete, brick and mortar as well as galvanized hardware cloth, and galvanized metal are some materials needed for rat proofing. Where Roof rats are encountered, rat proofing must include wires, vertical pipes and openings to upper floors and roofs.

Traps - These are useful around food establishments where rodenticides are not permitted or are hazardous, and where only slight infestations are predicted. Two main types of traps:

Live traps (O. Traps) used for catching live rats for study purposes

Killer traps (Snap Traps)

Poisoning - Rodenticides are categorized highly toxic, moderately toxic and low toxicity, based on criteria established in the Federal Insecticide, Fungicide and Rodenticide Act.

ACKNOWLEDGMENT

The above information on the identification and control of insects and rodents has been supplied through the courtesy of the United States Department of Health, Education and Welfare.

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Division of Food Safety and Inspection
Field Operations Manual**

**REFERENCE/GENERAL INFORMATION
EQUIPMENT WASHING AND HANDWASHING REQUIREMENTS
SUB-SECTION 5075**

OVERVIEW

Operators of retail food stores in New York State are required by law to provide functioning equipment cleaning, as well as handwashing facilities, within their establishments.

EQUIPMENT WASHING

Equipment cleaning sinks must consist of either two or three compartments and must be supplied with hot and cold potable running water.

If a three-compartment sink is utilized, the following sequence must be adhered to:

1. Equipment is to be thoroughly cleaned with a hot detergent solution in the first compartment;

AND

2. Equipment is to be rinsed in the second compartment;

AND

3. Equipment is to be sanitized in the third compartment with hot water immersion for at least ½ a minute in hot water 170°F or higher, or a chemical sanitizer equivalent.

If a two-compartment sink is utilized, one of the following sequences must be adhered to:

1. Equipment and utensils shall be thoroughly cleaned in the first compartment with a hot detergent solution that is kept clean and at a concentration indicated on the manufacturer's label and shall be sanitized by immersion for at least 1/2 minute in clean, hot water of a temperature of at least 170°F (congruent to 77°C) in the second compartment.

OR

2. Equipment and utensils shall be thoroughly cleaned in the first compartment with a hot detergent-sanitizer solution that is kept clean and at a concentration indicated on the manufacturer's label and shall be sanitized, by immersion, for at least 1/2 minute in clean, hot water of a temperature of at least 170°F (congruent to 77°C) in the second compartment, or with a solution containing that same detergent sanitizer at acceptable concentration levels for specific chemical sanitizers.

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Note: A detergent-sanitizer is a specific, commercially prepared, singular compound; not an on-site combination of a detergent and a sanitizer.

HANDWASHING

Handwashing facilities are required to be installed in retail food stores conveniently located to permit use by employees in food preparation and warewashing areas. Additionally, they must also be provided in or adjacent to toilet rooms or their vestibules.

All handwashing facilities must be provided with hot water of at least 105°F (40.5°C), and cold water tempered by means of a mixing valve or combination faucet. Soap and sanitary towels must also be provided.

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**REFERENCE/GENERAL INFORMATION
WATER EMERGENCY PROCEDURES
SUB-SECTION 5080**

OVERVIEW

If an establishment has a limited supply of water or the supply is contaminated the following guidelines shall be followed by the establishment with the concurrence of the Inspector for a short period of time.

These emergency guidelines are a temporary measure to allow an establishment to continue to operate while arranging for the installation or repair of a well, a chlorinator system, an ultra-violet system, etc.

Water or ice from a suspect or non-potable water supply shall never be used as an ingredient, in any form, in the manufacture of any food product or come in contact with foods, ingredients or food-contact surfaces.

OPERATION	WHEN WATER IS LIMITED OR UNAVAILABLE	WHEN WATER SUPPLY IS CONTAMINATED
Handwashing by employees	Use water from an approved alternate source.	Same (any alternative accepted for employee hand-washing must fully meet the need of regular and effective handwashing by employees).
Cleaning and sanitizing tableware, kitchenware, vending machine components, equipment and contact surfaces	Use only single-service tableware and single use kitchenware. Use water from or take components to a department approved alternate source elsewhere for cleaning.	Same. Same.
Cleaning floors, walls and other non-food contact surfaces	Use waterless cleaning methods.	Use nonpotable water if approved by this Division.

OPERATION	WHEN WATER IS LIMITED	WHEN WATER SUPPLY

REFERENCE/GENERAL INFORMATION
WATER EMERGENCY PROCEDURES
SUB-SECTION 5080

	OR UNAVAILABLE	IS CONTAMINATED
Storing dispensing utensils in dipper well.	Store utensils in food.	Same.
Using garbage grinders.	Discontinue use and dispose of garbage in proper containers together with other refuse.	Use nonpotable water if approved by this Division.
Flushing toilets.	Use adjacent approved facilities which are readily available.	Same.
	Use waterless toilets (portable toilets).	Same.
	Limit toilet use to employees only.	Use nonpotable water.
	Use water from an alternate source.	Same.
Preparing carbonated and other cold/hot beverages.	Replace with bottled or canned beverages.	Same.
	Use water from an approved alternate source.	Same.
		Disconnect water line to post-mix carbonated beverage machine, drain and disinfect lines prior to reuse.
Thawing of frozen foods.	Thaw only in refrigerator, or as part of cooking process if food weighs less than three pounds.	Same.
Washing produce.	Obtain and use prewashed packaged produce.	Same.
	Use produce washed prior to emergency. May have been washed with contaminated water.	Same.

**REFERENCE/GENERAL INFORMATION
WATER EMERGENCY PROCEDURES
SUB-SECTION 5080**

OPERATION	WHEN WATER IS LIMITED OR UNAVAILABLE	WHEN WATER SUPPLY IS CONTAMINATED
Washing produce (continued).	Use frozen or canned produce. Wash fresh produce with water from an approved alternate source.	Same. Same.
Spraying, dipping and soaking of produce.	Use water from an approved alternate source.	Same.
Preparing and cooking food, including reconstituting dried food.	Use only food that was prepared prior to the interruption. Discontinue sale of prepared foods. Use prepared food from an approved alternate source. Use water from an approved alternate source.	Same. Same. Same. Same.
Ice-making.	Use ice prepared before interruption. Do not use ice for preparing or serving beverages. Purchase packaged potable ice.	Disconnect machine from supply; drain and disinfect equipment prior to re-use. Same. Same.

Information Note

Non-potable water systems may be used for air conditioning, equipment cooling and fire protection. This water shall not contact food or food contact equipment. The non-potable water system shall be durably identified as such.

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**REFERENCE/GENERAL INFORMATION
RECOGNIZED PROCESSING AUTHORITIES
SUB-SECTION 5085**

Note: The following locations have provided scheduled processes for manufacturing plants affected by Part 262, Fish Processing and Smoking Establishments and 21 CFR, Part 114 - Acidified Foods. This is not, however, a complete listing of the processing authorities available.

Olga Padilla-Zakour, Ph.D. Director, NYS Food Venture Center Department of Food Science and Technology NYSAES - Cornell University 647 W. North Street Geneva, New York 14456-0462 Phone: (315) 787-2259 FAX: (315) 787-2284 EMAIL: oipl@cornell.edu	Processed Fish Acidified Foods Tomato Based Products
George W. Bierman, Ph.D. 19 Curwen Road Peabody, Massachusetts 01960-1205 Phone: (508) 535-3361 FAX: (508) 535-4812	Processed Fish Acidified Foods Tomato Based Products
Professor Laxman Kanduri Tri State Food Consultants 1733 E. 55th Street Brooklyn, New York 11234 Phone: (718) 253-6798 FAX: (718) 951-2621	Processed Fish
Dr. Melvin W. Eklund, Consultant 18727 35th Ave. NE Seattle, Washington 98155 Phone: (206) 364-3166 FAX: (206) 368-8975 EMAIL: mweklund@aol.com	Processed Fish

**REFERENCE GENERAL INFORMATION
RECOGNIZED PROCESSING AUTHORITIES
SUB-SECTION 5085**

Marvin E. Winston, President Winston Laboratories, Inc. 2695 Route 516 Suite 3, Browntown Office Amex Old Bridge, NJ 08857 PHONE: (732) 679-1121 FAX: (732) 679-1128 EMAIL: winlab@aol.com	Processed Fish

NYS Department of Agriculture and Markets
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REFERENCE/GENERAL INFORMATION
A HANDY GUIDE TO ADDITIVES
SUB-SECTION 5090

FUNCTION	COMMON FOOD ADDITIVES	USED IN:
Improve or maintain nutritional value	Vitamins A, C, D, E, B-vitamins, iron, calcium, iodine	Bread, cereal, pasta, rice, flour, salt, milk, margarine, beverages
Preserve freshness		
a). Antimicrobials (Prevent spoilage)	Calcium propionate or lactate, sodium benzoate, sorbic acid, lactic acid, propionic acid, sodium nitrate and nitrite	Beverages, table syrup, bread, baked goods, cheese, fruit juices, pie filling, cured meats, fruit products
b). Antioxidants (Prevent rancidity or discoloration)	BHA, BHT, citric acid, Vitamin C, Vitamin E, EDTA, propyl gallate	Fats and oils, baked goods, snack foods, cereals, dressings, processed fruits
Aid in processing or preparation		
a). Emulsifiers (distribute particles evenly)	Carrageenan, lecithin, mono- and diclycerides, polysorbate	Chocolate milk, baked goods, frozen desserts, salad dressings, bread, chocolate, margarine, cereal, cake mix, peanut butter, pudding and pie filling mix
b). Stabilizers, Thickeners and Texturizers (for smooth, uniform texture)	Alginates, pectin, agar, vegetable gums, cellulose, gelatin, modified food starch, carrageenan	Frozen desserts, jam, jelly, pudding, cream cheese, candy, pie filling, baked goods, sauces, soups, salad dressings, beverages
c). Leaveners	Yeast, baking powder, baking soda	Baked goods, bread
d). Acids/Bases (Control pH)	Acetic acid, citric acid, adipic acid, lactic acid, phosphoric acid, fumaric acid, tartaric acid	Baked goods, oils, chocolate, processed cheese, gelatin desserts, soft drinks, candy, sauces, dressings
e). Humectants (Retain moisture)	Glycerine, propylene glycol, sorbitol, glycerol monostearate	Flaked coconut, candy, gum, marshmallow

REFERENCE/GENERAL INFORMATION
A HANDY GUIDE TO ADDITIVES
SUB-SECTION 5090

Aid in processing or preparation (continued)		
f). Maturing and Bleaching Agents (Improve baking quality)	Azodicarbonamide peroxides, calcium bromate, potassium bromate	Flour, breads, cereals, instant potatoes, some cheeses
g). Anti-caking Agents (Prevent lumping)	Calcium silicate, iron ammonium citrate, silicon dioxide	Salt, baking powder, powdered foods
Increase food appeal		
a). Flavor Enhancers	Monosodium glutamate, hydrolyzed vegetable protein, disodium guanylate or inosinate	Soups, canned vegetables, processed meats, gravy, sauce mixes
b). Flavors (Natural and synthetic)	Aspartame, caffeine, sorbitol, sugar, salt, corn syrup, vanilla, herbs, spices and other natural seasonings	Baked goods, candy, ice cream, soft drinks, gelatin, pudding, salad dressing mix, pie filling, sauces
c). Colors (Natural and synthetic)	Carotene, caramel, beet powder, annatto extract, saffron, turmeric, paprika	Margarine, cheese, soft drinks, candy, jelly, jam, gelatin mixes, pudding and pie fillings, baked goods, ice cream

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**REFERENCE/GENERAL INFORMATION
CHEESE REFRIGERATION GUIDELINES
SUB-SECTION 5095**

The FDA/USDA Risk Categories for Cheeses are as follows:

HIGH	Soft unripened cheeses (refrigeration required)
MODERATE	Fresh soft cheeses (refrigeration desirable) Soft ripened cheeses Semi-soft cheeses
VERY LOW	Hard cheeses (refrigeration optional/unnecessary) Pasteurized process cheeses

Refrigeration Required:

Baker's Cheese, Chaumes, Cheese Curds (fresh), Cheese Spreads, Cold Pack Cheeses, Cook Cheese (koch kaese), Cottage Cheese, Cream Cheeses, Gammelost, High Moisture Cheeses¹, Limburger, Livarot, Mascarpone, Monterey Jack (>44% moisture), Mozzarella, Muenster, Neufchatel, Queso Fresco, Ricotta, Roquefort, Saga Blues, Taleggio, Triple Crème

Note: Intact packages of cheese from an approved food processing facility may be refrigerated at 45°F. Cheeses sliced in-house at retail, and generally repackaged for display, must be refrigerated at 41°F.

Refrigeration Desirable:

Blue, Brie, Brick, Camembert, Edam, Fontina, Gorgonzola, Gouda, Havarti, Mimolette, Nuworld

Refrigeration Optional²:

Cheddar, Cheshire, Comte, Gruyere, Idiazabal, Lancashire, Manchego, Muenster, Samsoe, Stilton

**REFERENCE/GENERAL INFORMATION
CHEESE REFRIGERATION GUIDELINES
SUB-SECTION 5095**

Refrigeration Unnecessary²:

Asiago, Caciocavallo-Siciliano, Colby, Feta, Grating Cheeses, Monterey Jack (moisture < 44%), Parmesan, Pasteurized Processed Cheese, Pecorino, Provolone, Reggiano, Romano, Sap Sago, Swiss/Emmentaler

1 – greater than 50% moisture (on product specification sheets)

2 - Based on a storage/room temperature that does not exceed 86°F/30°C. Some cheeses not kept under refrigeration will exhibit other defects that are not of public health concern, but that are considered undesirable by consumers. These may include weeping, syneresis, fat separation/oiling off, and formation of calcium lactate crystals.

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REFERENCE/GENERAL INFORMATION
TEMPERATURE-ABUSED FOOD GUIDELINES
SUB-SECTION 6000

RECOMMENDED STORAGE, TEMPERATURES AND TIMES FOR VARIOUS FOODS			
- MEAT -			
FOOD	POTENTIAL HAZARD WHEN PURCHASED	SUGGESTED TYPE AND LENGTH OF STORAGE	SIGNS OF QUALITY LOSS (Spoilage)
<u>Fresh Meats</u> (Roasts, steaks and chops)	Presence of salmonellae, <u>C. perfringens</u> , fecal streptococci, Staphylococcus aureus.	Refrigerate at 30 to 36°F. Loosely wrapped meats store longer than tightly wrapped. Loosely wrapped: 3 to 5 days or less. Tightly wrapped: 2 days or less. Never keep meat at room temperature except during actual preparation.	Discoloration to brown and gray; off-odor, slight to putrid; mold growth appears late in spoilage process.
<u>Ground and Stew Meat</u>	Same as steaks, roasts and chops, except that higher bacterial count must be expected, especially in ground meat. E.Coli	Refrigerate at 30 to 36°F. Freeze unless designated for immediate use. 1 to 2 days, preferably only 1 day. Longer storage possible if original quality high and refrigerator temperature is low (near 32°F).	Same as roasts, steaks and chops.
<u>Variety Meats</u>	Same as roasts, steaks and chops	Refrigerate at 30 to 36°F. Loosely wrapped: 1 to 2 days.	Same as roasts, steaks and chops.

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TEMPERATURE-ABUSED FOOD GUIDELINES
SUB-SECTION 6000

<u>Hams</u> (Tenderized, not fully cooked)	Heat-processed only to 140°F; not sterile; occasionally fecal streptococci and staphylococci (resistant to heat and salt) survive the processing.	Keep refrigerated at 30 to 36°F at all times including storage at vendor's premises 1 week only for best quality; 1 to 3 weeks is safe, unless mishandled (left out of refrigerator).	Discoloration; off-odor, softening; mold growth, if air is available. Iridescence on sliced ham does not indicate spoilage.
<u>Hams</u> (Tenderized, "fully cooked"; mildly cured, sometimes smoked; internal temperature of 150°F reached)	Hams are heat processed to 150°F and not pressure-cooked. Occasionally, heat resistant fecal streptococci contaminate these hams. Although the hams may come packaged in cans they are not sterile in the sense that pressure-cooked, canned hams are.	Refrigerate at all times (including at vendor's premises). Storage times same as above.	Discoloration; off-odor softening; mold growth if air is available.
		Same as above	Same as above
<u>Bacon, Cured</u>	Fecal streptococci contamination. Sliced bacon is handled more than slab and may receive staph during handling.	Refrigerate at 30 to 36°F, no more than 1 to 2 weeks.	Off-odor; sliminess; mold
<u>Cold Cuts</u> (Including frankfurters)	Staphylococci from handling are hazard. Listeria monocytogenes.	Refrigerate at 30 to 36 °F, wrapped with some access to air. Original quality and moisture content affect keeping quality. High-moisture cuts: 3 to 5 days; franks, approximately a week. Hard sausage: 2 or more weeks; inspect weekly for molds.	Off-odor; sliminess; mold

**REFERENCE/GENERAL INFORMATION
TEMPERATURE-ABUSED FOOD GUIDELINES
SUB-SECTION 6000**

<u>Frozen Meats</u>	Same as fresh meats	Freezer-store at 0°F or below. It is good to practice rapid turnover of frozen foods. The limits for storage are these: Beef, lamb: 9 to 12 months, Pork: 6 to 9 months, Veal: 4 to 6 months, Sausage, ham, slab bacon: 1 to 3 months, Beef Liver: 3 to 4 months, Pork liver: 1 to 2 months	Dehydration
- POULTRY, FISH AND SHELLFISH -			
<u>Poultry</u> (Fresh)	Primarily, Salmonella contamination; staph, <u>C. perfringens</u> and fecal streptococci may be other contaminants. Campylobacter.	Refrigerate at 30 to 36°F loosely wrapped; remove giblets from original wrap, rewrap loosely. 1 to 2 days (freeze if storage must be extended beyond a few days).	Off-odor; discoloration; sliminess.
<u>Poultry</u> (Frozen)	Same as fresh poultry.	Freezer at 0°F or below. Chicken: 6 to 8 months, Turkey: 4 to 5 months, Giblets: 2 to 3 months.	Prolonged freezer storage does not make poultry unsafe, but quality suffers.
<u>Fish and Shellfish</u>	If harvested from sewage-polluted waters, human pathogens may be contaminants of these foods. <u>Clostridium botulinum</u> Type E occurs in (continued next page) certain waters and fish may become contaminated with it.	<u>Fresh Fish:</u> refrigerate, loosely wrapped, at 30 to 32°F; or pack in ice and refrigerate; or freeze if fish cannot be used within 2 to 3 days.	<u>Fresh Fish:</u> softens, eyes are sunken; flesh has strong or off-odor.

**REFERENCE/GENERAL INFORMATION
TEMPERATURE-ABUSED FOOD GUIDELINES
SUB-SECTION 6000**

	For both quality and safety, purchase from a reliable vendor. Scombroid Poisoning.	<u>Fresh Shellfish</u> : refrigerate in original, covered container, 1 to 5 days. <u>Frozen fish and Shellfish</u> : hold at 0°F 4 to 6 months; shellfish, 3 to 4 months. <u>Smoked Fish</u> : if to be held longer than 3 days, freeze.	<u>Smoked fish, fish, oysters and clams</u> : abnormal appearance, sour odor, flavor or other off-odor.
- CANNED FOODS AND PRECOOKED FROZEN FOODS -			
<u>Canned Foods</u>	None, if commercially processed, and if cans are intact. Underprocessed, home canned, non-acid foods may contain <u>Clostridium botulinum</u> toxin.	Cool (50-60°F) dry storage. Freezing may break seal of can or jar or crack jar; leaks will allow bacteria to enter. Unless cans or jars are damaged, freezing will not make food unsafe. Maximum storage time 1 year, but 6 months is preferable.	Color change (red foods may lighten; colored foods fade in plain tin cans). All canned goods are gradually reduced in quality if held above 50°F.
<u>Frozen Precooked Foods</u>	Pathogens introduced from hands and equipment; delayed freezing; warm-up during thawing.	Freezer at 0°F or below. Length of storage depends on product. Do not store anything over 3 months.	Dehydration; discoloration; large ice crystals.

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**REFERENCE/GENERAL INFORMATION
GUIDE TO SAFELY REFREEZING THAWED FOOD
SUB-SECTION 6005**

CAN THAWED FOOD BE REFROZEN?		
Frozen Uncooked Foods	Thawed - but Cold 41° Degrees or Lower	Thawed - Warm (Above 41° Degrees)
Fruit	Yes	Probably safe - but may have fermented
Fruit Juice Concentrate	Yes - but flavor may be poor and reconstituted juice separate	No - may have fermented
Vegetables	Yes	Questionable - safer not to refreeze - especially corn, peas, and beans - discard
Meat	Yes - if odor is normal - If any odor - discard	Do not refreeze
Poultry	Yes - if odor is normal - If there is any odor - discard	No
Fish and Shellfish	Yes - if odor is normal - If there is any off odor - discard	No
Cooked Meat, Poultry and Fish	No	No
Combination Dishes, Pot Pies, Casseroles, Whole Meals	No	No
Soups	No	No
Ice Cream and Sherbet	No	No
Fruit Pies	Yes	Yes - but quality may be poor
Plain Cake and Cookies	Yes	Yes - but texture may be poor
Cream-filled Cake and Cookies	No	No

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REFERENCE/GENERAL INFORMATION
FISH PROCESSING AND SMOKING ESTABLISHMENTS
INTERPRETATION AND ENFORCEMENT GUIDELINES
SUB-SECTION 6010

1 NYCRR PART 262 - FISH PROCESSING AND SMOKING ESTABLISHMENTS

Manufacturers of the following products are affected:

1. Smoked Fish
2. Pickled Fish
(refrigerated)
3. Marinated Fish
(except those which are merely flavored and which require cooking prior to consumption)
4. Salted Fish
5. Fermented Fish

Note: Includes seafood (i.e., shrimp, clams, mussels). Excludes Low Acid Canned Food (LACF) and Acidified Foods from regulation.

Manufacturers of the following products are **not** affected:

1. Smoked Fish Salad
2. Seafood Salad
3. Herring in Cream Sauce
4. Minced Herring
5. Sushi Products

Note: Regulated firms are those that smoke, pickle, salt-cure, marinate or ferment fishery products.

Manufacturers will also need to comply with **Rules and Regulations Relating to Human Foods** (GMP's, Article 17).

Section 262.3 Raw Materials pertains to all processed fish manufacturers and addresses the following:

1. Wholesomeness of raw material - free from adulteration and organoleptically detectable spoilage
2. Temperature maintained at 38°F or below
3. Defrosting procedures (38°F preferred but not to exceed 45°F)
 - A. Under refrigeration
 - B. Continuous flowing water
 - C. Microwave equipment

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D. Evisceration required except for:

1. Small species of fish (i.e., anchovies, sprats)
2. Fermented fish (17% wps)
3. Cooked seafoods (i.e., smoked lobster)

E. Segregation of evisceration procedure required. A clear physical separation rather than walls will be allowed.

Section 262.4 Operations and Controls for Processed Fish requires that all processed fish be produced pursuant to a scheduled process established by a competent processing authority. The scheduled process includes processing methods, controls, labeling, and packaging. The controls for the process will include product safety criteria (i.e., temperature, wps, pH, water activity) and its recommended validation procedure (i.e., records, analysis). Vacuum Packaged/Modified Atmosphere Packaging (VP/MAP) smoked fish produced in accordance with Section 262.5 need not comply with this requirement. VP/MAP smoked fish which is not produced in accordance with Section 262.5 will need a scheduled process as required in this Section.

Note: The scheduled process shall be in writing and available for review by inspection personnel.

Process deviations - destruction of product or detention for further evaluation are options available to processors. They may choose to contact their processing authority to evaluate the deviation.

Temperature requirements for processed fish:

1. 38°F
2. 45°F if greater than 10% wps (multiple barrier for Botulinum A and B) or pH of 4.6 or below
3. None if greater than 17% wps
4. Thermometers required in refrigerated areas

VP/MAP processed fish have additional requirements in Section 262.4 as follows:

1. VP/MAP only in facility where produced
2. Product analysis (frequency determined by the scheduled process)

Note: Numerous scheduled processes received have recommended that products be analyzed on a quarterly basis.

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FISH PROCESSING AND SMOKING ESTABLISHMENTS
INTERPRETATION AND ENFORCEMENT GUIDELINES
SUB-SECTION 6010**

Section 262.5 VP/MAP Smoked Fish

1. Brining Procedures: (VP/MAP)
 - A. Brine not to exceed 60°F at start
 - B. Brining procedures greater than 4 hours to be conducted under refrigeration of 38°F
 - C. Dry salting placed under 38°F refrigeration after the salting step
 - D. Brines not to be reused
 - E. Mixing of fish species in brines not allowed
2. Smoking Procedures: (VP/MAP)
 - A. Fish not overcrowded in smokehouse so as to promote absorption and exposure
 - B. Generated smoke applied to fish during the first-half of process
 - C. Liquid smoke may be added before or during process

Hot Smoking

- 1) Temperature probe of 3 or more fish with the coldest reading being recorded on process record
- 2) Temperature recorded 3 times during heating
- 3) Process record to include batch load temperature and date
- 4) 145°F/30 minutes and 3.5% wps 145°F/30 minutes and 3.0% wps w/100-200 ppm nitrite

Cold Smoking

- 1) Smokehouse or chamber temperature monitored
- 2) 90°F/20 hours and 3.5% wps
90°F/20 hours and 3.0% wps w/100-200 ppm nitrite
50°F/24 hours and 3.5% wps
50°F/24 hours and 3.0% wps w/100-200 ppm nitrite

Sablefish 120°F/6 hours and 3.5% wps

Sablefish 120°F/6 hours and 3.0% wps w/100-200 ppm nitrite

3. Cooling Procedures: (VP/MAP)

50°F within 5 hours and 38°F within 12 hours

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SUB-SECTION 6010

Exemptions from 262.4 (b) (c) (d) and 262.5 include Finnan haddies, smoked cod fillets, and smoked scotch kippers. Packages must be clearly marked or labeled indicating they are to be cooked prior to consumption.

Section 262.7 Records

1. Current requirements per Article 20-C:
 - A. Production records - name of product, code, container size, number of containers
 - B. Distribution records - names, addresses, codes
2. Additional requirements per Section 262:
 - A. Process time and temperature where appropriate
 - B. Analysis results of VP/MAP processed fish or as outlined in a scheduled process
 - C. Data and pertinent information relative to a scheduled process

Section 262.8 Packaging and Labeling of Processed Fish

1. Finished product handled separate from unprocessed fish
2. Labeling as follows:
 - A. Frozen product labeled to indicate the product shall remain frozen until thawed at refrigerated temperatures and shall not be refrozen
 - B. Refrigerated product shall state **“Keep Refrigerated at 38⁰F or Below”**
3. Containers coded as per 20-C

Note: Containers of bulk shipped products (i.e., air packed smoked fish) may contain products from multiple production codes. Enforcement of coding is not practical in these cases. This would not apply to individual containers (i.e., jars, vacuum packages). Where air packed bulk products from multiple production codes are implicated in a recall, however, every suspect code will be affected.

Section 262.9 Sale of Processed Fish

1. Out-of-state or imported products shall have been produced and labeled in accordance with these requirements or other applicable statutes or regulations. Acceptability of such products

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FISH PROCESSING AND SMOKING ESTABLISHMENTS
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SUB-SECTION 6010

will be evaluated on a case-by-case basis. Special attention afforded VP/MAP products including those products packed in oil.

2. Data available indicate the following multiple barriers as safe:

- A. Air Packed Smoked Fish- 2.5% wps/38⁰F
(action level less than 2.0%)
- B. Pickled Fish/Marinated Fish - 5.0% wps/45⁰F
or 4.6 or below pH/45⁰F
- C. Fermented Fish - 17% wps/shelf stable
- D. Salted Fish - 10% wps/45⁰F (anaerobic)
5.0% wps/45⁰F (aerobic)
17.0% wps/shelf stable

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**PIES DISPLAYED AT AMBIENT TEMPERATURES
A QUICK REFERENCE GUIDE
SUB-SECTION 6015**

TYPE OF PIE	MANUFACTURER	JUSTIFICATION	CODES
Pumpkin Lemon Meringue Coconut Meringue Chocolate Meringue Sweet Potato Pie	Western Country Crust	Preservatives; pH < 4.6; microbial challenge	"WCP s/s" on pie tin
Pumpkin Pie <i>(prebaked & unbaked)</i> Sweet Potato Pie <i>(prebaked & unbaked)</i>	Sara Lee Bakery (Country Commons)	Preservatives; pH; microbial challenge Microbial challenge; preservatives; pH ≤ 5.6	NPH-AT-3 SLB5302, SLB5804 SLB5301, SLB5805 SLB8472, SLB8488 SLB8489, SLB5835 NPH-AT-3 5826, 5827, 5834 5835, 5870
Pumpkin Pie Lemon Meringue Lemon Chiffon Cream Chocolate Cream Pineapple Coconut Cream Banana Cream Chocolate Mousse Cream	Bonert's Slice of Pie	Preservatives; pH; microbial challenge; a _w ; preservatives	"Bonerts" Refrigerate After Opening
Pumpkin Pie	Hazelwood Farms Bakery	Microbial challenge; preservatives; pH max of 5.1	"Shelf Stable Pumpkin Pie"
Pecan Pie	Edwards Baking Co.	Microbial challenge; a _w < 0.85	
Pumpkin Pie	American Products Co. Smith's Food & Drug Centers Mrs. Smith's Frozen Foods Co. Country Home Bakers	Microbial challenge; preservatives; pH @ 5.0 Microbial challenge; preservatives; pH ≤ 5.0 Microbial challenge; preservatives; pH Microbial challenge; preservatives; pH ≤ 5.5	"SSP" "CT 3934" "JLCHB"

PIES DISPLAYED AT AMBIENT TEMPERATURES
A QUICK REFERENCE GUIDE
SUB-SECTION 6015

TYPE OF PIE	MANUFACTURER	JUSTIFICATION	CODES
Baked Pumpkin Pie Ready-to-bake Pumpkin Pie	Rich Products Corp.	Preservatives; pH Control	30390, 30453 04482, 14760
Southern Pumpkin Pie	Entenmann's	pH<4.6	
Sweet Cheese Croissants Raspberry Cheese Croissants	Au Bon Pain Company	pH <4.6	
Pumpkin Pie	Publix Super Markets, Inc. Mahoney Family Pies Pies, Inc.	Microbial challenge; preservatives; pH 6.0 Microbial challenge; preservatives; pH ≤5.5 Microbial challenge; preservatives; pH 5.9	"Deli Pumpkin Pie" "MFP 82"
Buttermilk Pie Pecan Pie	Glen-Mary Farms	Microbial challenge; preservatives; pH 5.6 & 6.0	
Pumpkin Pie	Oehme Pie Bakery, Inc. Sarsfield Foods Limited	Microbial challenge; preservatives, pH ≤5.9 Microbial challenge; preservatives; pH ≤5.2	"OPB14A" 8" x 24oz. - #16123 9" x 37oz. - #47923 10" x 44oz. - #61223

**PIES DISPLAYED AT AMBIENT TEMPERATURES
A QUICK REFERENCE GUIDE
SUB-SECTION 6015**

TYPE OF PIE	MANUFACTURER	JUSTIFICATION	CODES
Pumpkin Pie	Nabisco Foods Group	Microbial challenge; preservatives; pH	9" Pre-baked-24214 8" Pre-baked-44214 10" Pre-baked-54514 9" Un-baked 23214 8" Un-baked-43214

**This information is not all-inclusive; it is meant to serve as an outline to provide a quick reference source.
This list will be continually updated as new information becomes available.**

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**REFERENCE/GENERAL INFORMATION
ACIDITY/ALKALINITY (pH) VALUES OF VARIOUS FOODS
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Item	Approximate pH
Abalone	6.10 - 6.50
Abalone mushroom	5.00 -
Ackees	5.50
Aloe vera	6.10
Aloe Juice	6.00 - 6.80
Anchovies	6.50
Anchovies, stuffed w/capers, in olive oil	5.58
Antipasto	5.60 -
Apple, baked with sugar	3.20 - 3.55
Apple, eating	3.30 - 4.00
Apples	
Delicious	3.90
Golden Delicious	3.60
Jonathan	3.33
McIntosh	3.34
Juice	3.35 - 4.00
Sauce	3.10 - 3.60
Winesap	3.47
Apricots	3.30 - 4.80
Canned	3.40 - 3.78
Dried, stewed	3.30 - 3.51
Nectar	3.78
Pureed,	3.42 - 3.83
Strained	3.72 - 3.95
Arrowroot Crackers	6.63 - 6.80
Arrowroot Cruel	6.37 - 6.87
Artichokes	5.50 - 6.00
Artichokes, canned, acidified	4.30 - 4.60

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Artichokes, French, cooked	5.60 - 6.00
Artichokes, Jerusalem, cooked	5.93 - 6.00
Asparagus	6.00 - 6.70
Buds	6.70
Stalks	6.10
Asparagus, cooked	6.03 - 6.16
Asparagus, canned	5.00 - 6.00
Asparagus, frozen, cooked	6.35 - 6.48
Asparagus, green, canned	5.20 - 5.32
Asparagus, strained	4.80 - 5.09
Avocados	6.27 - 6.58
Baby corn	5.20 -
Baby Food Soup, unstrained	5.95 - 6.05
Bamboo Shoots +	5.10 - 6.20
Bamboo Shoots, preserved	3.50 - 4.60
Bananas	4.50 - 5.20
Bananas, red	4.58 - 4.75
Banana, yellow	5.00 - 5.29
Barley, cooked	5.19 - 5.32
Basil pesto	4.90
Bass, sea, broiled	6.58 - 6.78
Bass, striped, broiled	6.50 - 6.70
Beans	5.60 - 6.50
Black	5.78 - 6.02
Boston style	5.05 - 5.42
Kidney	5.40 - 6.00
Lima	6.50
Soy	6.00 - 6.60
String	5.60
Wax	5.30 - 5.70
Beans, pork & tomato sauce, canned	5.10 - 5.80

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Beans, refried	5.90
Beans, vegetarian, tomato sauce, canned	5.32
Beets	5.30 - 6.60
Beets, cooked	5.23 - 6.50
Beets, canned, acidified	4.30 - 4.60
Beets, canned	4.90 - 5.80
Beets, chopped	5.32 - 5.56
Beets, strained	5.32 - 5.56
Bird's nest soup	7.20 - 7.60
Blackberries, Washington	3.85 - 4.50
Blueberries, Maine	3.12 - 3.33
Blueberries, frozen	3.11 - 3.22
Bluefish, Boston, filet, broiled	6.09 - 6.50
Bran	
Flakes	5.45 - 5.67
All Bran	5.59 - 6.19
Bread, white	5.00 - 6.20
Bread, Boston, brown	6.53
Bread, Cracked wheat	5.43 - 5.50
Bread, pumpernickel	5.40 -
Bread, Rye	5.20 - 5.90
Bread, whole wheat	5.47 - 5.85
Breadfruit, cooked	5.33
Broccoli, cooked	6.30 - 6.52
Broccoli, frozen, cooked	6.30 - 6.85
Broccoli, canned	5.20 - 6.00
Brussels sprout	6.00 - 6.30
Buttermilk	4.41 - 4.83
Cabbage	5.20 - 6.80
Green	5.50 - 6.75

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Red	5.60 - 6.00
Savoy	6.30
White	6.20
Cactus	4.70
Calamary (Squid)	5.80
Cantaloupe	6.13 - 6.58
Capers	6.00
Carp	6.00
Carrots	5.88 - 6.40
Carrots, canned	5.18 - 5.22
Carrots, chopped	5.30 - 5.56
Carrots, cooked	5.58 - 6.03
Carrots, pureed	4.55 - 5.80
Carrots, strained	5.10 - 5.10
Cauliflower	5.60
Cauliflower, cooked	6.45 - 6.80
Caviar, American	5.70 - 6.00
Celery	5.70 - 6.00
Celery, cooked	5.37 - 5.92
Celery Knob, cooked	5.71 - 5.85
Cereal, strained	6.44 - 6.45
Chayote (mirliton), cooked	6.00 - 6.30
Cheese, American, mild	4.98
Cheese, Camembert	7.44
Cheese, Cheddar	5.90
Cheese, Cottage	4.75 - 5.02
Cheese, Cream, Philadelphia	4.10 - 4.79
Cheese Dip	5.80
Cheese, Edem	5.40
Cheese, Old English	6.15

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Cheese, Roquefort	5.10 - 5.98
Cheese, Parmesan	5.20 - 5.30
Cheese, Snippy	5.18 - 5.21
Cheese, Stilton	5.70
Cheese, Swiss Gruyere	5.68 - 6.62
Cherries, California	4.01 - 4.54
Cherries, frozen	3.32 - 3.37
Cherries, black, canned	3.82 - 3.93
Cherries, Maraschino	3.47 - 3.52
Cherries, red, Water pack	3.25 - 3.82
Cherries, Royal Ann	3.80 - 3.83
Chicory	5.90 - 6.05
Chili Sauce, acidified	2.77 - 3.70
Chives	5.20 - 6.31
Clams	6.00 - 7.10
Clam Chowder, New England	6.40
Coconut, fresh	5.50 - 7.80
Coconut milk	6.10 - 7.00
Coconut preserves	3.80 - 7.00
Codfish, boiled	5.30 - 6.10
Cod liver	6.20
Conch	7.52 - 8.40
Congee	6.40
Corn	5.90 - 7.30
Corn, canned	5.90 - 6.50
Corn Flakes	4.90 - 5.38
Corn, frozen, cooked	7.33 - 7.68
Corn, Golden Bantam, cooked on cob	6.22 - 7.04
Crab meat	6.50 - 7.00
Crabapple Jelly, corn	2.93 - 3.02

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Cranberry Juice, canned	2.30 - 2.52
Crabmeat, cooked	6.62 - 6.98
Cream, 20 per cent	6.50 - 6.68
Cream, 40 per cent	6.44 - 6.80
Cream of Asparagus	6.10
Cream of Coconut, canned	5.51 - 5.87
Cream of Potato soup	6.00
Cream of Wheat, cooked	6.06 - 6.16
Chrysanthemum drink	6.50
Cucumbers	5.12 - 5.78
Cucumbers, Dill pickles	3.20 - 3.70
Cucumbers, pickled	4.20 - 4.60
Curry sauce	6.00
Curry Paste,acidified	4.60 - 4.80
Cuttlefish	6.30
Dates, canned	6.20 - 6.40
Dates, Dromedary	4.14 - 4.88
Dungeness Crab Meat	
Eggplant	5.50 - 6.50
Eggs, new-laid, whole	6.58
White	7.96
Yolk	6.10
Eell	6.20
Escarolle	5.70 - 6.00
Enchalada sauce	4.40 - 4.70
Fennel (Anise)	5.48 - 5.88
Fennel, cooked	5.80 - 6.02
Figs, Calamyrna	5.05 - 5.98
Figs, canned	4.92 - 5.00
Flounder, boiled	6.10 - 6.90

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Flounder, filet, broiled	6.39 - 6.89
Four bean salad	5.60
Fruit cocktail	3.60 - 4.00
Garlic	5.80
Gelatin Dessert	2.60
Gelatin, plain jell	6.08
Gherkin	
Ginger	5.60 - 5.90
Ginseng , Korean drink	6.00 - 6.50
Gooseberries	2.80 - 3.10
Graham Crackers	7.10 - 7.92
Grapes, canned	3.50 - 4.50
Grapes, Concord	2.80 - 3.00
Grapes, Lady Finger	3.51 - 3.58
Grapes, Malaga	3.71 - 3.78
Grapes, Niagara	2.80 - 3.27
Grapes, Ribier	3.70 - 3.80
Grapes, Seedless	2.90 - 3.82
Grapes, Tokyo	3.50 - 3.84
Grapefruit	3.00 - 3.75
Grapefruit, canned	3.08 - 3.32
Grapefruit Juice, canned	2.90 - 3.25
Grass jelly	5.80 - 7.20
Greens, Mixed, chopped	5.05 - 5.22
Greens, Mixed, strained	5.22 - 5.30
Grenadine Syrup	2.31
Guava nectar	5.50
Guava, canned	3.37 - 4. 10
Guava Jelly	3.73
Haddock, Filet, broiled	6.17 - 6.82

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Hearts of Palm	5.70
Herring	6.10
Hominy, cooked	6.00 - 7.50
Honey	3.70 - 4.20
Honey Aloe	4.70
Horseradish, freshly ground	5.35
Huckleberries, cooked with sugar	3.38 - 3.43
Jackfruit	4.80 - 6.80
Jam, fruit	3.50 - 4.50
Jellies, fruit	3.00 - 3.50
Jujube	5.20 -
Junket type Dessert:	
Raspberry	6.27
Vanilla	6.49
Kale, cooked	6.36 - 6.80
Ketchup	3.89 - 3.92
Kippered, Herring, Marshall	5.75 - 6.20
Herring, Pickled	4.50 - 5.00
Kelp	6.30
Kumquat, Florida	3.64 - 4.25
Leeks	5.50 - 6.17
Leeks, cooked	5.49 - 6.10
Lemon Juice	2.00 - 2.60
Lentils, cooked	6.30 - 6.83
Lentil Soup	5.80
Lettuce	5.80 - 6.15
Lettuce, Boston	5.89 - 6.05
Lettuce, Iceberg	5.70 - 6.13
Lime Juice	2.00 - 2.35
Lime	2.00 - 2.80

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Lobster bisque	6.90 -
Lobster soup	5.70
Lobster, cooked	7.10 - 7.43
Loganberries	2.70 - 3.50
Loquat (May be acidified to pH 3.8)	5.10
Lotus Root	6.90 -
Lychee	4.70 - 5.01
Macaroni, cooked	5.10 - 6.41
Mackerel, King, boiled	6.26 - 6.50
Mackerel, Spanish, broiled	6.07 - 6.36
Mackerel, canned	5.90 - 6.40
Mangoes, ripe	3.40 - 4.80
Mangoes, green	5.80 - 6.00
Mangostine ?	4.50 -5.00
Maple syrup	5.15
Maple syrup, light (Acidified)	4.60
Matzos	5.70
Mayhaw (a variety of strawberry)	3.27 - 3.86
Melba Toast	5.08 - 5.30
Melon, Casaba	5.78 - 6.00
Melons, Honey dew	6.00 - 6.67
Melons, Persian	5.90 - 6.38
Milk, cow	6.40 - 6.80
Milk, Acidophilus	4.09 - 4.25
Milk, condensed	6.33
Milk, evaporated	5.90 - 6.30
Milk, Goat's	6.48
Milk, peptonized	7.10
Milk, Sour, fine curd	4.70 - 5.65
Milkfish	5.30

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Mint Jelly	3.01
Molasses	4.90 - 5.40
Muscadine (A variety of grape)	3.20 - 3.40
Mushrooms	6.00 - 6.70
Mushrooms, cooked	6.00 - 6.22
Mushroom Soup, Cream of, canned	5.95 - 6.40
Mussels	6.00 - 6.85
Mustard	3.55 - 6.00
Nata De Coco	5.00
Nectarines	3.92 - 4.18
Noodles, boiled	6.08 - 6.50
Oatmeal, cooked	6.20 - 6.60
Octopus	6.00 - 6.50
Okra, cooked	5.50 - 6.60
Olives, black	6.00 - 7.00
Olives, green, fermented	3.60 - 4.60
Olives, ripe	6.00 - 7.50
Onions, pickled	3.70 - 4.60
Onions, red	5.30 - 5.80
Onion white	5.37 - 5.85
Onions, yellow	5.32 - 5.60
Oranges, Florida	3.69 - 4.34
Oranges, Florida "color added"	3.60 - 3.90
Orange Juice, California	3.30 - 4.19
Orange, Juice Florida	3.30 - 4.15
Orange, Marmalade	3.00 - 3.33
Oysters	5.68 - 6.17
Oyster, smoked	6.00
Oyster mushrooms	5.00 - 6.00
Palm, heart of	6.70

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Papaya	5.20 - 6.00
Papaya Marmalade	3.53 - 4.00
Parsley	5.70 - 6.00
Parsnip	5.30 - 5.70
Parsnips, cooked	5.45 - 5.65
Pate	5.90
Peaches	3.30 - 4.05
Peaches, canned	3.70 - 4.20
Peaches, cooked with sugar	3.55 - 3.72
Peaches, frozen	3.28 - 3.35
Peanut Butter	6.28
Peanut Soup	7.5
Pears, Bartlett	3.50 - 4.60
Pears, canned	4.00 - 4.07
Pears, Sickle cooked w/sugar	4.04 - 4.21
Pear Nectar	4.03
Peas, canned	5.70 - 6.00
Peas, Chick, Garbanzo	6.48 - 6.80
Peas, cooked	6.22 - 6.88
Peas, dried (split green), cooked	6.45 - 6.80
Peas, dried (split yellow), cooked	6.43 - 6.62
Peas, frozen, cooked	6.40 - 6.70
Peas, pureed	4.90 - 5.85
Pea Soup, Cream of, Canned	5.70
Peas, strained	5.91 - 6.12
Peppers	4.65 - 5.45
Peppers, green	5.20 - 5.93
Persimmons	4.42 - 4.70
Pickles, fresh pack	5.10 - 5.40
Pimiento	4.40 - 4.90

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Pimento, canned, acidified	4.40 - 4.60
Pineapple	3.20 - 4.00
Pineapple, canned	3.35 - 4.10
Pineapple Juice, canned	3.30 - 3.60
Plum Nectar	3.45
Plums, Blue	2.80 - 3.40
Plums, Damson	2.90 - 3.10
Plums, Frozen	3.22 - 3.42
Plums, Green Gage	3.60 - 4.30
Plums, Green Gage, canned	3.22 - 3.32
Plums, Red	3.60 - 4.30
Plums, spiced	3.64
Plums, Yellow	3.90 - 4.45
Pollack, filet, broiled	6.72 - 6.82
Pomegranate	2.93 - 3.20
Porgy, broiled	6.40 - 6.49
Pork & Beans, rts.	5.70
Potatoes	5.40 - 5.90
Mashed	5.10
Prunes, dried, stewed	3.63 - 3.92
Sweet	5.30 - 5.60
Tubers	5.70
Potato Soup	5.90
Prune Juice	3.95 - 3.97
Prune, pureed	3.60 - 4.30
Prune, strained	3.58 - 3.83
Puffed Rice	6.27 - 6.40
Puffed Wheat	5.26 - 5.77
Pumpkin	4.90 - 5.50
Quince, fresh, stewed	3.12 - 3.40

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Quince Jelly	3.70
Radishes, red	5.85 - 6.05
Radishes, white	5.52 - 5.69
Raisins, seedless	3.80 - 4.10
Rambutan (Thailand)	4.90
Raspberries	3.22 - 3.95
Raspberries, frozen	3.18 - 3.26
Raspberries, New Jersey	3.50 - 3.82
Raspberry Jam	2.87 - 3.17
Razor Clams	6.20
Razor shell (sea asparagus)	6.00
Rattan, Thailand	5.20 -
Red Ginseng	5.50
Red Pepper Relish	3.10 - 3.62
Rhubarb, California, stewed	3.20 - 3.34
Rhubarb	3.10 - 3.40
Canned	3.40
Rice (all cooked)	
Brown	6.20 - 6.80
Krispies	5.40 - 5.73
White	6.00 - 6.70
Wild	6.00 - 6.50
Rolls, white	5.46 - 5.52
Romaine	5.78 - 6.06
Salmon, fresh, boiled	5.85 - 6.50
Salmon, fresh, broiled	5.36 - 6.40
Salmon, Red Alaska, canned	6.07 - 6.16
Salsa	
Sardines	5.70 - 6.60
Sardine, Portuguese, in olive oil	5.42 - 5.93

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Satay sauce	5.00
Sauce, Enchilada	5.50 -
Sauce, Fish	4.93 - 5.02
Sauce, Shrimp	7.01 - 7.27
Sauerkraut	3.30 - 3.60
Scallion	6.20 -
Scallop	6.00
Scotch Broth.	5.92
Sea Snail (Top shell)	6.00
Shad Roe, sauted	5.70 - 5.90
Shallots, cooked	5.30 - 5.70
Sherbet, raspberry	3.69
Sherry-wine	3.37
Shredded Ralston	5.32 - 5.60
Shredded Wheat	6.05 - 6.49
Shrimp	6.50 - 7.00
Shrimp Paste	5.00 - 6.77
Smelts, Sauted	6.67 - 6.90
Soda Crackers	5.65 - 7.32
Soup	
Broccoli Cheese Suop, condensed	5.60 -
Chicken Broth, rts.	5.80
Corn Soup, condensed	6.80
Cream of celery Saoup, condensed	6.20 -
Cream of Mushroom, condensed	6.00 - 6.20
Cream style corn, condensed	5.70 - 5.80
Cream of Potato soup, condensed	5.80 -
Cream of shrimp soup, condensed	5.80
Minestronen condensed	5.40
New England Clam Chowder,condensed	6.00-

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Oyster Stew, condensed	6.30 -
Tomato Rice Soup, condensed	5.50 -
Soy infant formula	6.60 - 7.00
Soy Sauce	4.40 - 5.40
Soy bean curd (tofu)	7.20
Soybean milk	7.00
Spaghetti, cooked	5.97 - 6.40
Spinach	5.50 - 6.80
Spinach, chopped	5.38 - 5.52
Spinach, cooked	6.60 - 7.18
Spinach, frozen, cooked	6.30 - 6.52
Spinach, pureed	5.50 - 6.22
Spinach, strained	5.63 - 5.79
Squash, acorn, cooked	5.18 - 6.49
Squash, Kubbard, cooked	6.00 - 6.20
Squash, white, cooked	5.52 - 5.80
Squash, yellow, cooked	5.79 - 6.00
Squid	6.00 - 6.50
Sturgeon	6.20
Strawberries	3.00 - 3.90
Strawberries, California	3.32 - 3.50
Strawberries, frozen	3.21 - 3.32
Strawberry Jam	3.00 - 3.40
Straw mushroom	4.90
Sweet Potatoes	5.30 - 5.60
Swiss Chard, cooked	6.17 - 6.78
Tamarind	3.00 -
Tangerine	3.32 - 4.48
Taro syrup	4.50
Tea	7.20

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Three-Bean Salad	5.40
Tofu (soybean Curd)	7.20
Tomatillo (resembling Cherry tomatoes)	3.83
Tomatoes	4.30 - 4.90
Tomatoes, canned	3.50 - 4.70
Tomatoes, Juice	4.10 - 4.60
Tomatoes, Paste	3.50 - 4.70
Tomatoes, Puree	4.30 - 4.47
Tomatoes, Strained	4.32 - 4.58
Tomatoes, Wine ripened	4.42 - 4.65
Tomato Soup, Cream of, canned	4.62
Trout, Sea, sauted	6.20 - 6.33
Truffle	5.30 - 6.50
Tuna Fish, canned	5.90 - 6.20
Turnips	5.29 - 5.90
Turnip, greens, cooked	5.40 - 6.20
Turnip, white, cooked	5.76 - 5.85
Turnip, yellow, cooked	5.57 - 5.82
Vegetable Juice	3.90 - 4.30
Vegetable soup, canned	5.16
Vegetable soup, chopped	4.98 - 5.02
Vegetable soup, strained	4.99 - 5.00
Vermicelli, cooked	5.80 - 6.50
Vinegar	2.40 - 3.40
Vinegar, cider	3.10
Walnuts, English	5.42
Wax gourd drink	7.20
Water Chestnut	6.00 - 6.20
Watercress	5.88 - 6.18
Watermelon	5.18 - 5.60

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Wheat Krispice	4.99 - 5.62
Wheatnena	5.85 - 6.08
Wheaties	5.00 - 5.12
Worcestershire sauce	3.63 - 4.00
Yams , cooked	5.50 - 6.81
Yeast	5.65
Yangsberries, frozen	3.00 - 3.70
Zucchini, cooked	5.69 - 6.10
Zwiebach	4.84 - 4.94

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2. Bridges, M. A., and Mattice, M.R. 1939. Over two thousand estimations of the pH of representative foods, American J. Digestive Diseases, 9:440-449.
3. Warren L. Landry and et al. 1995. Examination of canned foods. FDA Bacteriological Analytical Manual, 8th Ed. Chapter 21, Table 11, AOAC International, Gaithersburg, MD 20877
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**REFERENCE/GENERAL INFORMATION
WATER ACTIVITY (a_w) VALUES OF VARIOUS FOODS
SUB-SECTION 6025**

PRINCIPAL GROUPS OF FOODS BASED ON WATER ACTIVITY (a_w)

1. 0.98 a_w and Above

Fresh meats and fish
Fresh fruits and vegetables
Milk and other beverages
Canned vegetables in brine
Canned fruit in light syrup

These are very moist foods, including those containing less than 3.5% sodium chloride or 26% sucrose in the aqueous phase. Food-poisoning bacteria and common spoilage microorganisms, with the exception of extreme xerophiles and halophiles, grow almost unimpeded at levels of a_w within this range.

2. Below 0.98 to 0.93 a_w

Evaporated milk
Tomato paste
Lightly salted fish, pork, beef products
Canned cured meats
Fermented sausages (not dried)
Cooked sausages
Processed cheese
Gouda cheese
Canned fruits in heavy syrup
Bread
High moisture prunes

Maximum concentrations of salt or sugar in the aqueous phase of these foods will be near 10% and 50%, respectively. All known food-poisoning bacteria can grow at least in the upper part of this range.

3. Below 0.93 to 0.85 a_w

Dry or fermented sausage (Hungarian, Italian type)
Dried beef

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Raw ham
Aged cheddar cheese
Sweetened condensed milk

This group includes foods with up to 17% salt or saturated sucrose in the aqueous phase. Only one bacterium known to cause food poisoning (*Staphylococcus aureus*), but many molds that produce mycotoxins, can grow in this a_w range.

4. Below 0.85 to 0.60 a_w

Intermediate moisture foods
Dried fruit
Flour
Cereals
Jams and jellies
Molasses
Heavily salted fish
Meat extract
Some aged cheeses
Nuts

No pathogenic bacteria grow within this range. Spoilage by xerophilic, osmophilic, or halophilic organisms can occur.

5. Below 0.60 a_w

Confectionery
Chocolate
Honey
Noodles
Biscuits
Crackers
Potato chips
Dried egg, milk, vegetables

Microorganisms do not multiply below 0.60 a_w , but can remain viable for long periods.

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**REFERENCE/GENERAL INFORMATION
COLORING OR WAXING OF RAW AGRICULTURAL COMMODITIES
SUB-SECTION 6030**

POST HARVEST TREATMENT WITH COLORING AGENTS OR WAX OF RAW AGRICULTURAL COMMODITIES

The shipping container and consumer size package of such commodities must bear labeling which declares the presence of any coloring agent or wax applied after harvest. This statement must appear prominently and conspicuously in lettering at least one-sixteenth of an inch in height.

When such products are displayed to the purchaser at retail, the labeling from the shipping container must be plainly in view or a counter card or sign declaring the presence of the coloring agent or wax must be posted prominently and conspicuously. Any labeling at a retail display (Shipping container or sign) must have lettering at least one-fourth inch in height.

In the case of post harvest wax treatment the statement must read in one of the following forms as appropriate:

1. "Coated with food grade animal - based wax to maintain freshness" or
2. "Coated with food grade vegetable-, petroleum-, beeswax-, and/or shellac based wax or resin to maintain freshness"

The term "food-grade" and "to maintain freshness" are optional. The term "lac-resin" may be substituted for the term "shellac." The terms "Mineral" or "Mineral Based", wax or resin may not be used.

The terms "**may contain**"; "**may be coated**"; or "**may have been coated**", are not to be used.

Any cards or signs must identify which produce commodity or commodities have been coated with wax or resin. For signs covering multiple commodities the number of signs required will be dictated by the size of the produce section.

Where violations of the foregoing are noted during the course of routine inspections, an Advertising/Labeling Report, FSI-500, should be completed describing the violation and citing any supporting evidence. Where necessary, samples should be submitted to the laboratory for detection of the undeclared presence of color or wax.

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**REFERENCE/GENERAL INFORMATION
MEDIA REPRESENTATIVES AT DEPARTMENT INSPECTIONS
SUB-SECTION 6035**

MEDIA REPRESENTATIVES AT DEPARTMENT INSPECTIONS

The following information concerning the above matter is provided in response to recent inquiries on this subject.

The Department does not have authority to grant media representatives access to establishments under our regulatory jurisdiction. Any such entry (into non-public areas) without the operator's consent or other authority could constitute a trespass. We must not facilitate such a wrongdoing by doing anything that might confuse or mislead an establishment as to the status of a media representative present during an inspection. Therefore, any request by a reporter to accompany Department employees on an inspection without prior disclosure of the media representative's identity to the establishment operator must be denied.

While not barred per se, allowing a media representative to accompany Department employees on inspection of establishments that consent to such presence would also raise concerns. If the reporter accompanies a Department employee to the premises to be inspected, or our employee seeks the establishment's consent for the reporter, or otherwise assists in gaining such permission, the establishment operator might feel compelled or pressured to allow the reporter's presence out of concern that a refusal may adversely affect his inspection rating. Agency involvement in such arrangements could also result in the assertion of claims against the Department based on allegations of damages or injuries (to the operator or reporter) stemming from such action.

In view of the foregoing, it has been decided that media representatives are not to be notified of inspection times or given permission by any Department representative to accompany Department employees on inspections. Any requests therefore should be declined and the media representative informed that the Department is without the power to authorize his or her entry into an establishment. Of course, media representatives would not be precluded from being present during an inspection if they otherwise become aware of it and obtain permission from a person authorized to grant such access.

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**REFERENCE/GENERAL INFORMATION
CONSUMER PRODUCT TAMPERING
SUB-SECTION 6040**

FOOD TAMPERING INVESTIGATION POLICY

As a rule, in instances of suspected food tampering, we will not get involved unless requested to do so by a police agency. Consumers should be instructed to contact their local or state police.

OVERVIEW: CONSUMER PRODUCT TAMPERING LAW

The Laws of 1987 amended the Executive Law to add a new Section 216-d *Consumer Product Protection*, relating to consumer product tampering. The following are major provisions of this section:

Directs the Superintendent of the New York State Police in consultation with the Commissioner of the Division of Criminal Justice Services to establish a program to investigate actual or suspected cases of tampering.

State Police may, upon request, act as the coordinating agency in investigating suspected product tampering.

Requires that uniform procedures be developed that may be used by other agencies in such cases. These are to be developed by the New York State Police, in cooperation with the New York State Police, in cooperation with the New York State Department of Agriculture and Markets, Division of Criminal Justice Services, New York State Department of Health, and other pertinent agencies.

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**REFERENCE/GENERAL INFORMATION
SCHEDULED PROCESS/VARIANCE/RECORD-KEEPING REQUIREMENTS
SUB-SECTION 6050**

PRODUCT	SCHEDULED PROCESS REQUIRED	VARIANCE REQUIRED AT RETAIL	CCP RECORD KEEPING REQUIREMENTS (wps, pH, a _w , temperature, time, moisture/ protein ratio, etc.)	WHOLESALE DISTRIBUTION RECORDS		CODES		AUTHORITY
				REQUIRED	RECOMMENDED	REQUIRED	RECOMMENDED	
Smoked Fish*	X		X	X		X		1 NYCRR Part 262
Processed Fish (Salted, Acidified)	X		X	X		X		1 NYCRR Part 262
LACF'S	X		X	X		X		21 CFR Part 113
Acidified Low -Acid Foods (Relish)	X		X	X		X		21 CFR Part 114
a _w Controlled Foods > .85 < .91 (Chocolate Syrup)	X		X	X		X		21 CFR Part 113
Dried Fish Fish Products	X		X	X		X		1 NYCRR Part 262
Garlic in Oil (Refrigerated)			X		X	X		1 NYCRR Part 261
Smoked Meats** (Retail)		X	X				X	1 NYCRR Part 318, 319
Fermented Sausage** (Retail) Ambient Temperature		X	X				X	1 NYCRR Part 318, 319
Jerky (Retail)		X	X					1 NYCRR Part 318, 319
Processing Wild Game		X						1 NYCRR Part 271
Formulated Acidified Foods (Salad Dressing, Barbeque Sauce)			X					1 NYCRR Part 261
Tomato Products Spaghetti Sauce (Shelf-Stable)			X				X	1 NYCRR Part 261
Vacuum Packaging (Retail)			X			X		1 NYCRR Part 271
Exotic Foods, e.g., Acidified Rice			X					1 NYCRR Part 271

* - May use Part 262 as SP by RA

** - May use Part 318 & 319 as SP

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**REFERENCE/GENERAL INFORMATION
FRESH MUSHROOM PACKAGING POLICY
SUB-SECTION 6055**

FRESH MUSHROOM PACKAGING POLICY

Scientists have demonstrated that fresh mushrooms packaged in airtight containers (such as plastic film overwrapped trays), can create conditions whereby **Clostridium botulinum** spores will vegetate and produce the toxin responsible for the deadly disease, **botulism**.

As a result, the FDA has advised the American Mushroom Institute that fresh mushrooms packaged in overwrapped paperboard trays must be ventilated with at least two one-eighth inch holes in the overwrap.

Retailers also have a responsibility in this area. Retailers should:

1. Establish a product specification that packaged fresh mushrooms be ventilated
2. Refuse to accept shipments that do not comply with that specification
3. Establish in-store practices, which prevent fresh mushrooms from being placed in airtight bags or containers.

The presence of fresh mushrooms in airtight containers in commercial food handling establishments under the jurisdiction of the New York State Department of Agriculture and Markets will be treated as a violative condition and the product in question will be placed under seizure.

Your cooperation in preventing this potentially hazardous problem will be appreciated

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**REFERENCE/GENERAL INFORMATION
ADVANTAGES AND DISADVANTAGES OF VARIOUS SANITIZERS
SUB-SECTION 6060**

ADVANTAGES		DISADVANTAGES	
HYPOCHLORITES			
• Effective against a broad spectrum of microorganisms • Effective against spores and bacterial phages • Easy to use • Least expensive • Not affected by water hardness • Concentration easily measured by convenient field test		• Corrosive to stainless steel and other metals, if misused • May oxidize lipids • May discolor products • Effectiveness diminished by organic matter • May irritate skin • May affect the flavor and odor of food • Hazardous at high temperatures or under acid conditions	
IODOPHORES			
• Non-corrosive • Easy to use • Non irritating • Effective against a broad spectrum of microorganisms, both spore and non-spore forming • Not affected by water hardness		• May affect the flavor and odor of food • Forms purple colored stains with starch • Moderately expensive • Should not be used at temperatures above 122°F (50°C) • Narrow effective pH range (2.5 to 3.5) • Less effective than chlorine in killing bacterial spores	
QUATERNARY AMMONIUM COMPOUNDS (QUATS)			
• Non-corrosive • Non-irritating • Leaves no flavor or odor • Effective over a wide pH range (6 to 10) • Effective against most microorganisms, especially gram positive slime formers and molds • Effective at high temperatures • Stable in the presence of organic matter		• Not effective against coliforms and gram negative bacteria • Forms films on surface • May enhance the growth of Pseudomonas spp. • Expensive • Moderately toxic	
HOT WATER AND STEAM			
• Non-corrosive • Leaves no residue		• Antimicrobial effect depends on temperature and exposure time • Not effective against some spores • Mineral deposits on equipment, if water is hard • Higher energy costs	

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**REFERENCE/GENERAL INFORMATION
MOLD ON CHEESE
SUB-SECTION 6065**

MOLD ON CHEESE

The term “moldy” refers to the presence on cheese of atypical contaminating molds, generally species of *Penicillium*, *Aspergillus*, *Fusarium*, *Cladosporium* and *Alternaria*. It does not refer to the presence of molds, principally *Penicillium roqueforti* and *P. caseicolum*, which are intentionally added to curd or milk in order to produce such “mold-ripened” cheese as roquefort, blue, gorgonzola, brie and camembert.

Many of the common contaminant molds are psychrotrophic and grow at refrigeration temperatures. Temperatures around 40 degrees favor the growth of *Penicillium* sp. over most of the other molds.

All types of cheeses are susceptible to mold growth which may be more than an aesthetic problem. Some common mold species found on cheese produce toxic metabolites under some conditions. These mycotoxins have caused cancer and other adverse effects in experimental animals.

Molds are aerobic and usually grow on the surface of cheese, but may penetrate to the inside along air passages such as holes in swiss-type cheese. Mycotoxins, if produced, are produced near the surface, closely associated with the mold filaments. Mycotoxins can migrate into cheese if the cheese is stored for long periods at room temperature. Conversely, mycotoxin production and migration is greatly reduced at refrigeration temperatures, at least in the case of *Aspergillus* sp.

Cheese Trimming - In summary, under certain circumstances, some moldy cheese may be restored to a sound and safe condition by carefully cutting off and discarding:

1. A one-half inch thick layer if the cheese became moldy while under refrigeration (41°F)
2. An inch thick layer if the cheese became moldy at higher temperatures

The cutting must be done carefully to minimize the possibility of contaminating the newly exposed cheese surface.

Cheese that is too small for the required cutting, which has a high moisture content (cottage cheese, etc.) or has mold filaments deeply penetrating along the holes or eyes cannot be made sound and safe.

Washing or scraping the surface does not remove mycotoxins.

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**REFERENCE/GENERAL INFORMATION
SANITATION IN SOFT-SERVE FROZEN DESSERT OPERATIONS
SUB-SECTION 6070**

STORAGE AND HANDLING OF MIXES

Most frozen dessert mixes are not sterile, but generally have a low bacteria count when fresh. To keep the bacteria from growing, the mix should be stored under refrigeration as close to 32°F as possible. Some spoilage bacteria can begin to grow at temperatures just above freezing. The mixes should be rotated following the principle of “first in - first out,” and not be used beyond their code dates.

Mixes stored in a frozen state should be thawed in a refrigerator but in an emergency cold running water can be used. Never place frozen mixes in hot water, sunlight, under heat lamps or at room temperature to thaw.

Hoses used to transfer mixes should be as short as possible, kept under refrigeration and washed following the same program as the freezer.

CLEANING AND SANITIZING PROGRAM

Except for clean-in-place systems, all soft-serve freezers should be completely disassembled, washed and sanitized on a daily basis. The washed parts should be allowed to air dry before they are sanitized and reassembled. Only properly formulated dairy-type cleaners and approved sanitizers should be used. Common household and glassware detergents are not satisfactory for cleaning freezers.

TEN STEPS OF CLEANING AND SANITIZING

1. Drain any remaining mix from the freezer. Use a clean, sanitized container with closure and immediately refrigerate.
2. Rinse freezer barrel and supply tank with cold water, drain; rinse with lukewarm water and drain.
3. Disassemble parts and wash with warm detergent solution. Use proper brushes to reach all parts of the freezer including barrel, dasher, vales, freezer head, lid and hoses.
4. Rinse with warm water. **Note:** Use a commercial acid rinse at least twice a week, more frequently if water is hard.
5. Allow to air dry.

REFERENCE/GENERAL INFORMATION
SANITATION IN SOFT-SERVE FROZEN DESSERT OPERATIONS
SUB-SECTION 6070

6. Prepare at least 2 gallons of sanitizer solution. A 200 parts per million (ppm) chlorine solution is recommended, but other sanitizers approved by regulatory at equivalent concentrations can be used.
7. Submerge all disassembled parts in the sanitizer for at least **one** minute.
8. Assemble the freezer. Use food grade lubricants applied in a sanitary manner.
9. Add the sanitizer solution to the mix supply tank and sanitize all surfaces of the tank and lid.
10. Drain sanitizer into barrel while running the dasher to sanitize the dasher, barrel, and scraper blades. Do not run longer than 30 seconds or follow recommendation of the manufacturer of the freezer. **DO NOT RINSE WITH TAP WATER AFTER THE SANITIZER IS DRAINED.**

CARE OF HOLDOVER MIX

Holdover mix is one of the major sources of bacterial contamination in soft-serve ice cream. The following practices should help in reducing the risk of high bacteria counts from the use of holdover mix:

1. Utilize all remaining mix in producing ice cream pies, bars and other novelties at end of the day.
2. Regulate addition of new mix to the machine near the end of the day to prevent holdover.
3. Immediately refrigerate the holdover mix as close to 32°F as possible.
4. Always recharge the freezer in the morning with new mix and use the holdover during a period of high volume that day.
5. Discard the holdover mix at least twice a week to break the chain of bacterial contamination.

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**REFERENCE/GENERAL INFORMATION
INFECTED FOOD HANDLER GUIDELINES
SUB-SECTION 6075**

OVERVIEW

When the Department receives a report of a food worker who may be a carrier of a communicable disease that can be spread through food, immediate precautionary actions must be taken, specific to the disease agent involved. The following specific disease guidelines should be followed.

1. Amebiasis

No person excreting Entamoeba histolytica shall work as a food worker, unless the person is no longer clinically ill; and two fecal specimens collected at intervals not less than 24 hours apart have been examined in an approved laboratory or in the laboratory of the State Department of Health (WCL&R) and no Entamoeba histolytica organisms are found. If the person has been treated with a therapeutic regimen specimens should be taken no sooner than 48 hours after completion of therapy.

2. Campylobacter jejuni

No person shall engage in the handling of milk, dairy products, or other foods until clinical recovery from Campylobacter jejuni infection. Exclusion of asymptomatic individuals from food handling is indicated only for those with questionable hygienic habits; proper handwashing, and the use of disposable plastic gloves or utensils when preparing or serving foods that will not be subsequently cooked should be stressed.

3. Cholera

No person shall engage in the handling of milk, dairy products or other foods until clinical recovery from Vibrio cholera infection and until two fecal specimens collected at intervals not less than 24 hours apart have been examined in an approved laboratory or in the WCL&R and no Vibrio cholera organisms are found.

4. Diarrhea - Undiagnosed

No person shall engage in the handling of milk, dairy products or other foods until recovery from diarrhea or until non-infectious cause has been determined.

5. Diphtheria

The food worker shall be restricted from the food service establishment until two cultures taken from both the nose and throat or affected sites at intervals of not less than 24 hours apart, and not less than 24 hours after cessation of antimicrobial therapy have been found free from diphtheria bacilli in an approved laboratory or in the WCL&R.

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INFECTED FOOD HANDLER GUIDELINES
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6. Giardia lamblia

No person shall engage in the handling of milk, dairy products or other foods until clinical recovery from Giardia lamblia infection. Exclusion of asymptomatic individuals from food handling is indicated only for those with questionable hygienic habits; proper handwashing and the use of disposable plastic gloves or utensils when preparing or serving foods that will not be subsequently cooked should be stressed.

7. Hepatitis A (Infectious Hepatitis; Viral Hepatitis A) (See Table on Page 4)

Exclusion: No person shall engage in the handling of milk, dairy products or other foods until at least two weeks after the onset of clinical symptoms of Hepatitis A and no sooner than one week after the onset of jaundice.

Immunization of contacts: Hepatitis A virus can be transmitted by food contaminated by excreta from an infected food worker. When a food worker has a diagnosed case of acute Hepatitis A, health officials have the option of recommending immunoglobulin prophylaxis (IG, immune globulin) to patrons and co-workers. Use of disposable plastic gloves and/or utensils to prevent hand contact with foods that will not be subsequently cooked should be emphasized. Such a recommendation must take into account: (1) the potability of transmission of infectious virus; and (2) the probability of successful intervention of transmission with the use of IG. IgM antibody testing must be done to confirm Hepatitis A infection.

8. Poliomyelitis

Any case of poliomyelitis should be reported immediately to the New York State Department of Health, Bureau of Communicable Disease Control.

9. Salmonellosis

No person shall engage in the handling of milk, dairy products or other foods until clinical recovery from Salmonella infection and until two fecal specimens collected not less than 24 hours apart, but not sooner than 48 hours following discontinuance of antimicrobials, have been examined in an approved laboratory or in the WCL&R and no Salmonella organisms are found.

10. Shigellosis

No person shall engage in the handling of milk, dairy products or other foods until clinical recovery from Shigella infection and until two fecal specimens collected not less than two days after antimicrobial therapy and at intervals not less than 24 hours apart have been examined in an approved laboratory or in the WCL&R and no Shigella organisms are found.

11. Staphylococcal Infections - Cutaneous

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INFECTED FOOD HANDLER GUIDELINES
SUB-SECTION 6075

No person shall engage in the handling of milk, dairy products or other foods until the local health officer determines that the risk of transmitting staphylococcal bacteria has been eliminated. Any lesions involved must be completely healed.

12. Streptococcal Sore Throat and Streptococcal Skin Infections

No person shall engage in the handling of milk, dairy products or other foods until the local health officer determines that the risk of transmitting streptococcal disease through food has been eliminated as the result of treatment with penicillin or other effective antibiotic and any skin lesions involved have completely healed. Exclusion may be terminated after 48 hours treatment with penicillin or other effective antibiotics.

13. Tuberculosis

No person shall engage in the handling of milk, dairy products or other foods until two weeks of an approved therapeutic regimen has been completed, and the local health officer determines that the person is no longer at risk of transmitting tuberculosis to others. Tuberculosis is airborne spread, it is not spread through food. These precautions are to protect co-workers and close contacts.

14. Typhoid

“10 NYCRR 2.28 (b) Typhoid. Until recovery. The patient shall conform to the regulations for the control of typhoid carriers until three successive specimens of feces passed not less than two weeks after the last administration of any antibiotic or chemotherapeutic agent at an interval of not less than five days shall have been examined in an approved laboratory or in the laboratory of the State Department of Health and found to be free from typhoid bacilli; a person who has recovered from typhoid shall not engage in the handling of milk, dairy products or other foods until all secondary or complicating infections incited by the agents of this disease have disappeared and until three successive specimens of feces and urine passed not less than two weeks after the last administration of any antibiotic or other chemotherapeutic agent and at intervals of not less than five days have been examined in an approved laboratory or in the laboratory of the State Department of Health and found to be free from typhoid bacilli. Should the organism of typhoid be present one year after such person has recovered from typhoid, he shall be released from the restrictions for typhoid carriers only with the approval of the State Commissioner of Health.”

15. Vomiting - Undiagnosed

No person shall engage in the handling of milk, dairy products or other foods until clinical recovery from vomiting or until a non-infectious cause has been determined.

16. Yersinia enterocolitica

REFERENCE/GENERAL INFORMATION
INFECTED FOOD HANDLER GUIDELINES
SUB-SECTION 6075

No person shall engage in the handling of milk, dairy products or other foods until clinical recovery from Yersinia enterocolitica. Exclusion of asymptomatic individuals from food handling is indicated only for those with questionable hygienic habits; proper handwashing and the use of disposable plastic gloves or utensils when preparing or serving foods that will not be subsequently cooked should be stressed.

MANAGEMENT OF FOOD ESTABLISHMENT
EMPLOYEES WITH DISEASE TRANSMISSIBLE THROUGH FOOD
EMPLOYEE MAY RETURN TO WORK BASED ON

DISEASE	CESSATION OF SYMPTOMS	2 NEGATIVE STOOLS REQUIRED	APPROVAL OF LOCAL HEALTH OFFICER	INITIATION OF ACCEPTABLE THERAPEUTIC REGIMEN	TIME PERIOD SINCE ONSET OF ILLNESS
Amebiasis	X	X	X		
Campylobacter	X				
Cholera	X	X			
Diarrhea	X				
Diphtheria*	X		X		
Giardiasis	X				
Hepatitis A	X				2 Weeks
Polio**	X				
Salmonella	X	X			
Shigella	X	X			
Staphylococcal Disease	X		X		
Streptococcal Disease	X			48 Hours	
Tuberculosis	X		X	2 Weeks	
Typhoid***	X	X (3)	X		
Vomiting	X				
Yersinia	X				

*Negative cultures of throat or affected sites

**Call New York State Bureau of Communicable Disease Control immediately

***3 Stools in acute cases

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**REFERENCE/GENERAL INFORMATION
FOOD STORAGE GUIDELINES
SUB-SECTION 6080**

Before opening, shelf-stable foods should be safe unless the can or packaging has been damaged. After opening, store products in tightly closed containers. The storage of many shelf-stable items at room temperature is a quality issue – unless the product is contaminated (bugs in flour, for example). Some foods must be refrigerated after opening, such as tuna or chili.

Shelf-stable foods	Unopened on shelf	Opened, refrigerated	Opened on shelf
Baby food, jars or cans			
Fruits and vegetables	2 months after date	2-3 days	
Meats and eggs	2 months after date	1 day	
Cereal, dry mixes	Use-by date		2 months
Formula	Use-by date	1-2 days	
Bacon Bits, imitation	4 months		4 months
Baking Ingredients			
Baking powder	6 months		3 months
Baking soda	18 months		6 months
Biscuit or pancake mix	15 months		Pkg. use-by date
Cake, brownie and bread mixes	12-18 months		Pkg. use-by date
Cornmeal, regular degerminated	6-12 months	12 months	
stone ground or blue	1 month	2-3 months	
Cornstarch	18 months		18 months
Flour, white	6-12 months		6-8 months

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FOOD STORAGE GUIDELINES
SUB-SECTION 6080

Shelf-Stable Foods	Unopened on Shelf	Opened, Refrigerated	Open, on shelf
Flour, whole wheat	1 month	6-8 months	
Frosting, canned	10 months	1 week	
Frosting mixes	12 months		3 months
Beans, dried	12 months		12 months
Canned goods, low acid	2-5 years	3-4 days	
(such as meat, poultry, fish, gravy, stew, soups, beans, carrots, corn, pasta, peas, potatoes, spinach)			
Canned goods, high acid	12-18 months	5-7 days	
(such as juices, fruit, pickles, sauerkraut, tomato, soup, and foods in vinegar-based sauce)			
Cereal, ready-to-eat	6-12 months		3 months
Cook before eating (oatmeal, etc.)	12 months		6-12 months
Chocolate, unsweetened and semi-sweet, solid	18-24 months		1 year
Chocolate syrup	2 years	6 months	
Cocoa and cocoa mixes	Indefinitely		1 year
Coffee			
Whole beans, non- vacuum bag	1-3 weeks	3-4 months frozen	
Ground, in cans	2 years	2 weeks	
Instant, jars and tins	12 months		2-3 months
Condiments			
Barbecue sauce, bottled	12 months	4 months	1 month
Shelf-Stable Foods	Unopened on Shelf	Opened,	Open,

REFERENCE/GENERAL INFORMATION
FOOD STORAGE GUIDELINES
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		Refrigerated	on shelf
Catsup, tomato; cocktail sauce or chili sauce	12 months	6 months	1 month
Chutney	12 months	1-2 months	
Horseradish, in jars	12 months	3-4 months	
Mayonnaise, commercial	2-3 months	2 months	
Mustard	12 months	1 year	1-2 months
Olives, black and green	12-18 months	2 weeks	
Pickles	12 months	1-2 months	
Salad dressings, commercial, bottled	10-12 months	3 months	
Salsa, picante and taco sauces	12 months	1 month	
Cookies, packaged	2 months	8-12 months frozen	4 weeks
Crackers	8 months	Freeze or refrigerate 3-4 months	1 month
Diet powder mixes	6 months		3 months
Extracts, vanilla, lemon, etc.	3 years		1 year
Fruits, dried	6 months	6 months	
Garlic, chopped, commercial jars	18 months	Refrigerate; use by date on jar	
Gelatin, flavored	18 months		Use all or reseal for 3-4 months
Gelatin, unflavored	3 years		Use all or reseal for 3-4 months
Shelf-Stable Foods	Unopened on Shelf	Opened, Refrigerated	Open, on shelf

REFERENCE/GENERAL INFORMATION
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Gravy, jars & cans	2-5 years	1-2 days	
Dry gravy mixes	2 years		Mix entire packet
Herbs, dried	1-2 years		Store in cool dark place 1 year
Honey	12 months		12 months
Jams, jellies, preserves	12 months	6 months	
Juice, boxes	4-6 months	8-12 days	
Lentils, dried	12 months		12 months
Maple syrup, pure genuine	12 months	12 months	
Marshmallows, marshmallow creme	2-4 months		1 month
Milk, canned evaporated	12 months	4-5 days	
Molasses	12 months		6 months
Mushrooms, dried	6 months		3 months
Oils , olive or vegetable	6 months		4-6 months
walnut, macadamia, other nut oils	6 months	4 months	
vegetable oil sprays	2 years		1 year
Nuts, jars or cans	12 months	4-6 months, Freeze 9-12 months	
Pasta, dry, made without eggs	2 years		1 year
Dry egg noodles	2 years		1-2 months
Shelf-Stable Foods	Unopened on Shelf	Opened, Refrigerated	Open, on shelf

REFERENCE/GENERAL INFORMATION
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Peanut butter, commercial	6-9 months		2-3 months
Peas, dried split	12 months		12 months
Pectin	Use by package date		1 month
Popcorn , dry kernels in jar	2 years		1 year
Commercially popped in bags	2-3 months		1-2 weeks
Microwave packets	12 months		1-2 days popped
Potato chips	2 months		1-2 weeks
Potatoes, instant	6-12 months		6-12 months
Pudding mixes	12 months		3-4 months
Rice , white or wild	2 years		1 year
Brown	1 year	6 months	
Flavored or herb mixes	6 months		Use entire amount
Sauce mixes, non dairy (spaghetti, taco, etc.)	2 years		Use entire amount
cream sauces with milk solids	1 year		
Shortening, solid	8 months		3 months
Soda such as carbonated cola drinks, mixers:			
Diet sodas, bottles or cans	3 months after date	2-3 days	
Shelf-Stable Foods	Unopened on Shelf	Opened, Refrigerated	Open, on shelf

REFERENCE/GENERAL INFORMATION
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SUB-SECTION 6080

Regular sodas, cans	9 months after date	n.a.	
Soup mixes	12 months		Use entire amount
Spices , whole	2-4 years		Included in total
Ground	2-3 years		Included in total
Paprika, red pepper, chili powder	2 years	Store in refrigerator	
Sugar , brown	4 months		Sugar never spoils
Granulated	2 years		
Confectioners	18 months		
Sugar substitutes	2 years		
Syrup, pancake, maple & other flavors	12 months		12 months
Tapioca	12 months		12 months
Tea, bags	18 months		12 months
Loose	2 years		6-12 months
Instant	3 years		6-12 months
Toaster pastries, fruit filled	6 months		Keep foil packets sealed
non-fruit fillings	9 months		
Tomatoes, sun dried, packed in oil	12 months	6-12 months	
packed in cellophane	9 months		3-6 months
Vinegar	2 years		12 months

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Shelf-Stable Foods	Unopened on Shelf	Opened, Refrigerated	Open, on shelf
Yeast, dry, packets and jars	Use-by date	Refrigerate open jars	
Water, bottled	1-2 years		3 months
Worcestershire sauce	1 year		1 year

Bakery items containing custards, meat or vegetables, and frostings made of cream cheese, whipped cream or eggs must be kept refrigerated. Bread products not containing these ingredients are safe at room temperature, but eventually they will mold and become unsafe to eat.

Bakery Item	Shelf	Refrigerator	Freezer
Bread, commercial	2-4 days	7-14 days	3 months
Bread, flat (tortillas, pita)	2-4 days	4-7 days	4 months
Cakes, Angel Food*	1-2 days	7 days	2 months
Chiffon, sponge	1-2 days	7 days	2 months
Chocolate	1-2 days	7 days	4 months
Fruit cake	1 month	6 months	12 months
Made from mix	3-4 days	7 days	4 months
Pound cake	3-4 days	7 days	6 months
Cheesecake	No	7 days	2-3 months
Cookies, bakery or homemade	2-3 weeks	2 months	8-12 months
Croissants, butter	1 day	7 days	2 months
Doughnuts, glazed or cake	1-2 days	7 days	1 month
Bakery Item	Shelf	Refrigerator	Freezer

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dairy cream-filled	No	3-4 days	No
Muffins	No	3-4 days	No
Pastries, Danish	1-2 days	7 days	2 months
Pies, cream	No	3-4 days	2 months
Chiffon	No	1-2 days	No
Fruit	1-2 days	7 days	No
Mincemeat	1-2 days	7 days	8 months
Pecan	2 hours	3-4 days	8 months
Pumpkin	2 hours	3-4 days	1-2 months
Quiche	3-4 days	7 days	1-2 months
Rolls, yeast, baked	Package date	7 days	2 months
filled, meat or vegetables	2 hours	3-4 days	2 months

*Refrigerate any cake with frosting made of cream cheese, butter cream, whipped cream or eggs.

Raw fruits are safe at room temperature, but after ripening, will mold and rot quickly. For best quality, store ripe fruit in the refrigerator or prepare and freeze.

Fruits	Shelf	Refrigerator	Freezer
Apples	1-2 days	3 weeks	Cooked, 8 months
Apricots	Until ripe	2-3 days	No
Avocados	Until ripe	3-4 days	No
Bananas	Until ripe	2 days, skin will blacken	Whole, peeled, 1 month
Berries, Cherries	No	1-2 days	4 months
Citrus fruit	10 days	1-2 weeks	No
Fruits	Shelf	Refrigerator	Freezer

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Coconuts, fruits	1 week	2-3 weeks	Shredded, 6 months
Grapes	1 day	1 week	Whole, 1 month
Kiwi Fruit	Until ripe	3-4 days	No
Melons	1-2 days	3-4 days	Balls, 1 month
Papaya, mango	3-5 days	1 week	No
Peaches, nectarines	Until ripe	3-4 days	Sliced, lemon juice & sugar, 2 months
Pears, plums	3-5 days	3-4 days	No
Vegetable	Shelf	Raw, refrigerated	Blanched, cooked or frozen
Artichokes, whole	1-2 days	1-2 weeks	No
Asparagus	No	3-4 days	8 months
Beans, green or wax	No	3-4 days	8 months
Beets	1 day	7-10 days	6-8 months
Cabbage	No	1-2 weeks	10-12 months
Carrots, parsnips	No	2 weeks	10-12 months
Celery	No	1-2 weeks	10-12 months
Cucumbers	No	4-5 days	No
Eggplant	1 day	3-4 days	6-8 months
Garlic, ginger root	2 days	1-2 weeks	1 month
Greens	No	1-2 days	10-12 months
Herbs, fresh	No	7-10 days	1-2 months
Vegetable	Shelf	Raw, refrigerated	Blanched, cooked or frozen
Leeks	No	1-2 weeks	10-12 months

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Lettuce, iceberg	No	1-2 weeks	No
Lettuce, leaf	No	3-7 days	No
Mushrooms	No	2-3 days	10-12 months
Okra	No	2-3 days	10-12 months
Onions, dry	2-3 weeks	2 months	10-12 months
Spring or green	No	1-2 weeks	
Peppers, bell	No	4-5 days	6-8 months
or chili	No	4-5 days	6-8 months
Potatoes	1-2 months	1-2 weeks	Cooked and mashed, 10-12 months
Rutabagas	1 week	2 weeks	8-10 months
Spinach	No	1-2 days	10-12 months
Squash, summer	No	4-5 days	10-12 months
Winter	1 week	2 weeks	
Turnips	No	2 weeks	8-10 months
Tomatoes	Until ripe	2-3 days	2 months

When shopping, place frozen foods in the cart last, immediately before checking out. Take the foods directly home and place in freezer. For storage of meat and poultry purchased frozen, see refrigerated foods chart.

Frozen item	Freezer	In refrigerator after thawing
Bagels	2 months	1-2 weeks
Bread dough, commercial	Use-by date	After baking, 4-7 days
Burritos, sandwiches	2 months	3-4 days
Frozen item	Freezer	In refrigerator after thawing
Egg substitutes	12 months	Date on carton

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Fish, breaded	3 months	Do not defrost. Cook frozen.
Fish, raw	6 months	1-2 days
Fruit such as berries, melons	4-6 months	4-5 days
Guacamole	3-4 months	3-4 days
Ice cream	2-4 months	Not applicable
Juice concentrates	6-12 months	7-10 days
Lobster tails	3 months	2 days
Pancakes, waffles	2 months	3-4 days
Sausages, uncooked	1-2 months	1-2 days
precooked	1-2 months	7 days
Sherbert, sorbet	2-4 months	Not applicable
Shrimp, shellfish	12 months	1-2 days
Topping, whipped	6 months	2 weeks
TV dinners, entrees, breakfast	3 months	Do not defrost. Cook frozen.
Vegetables	8 months	3-4 days

Refrigerate foods to maintain quality as well as keep them safe. Some bacteria grow and multiply – although very slowly – at refrigerated temperatures. There is a limit to the time various foods will stay fresh and safe in a refrigerator. Food kept continuously frozen at 0°F will always be safe but the quality suffers with lengthy freezer storage.

Product	Refrigerated	Frozen
Beverages, fruit	3 weeks unopened	
Juices in cartons, fruit drinks, punch	7-10 days open	8-12 months

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Condiments		
Refrigerated pesto, salsa	Date on carton; 3 days after opening	1-2 months
Sour cream-based dip	2 weeks	Doesn't freeze well
Dairy products		
Butter	1-3 months	6-9 months
Buttermilk	7-14 days	3 months
Cheese, hard (such as cheddar, Swiss)	6 months unopened; 3-4 weeks opened	6 months
Cheese, soft (such as Brie, Bel Paese)	1 week	6 months
Cottage cheese, Ricotta	1 week	Doesn't freeze well
Cream cheese	2 weeks	Doesn't freeze well
Cream whipping, ultra-pasteurized	1 month	Do not freeze
Whipped, sweetened	1 day	1-2 months
Aerosol can, real whipped cream	3-4 weeks	Do not freeze
Aerosol can, non-dairy topping	3 months	Do not freeze
Cream, Half and Half	3-4 days	4 months
Egg, substitutes, liquid		
Product	Refrigerated	Frozen
unopened	10 days	Manufacturer says "Do not freeze"

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opened	3 days	Manufacturer says "Do not freeze"
Eggnog, commercial	3-5 days	6 months
Eggs, in shell	3-5 weeks	Do not freeze
Raw whites	2-4 days	12 months
Raw yolks	2-4 days	Doesn't freeze well
Hard cooked	1 week	Doesn't freeze well
Margarine	4-5 months	12 months
Milk	7 days	3 months
Pudding	Package date; 2 days after opening	Do not freeze
Sour cream	7-21 days	Doesn't freeze well
Yogurt	7-14 days	1-2 months
Deli Foods		
Entrees, cold or hot	3-4 days	2-3 months
Store-sliced lunch meats	3-5 days	1-2 months
Salads	3-5 days	Do not freeze
Dough		
Tube cans of biscuits, rolls, pizza dough, etc.	Use-by date	Do not freeze
Ready-to-bake pie crust	Use-by date	2 months
Cookie dough	Use-by date, unopened or	2 months

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	opened	
Fish		
Lean fish (cod, flounder, haddock, sole, etc.)	1-2 days	6 months
Fatty fish (bluefish, mackerel, salmon, etc.)	1-2 days	2-3 months
Caviar, non-pasteurized (fresh)	6 months unopened; 2 days after opening	Do not freeze
Caviar, pasteurized, vacuum-packaged	1 year unopened; 2 days after opening	Do not freeze
Cooked fish	3-4 days	4-6 months
Smoked fish	14 days or date on vacuum packaging	2 months in vacuum packaging
Shellfish		
Shrimp, scallops, crayfish, squid	1-2 days	3-6 months
Shucked clams, mussels and oysters	1-2 days	3-6 months
Live clams, mussels, crab, lobster and oysters	2-3 days	2-3 months
Cooked shellfish	3-4 days	3 months
Meat, fresh		
Beef, lamb, pork, or veal chops; Steaks, roasts	3-5 days	4-12 months
Ground meat	1-2 days	3-4 months

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Variety meats (liver, tongue, chitterlings, etc.)	1-2 days	3-4 months
cooked meats (after home cooking)	3-4 days	2-3 months
Meat, smoked or processed		
Bacon	7 days	1 month
Corned beef, in pouch with pickling juices	5-7 days	1 month
Ham, canned ("keep refrigerated" label)	6-9 months	Not in can
Ham, fully cooked, whole	7 days	1-2 months
Ham, fully cooked, slices or halves	3-4 days	1-2 months
Ham, cooked before eating	7 days	1-2 months
Hot dogs, sealed in package	2 weeks	1-2 months
Hot dogs, after opening	1 week	1-2 months
Lunch meats, sealed in package	2 weeks	1-2 months
Lunch meats, after opening	3-5 days	1-2 months
Sausage, raw, bulk type	1-2 days	1-2 months
Sausage, smoked links, patties	7 days	1-2 months
Sausage, hard, dry (pepperoni), sliced	2-3 weeks	1-2 months
Pasta, fresh		
Pasta, fresh	1-2 days or use-by date on	2 months

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SUB-SECTION 6080

	package	
Poultry, fresh		
Chicken or turkey, whole	1-2 days	12 months
Chicken or turkey, parts	1-2 days	9 months
Duckling or goose, whole	1-2 days	6 months
Giblets	1-2 days	3-4 months
Poultry, cooked or processed		
Chicken, nuggets, patties	1-2 days	1-3 months
Cooked poultry dishes	3-4 days	4-6 months
Fried chicken	3-4 days	4 months
Ground turkey or chicken	1-2 days	3-4 months
Lunch meats, sealed in package	2 weeks	1-2 months
Lunch meats, after opening	3-5 days	1-2 months
Pieces covered with broth or gravy	1-2 days	6 months
Rotisserie chicken	3-4 days	4 months

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
Field Operations Manual**

**REFERENCE/GENERAL INFORMATION
GUIDELINES FOR PREPARATION OF SUSHI PRODUCTS AT RETAIL
SUB-SECTION 6085**

OVERVIEW

This document is a guideline for the preparation of sushi products in a retail setting where immediate consumption is not likely. Any firm manufacturing a sushi product using acidified rice should first do a hazard analysis of their processing procedures, establish critical control points and follow a HACCP-based plan, which includes appropriate recordkeeping.

RICE

1. Follow written recipe requirements, especially regarding amounts of rice and water weights prior to cooking.
2. Prepare acidification agent per recipe with target pH of 4.1 or less, but not to exceed 4.6.
3. Cooked rice shall be placed into a clean container of such depth to promote uniform acidification.
4. A calibrated pH meter shall be used, according to manufacturer's instructions, to monitor pH in each batch with results properly recorded. In lieu of a pH meter, pH paper can be used if the pH is 4.0 or less. pH strips may be used if pH is less than 4.0.

GENERAL REQUIREMENTS

1. Use only dedicated food preparation sinks for preparation of ingredients.
2. Bare hand contact with ready-to-eat food products is prohibited. Sanitary gloves, utensils or other such devices must be utilized. Adequate and properly equipped handwash facilities shall be located in the sushi prep area. Clothing and hair restraints shall comply with New York State Department of Agriculture and Markets Food Store regulations.
3. All food contact surfaces and utensils shall be maintained in accordance with New York State Department of Agriculture and Markets Retail Food Store regulations.
4. Ingredients shall come from approved sources. Seafood products, if identified as a parasite hazard, shall be obtained from a supplier who has frozen the product to -4°F (-20°C) or below internal or external for seven (7) days or -31°F (-35°C) or below internal for 15 hours. If the species is identified as a histamine producer, documentation from the supplier shall show that temperature control from harvest through delivery was sufficient to prevent decomposition.
5. Ingredients such as fresh cut vegetables and produce shall be kept refrigerated at 41°F or less.
6. Bamboo mats used for product formation shall be wrapped in plastic wrap and rewrapped within 4 hours or between contact with different species of raw fish.

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SUB-SECTION 6085

7. Products where the internal temperature has been reduced below 41°F internally within 4 hours may be handled by the firm as any other refrigerated food.

RECORDS

1. Records of pH tests, letters of guarantee from suppliers and temperature checks shall be available for inspection.
2. HACCP plan records regarding critical control points should be maintained.
3. Standardized formulations that assure the proper pH of all batches must be verified at frequent levels. All formulations and verification records shall be maintained.

LABELING

1. Products shall be properly labeled.

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**REFERENCE/GENERAL INFORMATION
GUIDELINES FOR SANITARY CARE AND MAINTENANCE OF
ICE CHESTS AND ICE MACHINES
SUB-SECTION 6090**

OVERVIEW

Investigations by the Center for Disease Control (CDC) have determined that ice may become contaminated from use of impure water, contamination of ice-making machines or from improper storage or handling of ice.

The following are CDC's recommended procedures to reduce the likelihood of contamination of ice chests (ice storage compartments) and ice machines:

1. Ice machines that dispense ice directly into portable containers at the touch of a control provide a more sanitary method to store and obtain ice than use of ice chests, but such ice machines may be more expensive to purchase and to operate.
2. All ice handlers should be taught the following precautions:
 - A. Wash hands frequently
 - B. Hold scoop used with ice chest by handle; do not touch bowl surface with hands
 - C. Do NOT handle ice with hands
 - D. Do NOT return unused ice to an ice storage chest
 - E. Keep access doors to chests closed except when removing ice
3. Ice scoops should be smooth, impervious and easy to clean. They should be stored in a fashion that will preclude their contacting the floor (tethered, in sleeve, stored in ice within the unit). Scoops may also be kept on an uncovered, stainless steel, impervious plastic or fiberglass tray on top of the chest when not in use. The tray and the scoop should be run through a dishwasher or sterilized daily.
4. Remove all extraneous equipment and items from around or on the ice chests and machines. If possible, limit access to ice chests.
5. Clean ice storage compartments on a preset schedule; weekly to monthly cleaning of open chests is suggested; less frequent cleaning may be possible with ice dispensing machines. Cleaning should be carried out with a fresh soap or detergent solution after disconnecting the unit, removing and discarding all ice allowing the chest to warm to room temperature. Use clean rags or disposable wipes to scrub all surfaces. Pay particular attention to door tracks, guides and gaskets. After cleaning, rinse all surfaces of the compartment with potable water, rinse it again with a 100-ppm (mg/l) solution of hypochlorite, allow it to dry and then return the unit to service.
6. On an arbitrary schedule, perhaps monthly to quarterly, disconnect ice-making machines, discard all ice and disassemble removable parts of the machine. Thoroughly clean the machines and the parts. Check for the need of possible repair of any portion of the machine. Insure the presence of an air gap at all inlets for potable water. Inspect for insect or rodent infestation under the unit and treat, if necessary. Check the gasket around the ice chest door (open compartment models) for cleanliness

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GUIDELINES FOR SANITARY CARE AND MAINTENANCE OF
ICE CHESTS AND ICE MACHINES
SUB-SECTION 6090

and evidence of possible leakage or dripping of contaminants into the ice chest. Clean the ice storage compartment as in No. 5 above. Place a 50-ppm of solution of hypochlorite in the ice machine for at least 4 hours or a 200-ppm solution for at least 2 hours. Circulate the solution throughout the entire ice making and storing system according to the manufacturer's recommended cleaning and sanitizing procedures. Remove the disinfecting solution, flush the system with potable water, allow the ice compartment to dry and then return the unit to service.

Routine microbiologic sampling of ice from ice machines is recommended. To sample, remove and melt ice aseptically and do quantitative plate counts (or use membrane filter technique) on the resulting water; possible pathogens should be identified, if present. If laboratory service to conduct such evaluations is not readily available, ice melted in a sterile container might be submitted to the local health department in their water sampling bottles to determine whether or not coliform contamination is present. Sampling for microbial contamination on ice scoops could be conducted very occasionally for educational purposes.

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**REFERENCE/GENERAL INFORMATION
STANDARDIZED FOODS, ADDITIVES, AND FLAVORINGS (PURSUANT TO 21 CFR)
SUB-SECTION 6095**

PART 131-MILK AND CREAM

Milk	Heavy cream
Acidified milk	Light cream
Cultured milk	Light whipping cream
Concentrated milk	Sour cream
Sweetened condensed milk	Acidified sour cream
Nonfat dry milk	Eggnog
Nonfat dry milk fortified with vitamins A and D	Half-and-half
Evaporated milk	Yogurt
Dry whole milk	Low fat yogurt
Dry cream	Nonfat yogurt

PART 133-CHEESES AND RELATED CHEESE PRODUCTS

Asiago fresh and asiago soft cheese	Dry curd cottage cheese
Asiago medium cheese	Cream cheese
Asiago old cheese	Cream cheese with other foods
Blue cheese	Washed curd and soaked curd cheese
Brick cheese	Washed curd cheese for manufacturing
Brick cheese for manufacturing	Edam cheese
Caciocavallo siciliano cheese	Gammelost cheese
Cheddar cheese	Gorgonzola cheese
Cheddar cheese for manufacturing	Gouda cheese
Low sodium cheddar cheese	Granular and stirred cheese
Colby cheese	Granular cheese for manufacturing
Colby cheese for manufacturing	Grated cheeses
Low sodium Colby cheese	Grated American cheese food
Cold-pack and club cheese	Hard grating cheeses
Cold-pack cheese food	Gruyere cheese
Cold-pack cheese food with fruits, vegetables, or meats	Hard cheeses
Cook cheese, Koch kaese	Limburger cheese
Cottage cheese	Monterey cheese and monterey jack cheese
High-moisture jack cheese	Pasteurized cheese spread with fruit, vegetables, or meats
Mozzarella cheese and scamorza cheese	Pasteurized Neufchatel cheese spread with other foods
Low-moisture mozzarella and scamorza cheese	Pasteurized process cheese spread
Part-skim mozzarella and scamorza cheese	Pasteurized process cheese spread with fruits, vegetables, or meats
Low-moisture and part-skim mozzarella and scamorza cheese	Provolone cheese
Muenster and munster cheese	Soft ripened cheese
Muenster and munster cheese for manufacturing	Romano cheese
Neufchatel cheese	

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STANDARDIZED FOODS, ADDITIVES, AND FLAVORINGS (PURSUANT TO 21 CFR)
SUB-SECTION 6095

PART 133-CHEESES AND RELATED CHEESE PRODUCTS (Continued)

Nuworld cheese	Roquefort cheese, sheep's milk, bluemold,
Parmesan and reggiano cheese	and bluemold cheese from sheep's milk
Pasteurized blended cheese	Samsoe cheese
Pasteurized blended cheese with fruits,	Sap sago cheese
vegetables, or meats	Semisoft cheeses
Pasteurized process cheese	Semisoft part-skim cheeses
Pasteurized process cheese with fruit, vegetables,	Skim milk cheese for manufacturing
or meats	Spiced cheeses
Pasteurized process pimento cheese	Part-skim spiced cheeses
Pasteurized process cheese food	Spiced, flavored standardized cheeses
Pasteurized process cheese food with fruit,	Swiss and emmentaler cheese
vegetables, or meats	Swiss cheese for manufacturing
Pasteurized cheese spread	

PART 135-FROZEN DESSERTS

Ice cream and frozen custard
Goat's milk ice cream
Mellorine
Sherbet
Water ices

PART 136-BAKERY PRODUCTS

Bread, rolls, and buns
Enriched bread, rolls, and buns
Milk bread, rolls, and buns
Raisin bread, rolls, and buns
Whole wheat bread, rolls, and buns

PART 137-CEREAL FLOURS AND RELATED PRODUCTS

Flour	Whole durum flour
Bromated flour	White corn meal
Enriched bromated flour	Bolted white corn meal
Enriched flour	Enriched corn meals
Instantized flours	Degerminated white corn meal
Phosphated flour	Self-rising white corn meal
Self-rising flour	Yellow corn meal
Enriched self-rising flour	Bolted yellow corn meal
Cracked wheat	Degerminated yellow corn meal
Crushed wheat	Self-rising yellow corn meal
Whole wheat flour	Farina
Bromated whole wheat flour	Enriched farina
White corn flour	Semolina
Yellow corn flour	Enriched rice
Durum flour	

REFERENCE/GENERAL INFORMATION
STANDARDIZED FOODS, ADDITIVES, AND FLAVORINGS (PURSUANT TO 21 CFR)
SUB-SECTION 6095

PART 139-MACARONI AND NOODLE PRODUCTS

Macaroni products	Whole wheat macaroni products
Enriched macaroni products	Wheat and soy macaroni products
Enriched macaroni products with fortified protein	Noodle products
Milk macaroni products	Enriched noodle products
Nonfat milk macaroni products	Vegetable noodle products
Enriched nonfat milk macaroni products	Enriched vegetable noodle products
Vegetable macaroni products	Wheat and soy noodle products
Enriched vegetable macaroni products	

PART 145-CANNED FRUITS

Canned applesauce	Canned seedless grapes
Canned apricots	Canned grapefruit
Artificially sweetened canned apricots	Canned peaches
Canned berries	Artificially sweetened canned peaches
Canned cherries	Canned pears
Artificially sweetened canned cherries	Artificially sweetened canned pears
Canned figs	Canned pineapple
Artificially sweetened canned figs	Artificially sweetened canned pineapple
Canned preserved figs	Canned plums
Canned fruit cocktail	Canned prunes
Artificially canned fruit cocktail	

PART 146-CANNED FRUIT JUICES

Lemon juice	Canned prune juice
Frozen concentrate for lemonade	Orange juice from concentrate
Frozen concentrate for artificially sweetened lemonade	Frozen concentrated orange juice
Frozen concentrate for colored lemonade	Reduced acid frozen concentrated orange juice
Grapefruit juice	Canned concentrated orange juice
Orange juice	Orange juice for manufacturing
Frozen orange juice	Orange juice with preservative
Pasteurized orange juice	Concentrated orange juice for manufacturing
Canned orange juice	Concentrated orange juice with preservative
	Pineapple juice

PART 150-FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

Fruit butter
Fruit jelly
Artificially sweetened fruit jelly
Fruit preserves and jams
Artificially sweetened fruit preserves and jams

REFERENCE/GENERAL INFORMATION
STANDARDIZED FOODS, ADDITIVES, AND FLAVORINGS (PURSUANT TO 21 CFR)
SUB-SECTION 6095

PART 152-FRUIT PIES

Frozen cherry pie

PART 155-CANNED VEGETABLES

Canned green beans and canned wax beans
Canned corn
Canned field corn
Canned peas
Canned dry peas

Canned tomatoes
Tomato concentrates
Catsup
Certain other canned vegetables
Canned mushrooms

PART 156-VEGETABLE JUICES

Tomato juice

PART 158-FROZEN VEGETABLES

Frozen peas

PART 160-EGGS AND EGG PRODUCTS

Eggs
Dried eggs
Frozen eggs
Liquid eggs
Egg whites

Dried egg whites
Frozen egg whites
Egg yolks
Dried egg yolks
Frozen egg yolks

PART 161-FISH AND SHELLFISH

Oysters
Olympia oysters
Canned oysters
Canned pacific salmon
Canned wet pack shrimp in transparent or nontransparent containers
Frozen raw breaded shrimp
Frozen raw lightly breaded shrimp
Canned tuna

PART 163-COCOA PRODUCTS

Cocoa nibs
Chocolate liquor
Breakfast cocoa
Cocoa
Lowfat cocoa

Milk Chocolate
Buttermilk chocolate
Skim milk chocolate
Mixed dairy product chocolates
Sweet cocoa and vegetable fat coating

PART 163-COCOA PRODUCTS (Continued)

REFERENCE/GENERAL INFORMATION
STANDARDIZED FOODS, ADDITIVES, AND FLAVORINGS (PURSUANT TO 21 CFR)
SUB-SECTION 6095

Cocoa with dioctyl sodium sulfosuccinate
for manufacturing
Sweet chocolate

Sweet chocolate and vegetable fat coating
Milk chocolate and vegetable fat coating

PART 164-TREE NUT AND PEANUT PRODUCTS

Mixed nuts
Shelled nuts in rigid or semirigid containers
Peanut butter

PART 165-BEVERAGES

Bottled water

PART 166-MARGARINE

Margarine

PART 168-SWEETENERS AND TABLE SYRUPS

Dextrose anhydrous
Dextrose monohydrate
Glucose syrup
Dried glucose syrup
Lactose

Cane syrup
Maple syrup
Sorghum syrup
Table syrup

PART 169-FOOD DRESSINGS AND FLAVORINGS

French dressing
Mayonnaise
Salad dressing
Vanilla extract
Concentrated vanilla extracts
Vanilla flavoring

Concentrated vanilla flavoring
Vanilla powder
Vanilla-vanillin extracts
Vanilla-vanillin flavoring
Vanilla-vanillin powder

**NYS Department of Agriculture and Markets
Division of Food Safety and Inspection
10B Airline Drive
Albany, New York 12235**

**LISTERIA PROTOCOL
SUB-SECTION 7000**

Please adhere to the following protocol when a sample of a ready-to-eat deli item has been identified as positive for *Listeria monocytogenes*:

- Inventory environmental swab supply and ensure they are within code. If more are needed, notify the Central Office at 518-457-5380.
- Return to firm and score the positive *Listeria* sample as a critical deficiency on a limited-in-scope inspection.
- When appropriate, have firm initiate a Class I recall of the product, including press release. Included in the press release should be the product, brand name, code, and any other pertinent information.
- Establishment is to verify, if possible, through written documentation (i.e. cleaning schedule, HACCP Plan, written SOP's, etc.) whether deli case and food contact and non-contact equipment impacted by the affected product was thoroughly cleaned and sanitized after date of sample collection.
- Where above verification is not available, seize any open packages of product if the firm fails to voluntarily destroy them. Samples of seized products in open packages are to be collected.
- Sample any open packages of like (*Listeria* contaminated) product with different codes. Also sample intact packages of the same and/or like codes if available.
- Request firm to cease deli operation immediately.
- If one is not available instruct firm to develop a written action plan and suggest that it may be beneficial to them to employ an outside consultant.
- Verify the closing of the deli, and the commencement of cleaning and sanitizing of all food contact equipment and non-food contact surfaces.

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- Deli operation may be re-opened after the cleaning and sanitization has been completed and the swabbing results are negative for *Listeria monocytogenes*; **or if after monitoring and review of the cleaning and sanitizing process by a qualified individual verifies in writing the process was sufficient to eliminate *Listeria monocytogenes*.**
- If swabbing is to be done, the firm will need to notify you when cleaning and sanitization is complete. This can be accomplished by telephoning the appropriate regional supervisor.
- Take enough swabs so the deli processing area is well represented, i.e. cases, equipment, utensils, sinks, tables, etc.
- Notify this office at 518-457-5380 as to how many swabs you are shipping and when. Make sure swabs are numbered 1 of 6, 2 of 6, etc. Remember to properly refrigerate them.