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DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Interim Director of the Department of Health, pursuant to sections 2(c) and 2(i) of the Food Regulation Amendment Act of 2002 (Act), effective May 2, 2002 (D.C. Law 14-116; D.C. Official Code §§ 48-104 and 48-110), and Mayor's Order 2002-103, dated June 18, 2002, hereby gives notice of his intent to adopt the following new Title 25A of the *District of Columbia Municipal Regulations*. The proposed rules protect the health and safety of consumers of food in the District by establishing sanitary standards for wholesale food operations that do not provide food directly to the consumer, including manufacturers, processors, repackagers, and distributors of food. The rules enhance the Department's regulatory oversight of food operations, including but not limited to bakery plants, food manufacturing plants, food warehouses and distribution centers, ice manufacturing plants, fresh and frozen seafood processing plants, and shellfish processors.

The Director also give notice of intent to take final rulemaking action to adopt the proposed rules in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*. Further, pursuant to section 2(i) of the Act, the proposed rules shall be submitted to the Council for a forty-five (45) day period of review, excluding Saturdays, Sundays, legal holidays, and days of Council recess. The proposed rules shall not become effective until affirmatively approved by the Council within this forty-five (45) day review period.

The *District of Columbia Municipal Regulations* are amended by adding a new Title 25A to read as follows:

SUBTITLE A: PURPOSE**CHAPTER 1 TITLE, INTENT, SCOPE****100 TITLE — FOOD PROCESSING OPERATIONS CODE**

100.1 These provisions shall be known as the Food Processing Operations Code, hereinafter referred to as “this Code.”

101 INTENT — FOOD SAFETY, SANITATION

101.1 The purpose of this Code is to provide food safety and sanitation requirements for food processing operations. These requirements will safeguard public health by:

- (a) Ensuring that food products are safe and unadulterated as defined in section 402(a)(3) and (4) of the Federal Food Act and section 3 of An Act Relating to the adulteration of food and drugs in the District of Columbia, approved February 17, 1898 (30 Stat. 248; D.C. Official Code § 48-103);
- (b) Protecting the consuming public from products that have been produced under unsanitary conditions; and
- (c) Ensuring that shellfish is processed in a safe and sanitary manner.

102 SCOPE — STATEMENT

102.1 This Code establishes definitions; sets quality control standards for personnel, health, sanitary operations, equipment, facilities, and food processing methods; provides for the issuance of licenses and certifications, inspections, and employee restrictions; and provides for enforcement through suspension and revocation of licenses and certifications, embargo and condemnation of foods and equipment, and fines and penalties.

102.2 Subtitle H of this Code establishes a shellfish safety and sanitation program that regulates shellfish processing procedures and facilities; product labeling of shellfish; storage, handling and packing of shellfish; shellfish shipment in interstate commerce; and shellfish dealers pursuant to the National Shellfish Sanitation Program (NSSP).

102.3 Certain provisions of this Code are identified as critical. Critical provisions are those provisions where noncompliance is more likely to contribute to food contamination, illness, or an environmental health hazard. A critical item is denoted with an asterisk (*).

- 102.4 Certain provisions of this Code are identified as noncritical. Noncritical provisions are those provisions where noncompliance is less likely to contribute to food contamination, illness, or environmental degradation. A part that is denoted in the Code without an asterisk (*) after the headnote is a noncritical item. A part designated as a critical item may have a provision within the part designated as a noncritical item. This is indicated by a superscripted letter “N” following the provision.

**SUBTITLE B: MANAGEMENT
AND PERSONNEL**

CHAPTER 2 SUPERVISION AND TRAINING

200 SUPERVISORS – QUALIFICATION, ASSIGNMENT & POSTING*

- 200.1 The licensee shall ensure that supervisors meet the training, certification, and registration requirements in this chapter and in the federal regulations identified in this chapter.
- 200.2 The licensee shall ensure that supervisors responsible for preventing sanitation failures or food contamination have an educational background or experience, or a combination thereof, in FDA and USDA good manufacturing practice for the safe manufacturing, processing, and packing processes of acidified foods and thermally processed low-acid foods in hermetically sealed containers.
- 200.3 The licensee shall ensure that supervisors involved in thermal processing systems, acidification, and container closure evaluation programs for low-acid and acidified canned foods are certified by an FDA and USDA approved institution.
- 200.4 The licensee shall ensure that supervisors who are certified as specified in section 200.3 are also registered with the FDA as qualified food canning supervisors.
- 200.5 The licensee shall ensure that all food employees involved in acidification, ph control, heat treatment, or other critical factors of a food processing operation are under the direct supervision of a person who:
- (a) Has satisfactorily completed the required training specified in section 200.2 and the following federal regulations:
 - (1) 9 CFR 318.310 – Personnel and training;
 - (2) 9 CFR 381.310 – Personnel and training;

- (3) 21 CFR 108.25 (f) – Acidified foods;
 - (4) 21 CFR 108.35 (g) – Thermal processing of low-acid foods packaged in hermetically sealed containers;
 - (5) 21 CFR 113.10 – Personnel;
 - (6) 21 CFR 114.10 – Personnel; and
 - (b) Has received training in food-handling techniques, food protection principles, personal hygiene, and plant sanitation practices as specified in section 200.7.
- 200.6 Supervisors who are certified and registered with the FDA as required under sections 200.3 and 200.4 shall supervise only in areas in which they are certified. A food processing operation shall have supervisors certified in all relevant food processing activities on the premises at all times when such activities are being conducted.
- 200.7 Supervisors who are certified and registered with the FDA as required under sections 200.3 and 200.4 shall be knowledgeable in the following areas:
- (a) The relationship between the prevention of foodborne disease and the personal hygiene of a food employee;
 - (b) The responsibility of supervisors for preventing the transmission of foodborne disease by a food employee who has an illness or medical condition that may cause a foodborne disease;
 - (c) Symptoms associated with the diseases that are transmissible through food;
 - (d) The relationship between the prevention of foodborne illness and the management and control of the following:
 - (1) Cross contamination;
 - (2) Hand contact with ready-to-eat foods;
 - (3) Handwashing; and
 - (4) Maintaining the food processing operation in a clean condition and in good repair;

- (e) The correct procedures for cleaning and sanitizing equipment, utensils and food-contact surfaces;
- (f) Poisonous or toxic materials identification and the procedures necessary to ensure that these materials are safely stored, dispensed, used, and disposed of in accordance with applicable District law;
- (g) Important processing points in the food processing operation from purchasing through sale or service;
- (h) The principles and details of an HACCP plan, if used or required by District or federal laws or regulations or under an agreement between the Department and the licensee; and
- (i) Water source identification and measures to be taken to ensure that water sources remain protected from contamination, such as providing protection from backflow and precluding the creation of cross-connections.

200.8 Documentation that a supervisor is certified and registered with the FDA as required under sections 200.3 and 200.4 shall be conspicuously posted in the food processing operation next to the food processing operation's District-issued license. This documentation shall be removed when the individual is no longer employed on-site by the food processing operation.

200.9 All supervisors of food processing operations required to be certified and registered by the FDA under section 200.3 and 200.4 shall obtain an identification card, issued by the Department, which shall be renewed every two (2) years.

201 DUTIES — SUPERVISORS

201.1 Supervisors shall ensure that persons unnecessary to plant operations are not allowed in areas used for food operations, except that brief visits and tours may be authorized by supervisors if steps are taken to ensure that exposed food, clean equipment, utensils, food-contact surfaces, and food-packaging materials are protected from contamination.

201.2 Supervisors shall ensure that food employees and other persons, such as delivery and maintenance persons and pesticide applicators, entering areas used for food operations comply with this Code.

201.3 Supervisors shall ensure that food employees are effectively cleaning their hands by routinely monitoring the employees' handwashing to ensure compliance with sections 401, 402, and 403.

- 201.4 Supervisors shall ensure that food employees are visibly observing food and food shipments as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, honestly presented, and accurately labeled by routinely monitoring the employees' observations and periodically evaluating food and food shipments upon their receipt, storage, handling, packing, transportation, sale, and distribution.
- 201.5 Supervisors shall ensure that food employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing.
- 201.6 Supervisors shall take every reasonable measure and precaution to ensure compliance with 21 CFR 110.10 – Personnel, and this Code, and that food employees are properly trained in food safety as it relates to their assigned duties.

CHAPTER 3 EMPLOYEE HEALTH

300 DISEASE OR MEDICAL CONDITION – RESPONSIBILITY OF FOOD EMPLOYEES AND CONDITIONAL EMPLOYEES TO REPORT SYMPTOMS AND DIAGNOSIS*

- 300.1 The licensee shall require food employees and conditional employees to report to their supervisors, in accordance with this section, information about their health and activities as they relate to diseases that are transmissible through food.
- 300.2 A food employee or conditional employee shall report the information in a manner that allows the supervisor to reduce the risk of foodborne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness or of a diagnosis without symptoms.
- 300.3 A food employee or conditional employee shall report to his or her supervisor when he or she has any of the following symptoms:
- (a) Vomiting;
 - (b) Diarrhea;
 - (c) Jaundice;
 - (d) Sore throat with fever; or

- (e) A lesion containing pus, such as a boil or infected wound that is open or draining and is:
 - (1) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;
 - (2) On exposed portions of the arms, unless the lesion is protected by an impermeable cover; or
 - (3) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage.

300.4 A food employee or conditional employee shall report to his or her supervisor if he or she has an illness diagnosed by a licensed physician due to:

- (a) Norovirus;
- (b) Hepatitis A virus;
- (c) *Shigella* spp.;
- (d) Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli*; or
- (e) *Salmonella* Typhi.

300.5 A food employee or conditional employee shall report to his or her supervisor if he or she had a previous illness, diagnosed by a licensed physician, within the past three (3) months due to *Salmonella* Typhi, without having received antibiotic therapy.

300.6 A food employee or conditional employee shall report to his or her supervisor if he or she has been exposed to, or is the suspected source of, a confirmed disease outbreak involving one of the diseases specified in section 300.4, because the food employee or conditional employee:

- (a) Consumed or prepared food implicated in the outbreak;
- (b) Consumed food at an event prepared by a person who is infected or ill with the disease;
- (c) Was exposed by attending or working in a setting where there is a confirmed disease outbreak;

- (d) Is living in the same household as an individual who works in or attends a setting where there is a confirmed disease outbreak, and the employee has knowledge of that person's exposure; or
- (e) Is living in the same household as an individual diagnosed with an illness and has knowledge of the diagnosis.

300.7 A food employee or conditional employee shall make the report required under section 300.6 if the exposure was to:

- (a) Norovirus and the most recent exposure occurred within the past forty-eight (48) hours;
- (b) Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli*, or *Shigella* spp. and the most recent exposure occurred within the past three (3) days;
- (c) *Salmonella* Typhi and the most recent exposure occurred within the past fourteen (14) days; or
- (d) Hepatitis A virus and the most recent exposure occurred within thirty (30) days.

301 DISEASE OR MEDICAL CONDITION — RESPONSIBILITY OF SUPERVISOR TO REPORT SPECIFIC ILLNESS OF FOOD EMPLOYEE TO THE DEPARTMENT

301.1 A supervisor shall notify the Department when a food employee is:

- (a) Jaundiced; or
- (b) Diagnosed with an illness due to a pathogen specified in section 300.4.

302 DISEASE OR MEDICAL CONDITION — RESPONSIBILITY OF SUPERVISOR TO PROHIBIT A CONDITIONAL EMPLOYEE WITH A SPECIFIC ILLNESS FROM BECOMING A FOOD EMPLOYEE

302.1 A supervisor shall ensure that a conditional employee who exhibits or reports a symptom, or reports a diagnosed illness as specified in sections 300.3 through 300.5, is prohibited from becoming a food employee until the conditional employee satisfies the requirements for reinstatement associated with specific symptoms or diagnosed illnesses specified in section 307.

303 DISEASE OR MEDICAL CONDITION — RESPONSIBILITY OF SUPERVISOR TO EXCLUDE OR RESTRICT ILL FOOD EMPLOYEES*

303.1 A supervisor shall ensure that a food employee who exhibits or reports a symptom or who reports a diagnosed illness as specified in sections 300.3 through 300.5 is:

- (a) Excluded as specified in sections 305, except as provided in section 307; or
- (b) Restricted as specified in section 306, except as provided in section 307.

304 DISEASE OR MEDICAL CONDITION — RESPONSIBILITY OF FOOD EMPLOYEES TO COMPLY WITH EXCLUSIONS OR RESTRICTIONS

304.1 A food employee shall comply with:

- (a) An exclusion imposed pursuant to section 305, unless reinstated pursuant to section 307; or
- (b) A restriction imposed pursuant to section 306, unless reinstated pursuant to section 307.

305 DISEASE OR MEDICAL CONDITION — CONDITIONS REQUIRING EXCLUSION OF ILL FOOD EMPLOYEES

305.1 A supervisor shall exclude a food employee from a food processing operation if the food employee is:

- (a) Symptomatic with vomiting or diarrhea; or
- (b) Symptomatic with vomiting or diarrhea and diagnosed with an infection from *Norovirus*, *Shigella* spp., or Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli*.

305.2 A supervisor shall exclude a food employee who is:

- (a) Jaundiced and the onset of jaundice occurred within the last seven (7) calendar days, unless the food employee provides his or her supervisor with written medical documentation from a licensed physician specifying that the jaundice is not caused by hepatitis A virus or other fecal-orally transmitted infection;

- (b) Diagnosed with an infection from hepatitis A virus within fourteen (14) calendar days after the onset of any illness symptoms, or within seven (7) calendar days after the onset of jaundice; or
- (c) Diagnosed with an infection from hepatitis A virus without developing symptoms.

305.3 A supervisor shall exclude a food employee who is diagnosed with an infection from *Salmonella* Typhi, or reports a previous infection with *Salmonella* Typhi within the past three (3) months without having received antibiotic therapy.

306 DISEASE OR MEDICAL CONDITION — CONDITIONS REQUIRING RESTRICTION OF ILL FOOD EMPLOYEES

306.1 If a food employee is diagnosed with an infection from Norovirus, *Shigella* spp., or Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli*, and is asymptomatic, a supervisor shall restrict the food employee.

306.2 If a food employee is ill with symptoms of acute onset of sore throat with fever, a supervisor shall restrict the food employee.

306.3 A supervisor shall restrict a food employee who is infected with a skin lesion containing pus, such as a boil or infected wound that is open or draining and not properly covered as specified in section 300.3(e).

307 DISEASE OR MEDICAL CONDITION — RESPONSIBILITY OF SUPERVISOR TO REMOVE, ADJUST, OR RETAIN EXCLUSIONS AND RESTRICTIONS OF ILL FOOD EMPLOYEES*

307.1 A supervisor may reinstate a food employee who was excluded under section 305.1(a) for being symptomatic with vomiting or diarrhea if the food employee:

- (a) Is asymptomatic for at least twenty-four (24) hours; or
- (b) Provides his or her supervisor with written medical documentation from a licensed physician that states the symptom is from a noninfectious condition.

307.2 If a food employee was diagnosed with an infection from Norovirus and excluded under section 305.1(b), a supervisor may restrict the food employee after he or she has been asymptomatic for at least twenty-four (24) hours, and may reinstate the food employee after the conditions for reinstatement specified in sections 307.6 have been met.

- 307.3 If a food employee was diagnosed with an infection from *Shigella* spp. or Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli* and excluded under section 305.1(b), a supervisor may restrict the food employee after he or she has been asymptomatic for at least twenty-four (24) hours, and may reinstate the food employee after the conditions for reinstatement specified in sections 307.7 have been met; or
- 307.4 A supervisor may reinstate a food employee who was excluded due to jaundice or a diagnosis of hepatitis A under section 305.2 if the supervisor obtains approval from the Department and one (1) of the following conditions is met:
- (a) The food employee has been jaundiced for more than seven (7) calendar days;
 - (b) The anicteric food employee has had symptoms other than jaundice for more than fourteen (14) calendar days; or
 - (c) The food employee provides his or her supervisor with written medical documentation from a licensed physician that states the food employee is free of a hepatitis A virus infection.
- 307.5 A supervisor may reinstate a food employee who was excluded for *Salmonella* Typhi under section 305.3 if:
- (a) The supervisor obtains approval from the Department; and
 - (b) The food employee provides his or her supervisor with written medical documentation from a licensed physician that states the food employee is free from *Salmonella* Typhi infection.
- 307.6 A supervisor may reinstate a food employee who was excluded under section 305.1(b) or restricted under section 306.1 or 307.2 for Norovirus if the supervisor obtains approval from the Department and one (1) of the following conditions is met:
- (a) The excluded or restricted employee provides his or her supervisor with written medical documentation from a licensed physician that states the food employee is free of Norovirus infection;
 - (b) The food employee was restricted after symptoms of vomiting or diarrhea resolved, and more than forty-eight (48) hours have passed since the food employee became asymptomatic; or

- (c) The food employee was restricted and did not develop symptoms and more than forty-eight (48) hours have passed since the food employee was diagnosed.

307.7 A supervisor may reinstate a food employee who was excluded under section 305.1(b) or restricted under section 306.1 or 307.3 for *Shigella* spp. or Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli* if the supervisor obtains approval from the Department and one (1) of the following conditions is met:

- (a) The excluded or restricted food employee provides his or her supervisor with written medical documentation from a licensed physician that states the food employee is free of a *Shigella* spp. or Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli* infection based on test results showing two (2) consecutive negative stool specimen cultures that are taken:
 - (1) Not earlier than forty-eight (48) hours after discontinuance of antibiotics, and
 - (2) At least twenty-four (24) hours apart;
- (b) The food employee was restricted after symptoms of vomiting or diarrhea resolved, and more than seven (7) calendar days have passed since the food employee became asymptomatic; or
- (c) The food employee was restricted and did not develop symptoms and more than seven (7) calendar days have passed since the food employee was diagnosed.

307.8 A supervisor may reinstate a food employee who was restricted under section 306.2 for sore throat with fever if the food employee provides his or her supervisor with written medical documentation from a licensed physician that states the food employee meets one (1) of the following conditions:

- (a) Has received antibiotic therapy for *Streptococcus pyogenes* infection for more than twenty-four (24) hours;
- (b) Has at least one negative throat specimen culture for *Streptococcus pyogenes* infection; or
- (c) Is otherwise determined by a licensed physician to be free of a *Streptococcus pyogenes* infection.

- 307.9 A supervisor may reinstate a food employee who was restricted as specified in section 306.3 if the skin, infected wound, cut, or pustular boil is properly covered with one (1) of the following:
- (a) An impermeable cover such as a finger cot or stall and a single-use glove over the impermeable cover if the infected wound or pustular boil is on the hand, finger, or wrist;
 - (b) An impermeable cover on the arm if the infected wound or pustular boil is on the arm; or
 - (c) A dry, durable, tight-fitting bandage if the infected wound or pustular boil is on another part of the body.

CHAPTER 4 PERSONAL CLEANLINESS AND HYGIENIC PRACTICES OF FOOD EMPLOYEES

400 HANDS AND ARMS — CLEAN CONDITION *

- 400.1 Food employees shall keep their hands and exposed portions of their arms clean.

401 HANDS AND ARMS — CLEANING PROCEDURE*

- 401.1 Except as specified in section 401.4, food employees shall clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands or arms, for at least twenty (20) seconds, using a cleaning compound in a handwashing sink that is equipped as specified in sections 1402 and 1900 through 1906.
- 401.2 Food employees shall use the following cleaning procedure in the order stated to clean their hands and exposed portions of their arms, including surrogate prosthetic devices for hands and arms:
- (a) Rinse under clean, running warm water;
 - (b) Apply an amount of cleaning compound recommended by the cleaning compound manufacturer;
 - (c) Rub together vigorously for at least ten (10) to fifteen (15) seconds while:
 - (1) Paying particular attention to removing soil from underneath the fingernails during the cleaning procedure, and

- (2) Creating friction on the surfaces of the hands and arms or surrogate prosthetic devices for hands and arms, finger tips, and areas between the fingers;
 - (d) Thoroughly rinse under clean, running warm water;
 - (e) Immediately follow the cleaning procedure with thorough drying using a method specified in section 1903; and
 - (f) Sanitize hands when appropriate in addition to, but not in place of, the proper handwashing methods.
- 401.3 To avoid recontaminating their hands or surrogate prosthetic devices, food employees may use disposable paper towels or similar clean barriers when touching surfaces such as manually operated faucet handles on a handwashing sink or the handle of a restroom door.
- 401.4 If approved and capable of removing the types of soils encountered in the food operations involved, food employees may use an automatic handwashing facility to clean their hands or surrogate prosthetic devices.

402 HANDS AND ARMS – WHEN TO WASH*

- 402.1 Food employees shall clean their hands and exposed portions of their arms as specified in section 401 immediately before working in direct contact with food, equipment, utensils, food-contact surfaces, or food-packaging materials, and:
- (a) After touching bare human body parts other than clean hands and clean, exposed portions of arms;
 - (b) After using the toilet room;
 - (c) After coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
 - (d) After handling soiled surfaces, equipment, or utensils;
 - (e) During food preparation, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks;
 - (f) After each absence from the work station;
 - (g) Immediately before touching ready-to-eat food or food-contact surfaces;

- (h) When switching between working with raw food and working with ready-to-eat food;
- (i) Before donning gloves for working with food; and
- (j) After engaging in other activities that contaminate the hands.

403 HANDS AND ARMS – WHERE TO WASH

- 403.1 Food employees shall clean their hands in a handwashing sink or approved automatic handwashing facility and shall not clean their hands in a sink used for food preparation or warewashing, or in a service sink or a curbed cleaning facility used for the disposal of mop water or similar liquid waste.

404 HANDS AND ARMS – HAND ANTISEPTICS

- 404.1 A hand antiseptic used as a topical application, a hand antiseptic solution used as a hand dip, or a hand antiseptic soap shall:

- (a) Comply with one of the following:
 - (1) Be an approved drug that is listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* based on safety and effectiveness; or
 - (2) Have active antimicrobial ingredients that are listed in the FDA monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products as an antiseptic handwash;
- (b) Comply with one of the following:
 - (1) Have components that are exempt from the requirements of being listed in the federal food additive regulations as specified in 21 CFR 170.39 – Threshold of regulation for substances used in food-contact articles;
 - (2) Comply with and be listed in 21 CFR Part 178 – Indirect Food Additives: Adjuvants: Production Aids, and Sanitizers; or
 - (3) Comply with and be listed in 21 CFR Part 182 – Substances Generally Recognized as Safe, 21 CFR Part 184 – Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR Part 186 – Indirect Food Substances Affirmed as Generally Recognized as Safe; and

(c) Be applied only to hands that are cleaned as specified in section 401.

404.2 If a hand antiseptic or a hand antiseptic solution used as a hand dip does not meet the criteria specified in section 404.1(b), use shall be:

(a) Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; or

(b) Limited to employees working in situations that involve no direct contact with food by the bare hands.

404.3 A hand antiseptic solution used as a hand dip shall be maintained clean and at a strength equivalent to at least one hundred parts per million of chlorine (100 ppm chlorine) or twenty-five parts per million of iodine (25 ppm iodine) and changed every four (4) hours while in use.

404.4 A hand antiseptic solution used as a hand dip or a hand sanitizing station shall be provided and properly positioned and maintained in all food operations where food would normally undergo washing, cleaning, cooking or other processing activities.

404.5 Food employees shall have ready access to hand sanitizing stations when returning from toilet facilities, handwashing facilities, lunch and breaks, and whenever necessary while working.

404.6 Food operations shall provide at least one (1) hand sanitizing station:

(a) Inside entryways of food processing areas; and

(b) On each side of food processing tables, lines and equipment where food is being manipulated by hand; and

(c) For every ten (10) food employees at food processing tables, lines and equipment.

405 HANDS AND ARMS — FINGERNAIL MAINTENANCE

405.1 All persons working in direct contact with food, equipment, utensils, food-contact surfaces, or food-packaging materials shall keep their fingernails trimmed, filed, and maintained so that the edges and surfaces are cleanable and not rough.

405.2 Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial fingernails when working with exposed food, equipment, utensils, food-contact surfaces, or food-packaging materials.

406 HANDS AND ARMS — JEWELRY PROHIBITION

- 406.1 Persons working in direct contact with food, equipment, utensils, food-contact surfaces, or food-packaging materials shall not wear jewelry, including medical information jewelry on their arms and hands, except for a plain ring such as a wedding band.

407 FOOD CONTAMINATION PREVENTION — OUTER CLOTHING, CLEAN CONDITION

- 407.1 All persons working in direct contact with food, equipment, utensils, food-contact surfaces, or food-packaging materials shall wear clean and protective clothing that is:

- (a) Clean at the start of the work shift;
- (b) Changed when the clothing becomes so soiled during the course of the work shift that contamination of food, equipment, utensils, food-contact surfaces, or food-packaging materials becomes imminent; and
- (c) Suitable to the specific food processing operation for protection against the contamination of food, equipment, utensils, food-contact surfaces, or food-packaging materials.

408 FOOD CONTAMINATION PREVENTION — EATING, DRINKING, USING TOBACCO, FOREIGN SUBSTANCES*

- 408.1 Persons working in direct contact with food, equipment, utensils, food-contact surfaces, or food-packaging materials shall not eat, drink, chew gum, or use any form of tobacco, except in designated areas where food, food processing equipment, utensils, food-contact surfaces or food-packing materials are not exposed, and where equipment or utensils are not washed or stored.

- 408.2 All persons working in direct contact with food, equipment, utensils, food-contact surfaces, or food-packaging materials shall take all necessary precautions to protect against the contamination of food, equipment, utensils, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, the following:

- (a) Perspiration;
- (b) Hair;
- (c) Cosmetics;

- (d) Tobacco;
- (e) Chemicals; or
- (f) Medicines applied to the skin.

409 FOOD CONTAMINATION PREVENTION — DISCHARGES FROM THE EYES, NOSE, AND MOUTH*

- 409.1 Food employees experiencing persistent sneezing, coughing, or a runny nose that causes a discharge from the eyes, nose, or mouth shall not work with exposed food, equipment, utensils, food-contact surfaces, or food-packaging materials.

410 FOOD CONTAMINATION PREVENTION — HAIR RESTRAINTS, EFFECTIVENESS

- 410.1 Food employees shall wear clean and effective hair restraints, such as hairnets or beard nets, if appropriate, and clothing that covers body hair and is designed and worn to effectively keep hair from contacting exposed food, clean equipment, utensils, food-contact surfaces, or food-packing materials. Hats, caps, scarves or other head covers are acceptable if the hair is contained to protect from contamination. Hair spray and tying back the hair in a ponytail are not effective hair restraints.

411 FOOD CONTAMINATION PREVENTION — ANIMALS, PROHIBITION ON HANDLING *

- 411.1 Food employees shall not care for or handle animals that may be present in the food processing operation, such as patrol dogs, or service animals that are allowed as specified in section 2012.1.

SUBTITLE C: COMPLIANCE WITH FEDERAL LAWS, FOOD REQUIREMENTS, FOOD PROCESSING, PACKAGING, MANUFACTURING, STORAGE, TRANSPORTATION AND LABELING

CHAPTER 5 COMPLIANCE WITH FEDERAL LAWS

500 COMPLIANCE WITH FEDERAL LAWS

- 500.1 The most current versions of the following federal regulations are hereby incorporated by reference:

- (a) 7 CFR 57.200 – Part 57 – Inspection of Eggs (Egg Products Inspection Act), Subpart A – Regulations Governing the Inspection of Eggs, Records and related requirements;
- (b) 9 CFR 317.24 – Part 317 – Labeling, Marking Devices, and Containers, Subpart A – General, Packaging Materials;
- (c) 9 CFR 317.345 – Part 317 – Labeling, Marking Devices, and Containers, Subpart B – Nutrition Labeling, Guidelines for voluntary nutrition labeling of single ingredient, raw products;
- (d) 9 CFR 318.310 – Part 318 – Entry into Official Establishments: Reinspection and Preparation of Products, Subpart G – Canning and Canned Products, Personnel and training;
- (e) 9 CFR 381.310 – Part 381 – Poultry Products Inspection Regulations, Subpart X – Canning and Canned Products, Personnel and training;
- (f) 9 CFR 590.200 – Part 590 – Inspection of Eggs and Egg Products (Egg Products Inspection Act), Records and related requirements;
- (g) 9 CFR 590.905 – Part 590 – Inspection of Eggs and Egg Products (Egg Products Inspection Act), Importation of restricted eggs or eggs containing more restricted eggs than permitted in the official standards for U.S. Consumer Grade B;
- (h) 16 CFR 502.3 – Part 502 – Regulations Under Section 5(C) of the Fair Packaging and Labeling Act, Prohibited acts;
- (i) 21 CFR 1.225 – Part 1 – General Enforcement Regulations, Subpart H – Registration of Food Facilities, Who must register under this subpart?;
- (j) 21 CFR 7.3 – Part 7 – Enforcement Policy, Subpart A – General Provisions, Definitions;
- (k) 21 CFR 7.42 – Part 7 – Enforcement Policy, Subpart C – Recalls (Including Product Corrections) – Guidance on Policy, Procedures, and Industry Responsibilities, Recall strategy;
- (l) 21 CFR 11.10 – Part 11 – Electronic Records; Electronic Signatures, Subpart B – Electronic Records, Controls for closed systems;
- (m) 21 CFR 101.3 – Part 101 – Food Labeling, Subpart A – General Provisions, Identity labeling of food in packaged form;

- (n) 21 CFR 107.230 – Part 107 – Infant Formula, Subpart E – Infant Formula Recalls, Elements of an infant formula recall;
- (o) 21 CFR 108.25 (f) – Part 108 – Emergency Permit Control, Subpart B – Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit, Acidified foods;
- (p) 21 CFR 108.35 (g) – Part 108 – Emergency Permit Control, Subpart B – Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit, Thermal processing of low-acid foods packaged in hermetically sealed containers;
- (q) 21 CFR 110.5 – Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Subpart A – General Provisions, Current good manufacturing practice;
- (r) 21 CFR 110.10 – Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Subpart A – General Provisions, Personnel;
- (s) 21 CFR 110.20 – Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Subpart B – Buildings and Facilities, Plant and grounds;
- (t) 21 CFR 110.35 – Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Subpart B – Buildings and Facilities, Sanitary operations;
- (u) 21 CFR 110.37 – Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Subpart B – Building and Facilities, Sanitary facilities and controls;
- (v) 21 CFR 110.40 – Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Subpart C – Equipment, Equipment and utensils;
- (w) 21 CFR 110.80 – Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Subpart E – Production and Process Controls, Processes and controls;
- (x) 21 CFR 110.93 – Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Subpart E – Production and Process Controls, Warehousing and distribution;

- (y) 21 CFR 113.5 – Part 113 – Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, Subpart A – General Provisions, Current good manufacturing practice;
- (z) 21 CFR 113.10 – Part 113 – Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, Subpart A – General Provisions, Personnel;
- (aa) 21 CFR 113.100 – Part 113 – Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, Subpart F – Records and Reports, Processing and production records;
- (bb) 21 CFR 114.5 – Part 114 – Acidified Foods, Subpart A – General Provisions, Current good manufacturing practice;
- (cc) 21 CFR 114.10 – Part 114 – Acidified Foods, Subpart A – General Provisions, Personnel;
- (dd) 21 CFR 114.100 – Part 114 – Acidified Foods, Subpart F – Records and Reports, Records;
- (ee) 21 CFR 115.50 – Part 115 – Shell Eggs, Refrigeration of shell eggs held for retail distribution;
- (ff) 21 CFR Part 123 – Fish and Fishery Products;;
- (gg) 21 CFR 129.1 – Part 129 – Processing and Bottling of Bottled Drinking Water, Subpart A - General Provisions, Current good manufacturing practice;
- (hh) 21 CFR 130.10 – Part 130 – Food Standards: General, Subpart A – General Provisions, Requirements for foods named by use of a nutrient content claim and a standardized term;
- (ii) 21 CFR 161.130 – Part 161 – Fish and Shellfish, Subpart B – Requirements for Specific Standardized Fish and Shellfish, Oysters;
- (jj) 21 CFR 165.110 – Part 165 – Beverages, Subpart B – Requirements for Specific Standardized Beverages, Bottled water;
- (kk) 21 CFR 170.19 – Part 170 – Food Additives, Subpart A – General Provisions, Pesticide chemicals in processed foods;
- (ll) 21 CFR 170.22 – Part 170 – Food Additives, Subpart B – Food Additive Safety, Safety factors to be considered;

- (mm) 21 CFR Part 170.30 – Part 170 – Food Additives, Subpart B – Food Additive Safety, Eligibility for classification as generally recognized as safe (GRAS);
- (nn) 21 CFR 170.39 – Part 170 – Food Additives, Subpart B – Food Additive Safety, Threshold of regulation for substances used in food-contact articles
- (oo) 21 CFR 173.310 – Part 173 – Secondary Direct Food Additives Permitted in Food for Human Consumption, Subpart D – Specific Usage Additives, Boiler water additives;
- (pp) 21 CFR 173.315 – Part 173 – Secondary Direct Food Additives Permitted in Food for Human Consumption, Subpart D – Specific Usage Additives, Chemicals used in washing or to assist in the peeling of fruits and vegetables;
- (qq) 21 CFR 174.5 – Part 174 – Indirect Food Additives: General, General provisions applicable to indirect food additives;
- (rr) 21 CFR 174.6 – Part 174 – Indirect Food Additives: General, Threshold of regulation for substances used in food-contact articles;
- (ss) 21 CFR Part 175 – Indirect Food Additives: Adhesives and Components of Coatings;
- (tt) 21 CFR Part 176 – Indirect Food Additives: Paper and Paperboard Components;
- (uu) 21 CFR Part 177 – Indirect Food Additives: Polymers;
- (vv) 21 CFR Part 178 – Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers;
- (ww) 21 CFR 178.1010 – Part 178 – Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, Subpart B – Substances Utilized to Control the Growth of Microorganisms, Sanitizing solutions;
- (xx) 21 CFR 178.3570 – Part 178 – Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, Subpart D – Certain Adjuvants and Production Aids, Lubricants with incidental food contact;
- (yy) 21 CFR Part 181 – Prior-Sanctioned Food Ingredients;
- (zz) 21 CFR 181.22 – Part 181 – Prior-Sanctioned Food Ingredients, Subpart B – Specific Prior-Sanctioned Food Ingredients, Certain

substances employed in the manufacture of food-packaging materials;

- (aaa) 21 CFR Part 182 – Substances Generally Recognized as Safe;
- (bbb) 21 CFR Part 184 – Direct Food Substances Affirmed as Generally Recognized as Safe;
- (ccc) 21 CFR Part 186 – Indirect Food Substances Affirmed as Generally Recognized as Safe;
- (ddd) 40 CFR Part 141 – National Primary Drinking Water Regulations;
- (eee) 40 CFR 142.2 – Part 142 – National Primary Drinking Water Regulations Implementation, Subpart A – General Provisions, Definitions;
- (fff) 40 CFR 152.170 – Part 152 – Pesticide Registration and Classification Procedures, Subpart I – Classification of Pesticides, Criteria for restriction to use by certified applicators.

CHAPTER 6 FOOD REQUIREMENTS

600 CONDITION OF FOOD*

600.1 Food and food ingredients processed in a food processing operation shall be:

- (a) Safe for human consumption;
- (b) Clean;
- (c) Free of spoilage;
- (d) From an approved source; and
- (e) Generally recognized as safe (GRAS).

601 ADULTERATED FOOD

601.1 Adulterated food shall not be offered as food to human beings.

601.2 Adulterated food that is not for rework to ensure safety, wholesomeness, and proper labeling shall be:

- (a) Destroyed or diverted to non-food uses; and

- (b) When within a food processing operation, stored only in a designated area, as specified in section 1912, that is:
 - (1) Separated from all other food, equipment, utensils, food-contact surfaces, food-packaging materials, and food operations; and
 - (2) Conspicuously marked as an area for distressed merchandise.

602 IMPORTED MANUFACTURED OR PROCESSED FOOD

- 602.1 Manufacturers, processors, and packers that import food for human consumption into the District, or operators of storage facilities that hold food for human or animal consumption in the District shall be registered with the FDA in accordance with 21 CFR 1.225 – Who must register under this subpart?

CHAPTER 7 UNIT PROCESSING OPERATIONS, PROCESSING FOOD FOR SAFETY

700 PRODUCTION AND PROCESS CONTROLS

- 700.1 Food shall be manufactured, processed, and packaged in accordance with this chapter.
- 700.2 Acidified foods shall be manufactured, processed, and packaged in a manner that prevents adulteration in accordance with 21 CFR 114.5 – Current good manufacturing practice.
- 700.3 Thermally processed low-acid foods shall be manufactured, processed and packaged so as to meet the criteria referenced in 21 CFR 113.5 – Current good manufacturing practice.
- 700.4 Records and reports shall be completed and maintained for acidified foods in accordance with 21 CFR 114.100 – Records; and for low acid foods in accordance with 21 CFR 113.100 – Records.
- 700.5 If a processor makes an electronic record of pH with respect to acidified foods by connection of the pH meter to a computer or by manually keying the pH values into a computer as the primary record, then that record shall be subject to 21 CFR 11.10 – Controls for closed systems.
- 700.6 Complete records covering all aspects of the establishment of the process and associated incubation tests for acidified foods shall be prepared and permanently retained by the person or organization making the determination.

- 700.7 Records that document compliance with this chapter shall be:
- (a) Maintained on site; and
 - (b) Available for inspection by the Department in accordance with section 3200.2(d).

701 RAW MATERIALS AND OTHER INGREDIENTS

- 701.1 General production and processing of raw materials and other food ingredients shall be conducted so as to meet the criteria referenced in 21 CFR 110.5 – Current good manufacturing practice.
- 701.2 The handling and storage of raw materials and other ingredients and rework shall be performed in accordance with 21 CFR 110.80(a) – Processes and controls.
- 701.3 The control of contaminants in raw materials and other food ingredients shall be accomplished in accordance with 21 CFR 110.80(a) – Processes and controls.
- 701.4 Food shall contain only approved food additives or additives that are within permissible limits as specified in 21 CFR 170.19 – Pesticide chemicals in processed foods; 21 CFR 170.22 – Safety factors to be considered; 21 CFR 170.30 – Eligibility for classification as generally recognized as safe (GRAS); 21 CFR Part 181 – Prior Sanctioned Food Ingredients; 21 CFR Part 182 – Substances Generally Recognized as Safe; 21 CFR Part 184 – Direct Food Substances Affirmed as Generally Recognized as Safe; or 21 CFR Part 186 – Indirect Food Substances Affirmed as Generally Recognized as Safe.

702 SHELL EGGS AND EGG PRODUCTS

- 702.1 All persons engaged in the business of transporting, shipping, receiving any eggs or egg products, or holding such articles so received, and all egg handlers, shall maintain records on a form provided by the Department showing the receipt, delivery, sale, movement, and disposition of all eggs and egg products in accordance with 7 CFR Part 57.200 – Records and related requirements; 9 CFR 590.905 – Importation of restricted eggs or eggs containing more restricted eggs than permitted in the official standards for U.S. Consumer Grade B; and 21 CFR 115.50 – Refrigeration of shell eggs held for retail distribution.

703 FISH AND FISHERY PRODUCTS

- 703.1 Fish and fishery products shall be processed in accordance with the requirements referenced in 21 CFR Part 123 – Fish and Fishery Products, and subtitle H of this Code.

704 HACCP PLAN REQUIREMENTS

- 704.1 When a food processing operation is required under section 3002 to submit an HACCP Plan to the Department, the plan and specifications shall contain:

- (a) A flow diagram by specific food processing method identifying critical control points and providing information on the following:
 - (1) Ingredients, materials, and equipment used in the food production; and
 - (2) Formulations that delineate methods and procedural control measures used to address the food safety concerns involved;
- (b) A food employee and supervisory training plan that addresses food safety issues;
- (c) A statement of standard operating procedures for the plan under consideration, including clearly identifying:
 - (1) Each critical control point;
 - (2) The critical limits for each critical control point;
 - (3) The method and frequency for monitoring and controlling each critical control point by the food employee designated by supervisory personnel;
 - (4) The method and frequency for supervisors to routinely verify that the food employee is following standard operating procedures and monitoring critical control points;
 - (5) Actions to be taken by supervisors if the critical limits for each critical control point are not met; and
 - (6) Records to be maintained by supervisors to demonstrate that the HACCP Plan is properly operated and managed.

- 704.2 A HACCP Plan required under section 3002 shall comply with the requirements of section 801.2 or chapter 25, as applicable, and this section.
- 704.3 The HACCP Plan shall be signed and dated, either by the most responsible individual on site at the food processing operation, or by a higher-level official of the licensee or dealer. This signature shall signify that the licensee or dealer has accepted the HACCP Plan for implementation.
- 704.4 The HACCP Plan shall be signed and dated upon:
- (a) Initial acceptance;
 - (b) Any modification; and
 - (c) Verification of the HACCP Plan.

CHAPTER 8 PACKAGING FOOD AND FOOD PACKAGING MATERIALS

800 PACKAGING FOOD — SUPERVISORY RESPONSIBILITIES

- 800.1 A certified supervisor shall ensure that food packaging is:
- (a) Designed and installed to maintain food safety and integrity;
 - (b) Made from materials that:
 - (1) Are safe;
 - (2) Are appropriate for the intended use;
 - (3) Will not migrate to or be absorbed by food; and
 - (4) Comply with the FDA requirements stated in 21 CFR 174.5 – General provisions applicable to indirect food additives; 21 CFR 174.6 – Threshold of regulation for substances used in food-contact articles; 21 CFR 178.1010 – Sanitizing solutions; and 21 CFR 178.3570 – Lubricants with incidental food contact; and
 - (c) Evaluated before use for characteristics that may impact the food, such as permeability to:
 - (1) Water and water vapor;
 - (2) Oxygen; and

- (3) Other gases.

801 PACKAGING FOOD — REQUIREMENTS

- 801.1 A food processing operation that packages food using a reduced oxygen packaging method, with *Clostridium botulinum* identified as the target organism for destruction in the final packaged form shall in addition to modifying the oxygen content use at least two (2) of the following barriers: refrigeration, pH, or water activity to control the growth and toxin formation of *Clostridium botulinum*.
- 801.2 A food processing operation that packages food using a reduced oxygen packaging method with *Clostridium botulinum* identified as a microbiological hazard in the final packaged form, shall have a HACCP plan that complies with the requirements of section 704 and:
- (a) Contains a flow diagram by specific food or category type identifying critical control points and providing information on the following:
 - (1) Ingredients, materials, and equipment used in the preparation of that food; and
 - (2) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
 - (b) Contains a statement of standard operating procedures for the plan that clearly identifies the following:
 - (1) Each critical control point;
 - (2) The critical limits for each critical control point;
 - (3) The method and frequency for monitoring and controlling each critical control point by the food employee designated by a supervisor;
 - (4) The method and frequency for supervisors to routinely verify that the food employee is following standard operating procedures and monitoring critical control points;
 - (5) Action to be taken by supervisors if the critical limits for each critical control point are not met; and

- (6) Records to be maintained by supervisors to demonstrate that the HACCP plan is properly operated and managed;
- (c) Identifies the food to be packaged;
- (d) Limits the food packaged to a food that does not support the growth of *Clostridium botulinum* because it meets with one (1) of the following criteria:
 - (1) Has an aw of ninety-one hundredths (0.91) or less;
 - (2) Has a pH of four and six tenths (4.6) or less;
 - (3) Is a meat or poultry product cured at a food processing operation regulated by the USDA and is received in an intact package; or
 - (4) Is a food with a high level of competing organisms, such as raw meat or raw poultry;
- (e) Specifies methods for maintaining food at forty-one degrees (41° F) (five degree Centigrade (5° C)) or below;
- (f) 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:
 - (1) Maintain the food at forty-one degrees Fahrenheit (41° F) (five degree Centigrade (5° C)) or below; and
 - (2) Discard the food if within fourteen (14) calendar days of its packaging it is not sold for consumption;
- (g) Limits the shelf life to no more than fourteen (14) calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;
- (h) Includes operational procedures that prohibit contacting food with bare hands;
- (i) Includes operational procedures that identify a designated area and the method by which:
 - (1) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination; and

- (2) Access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation;
- (j) Delineates cleaning and sanitization procedures for food-contact surfaces; and
- (k) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:
 - (1) Concepts required for a safe operation;
 - (2) Equipment and facilities; and
 - (3) Procedures specified under sections 801.2(b) and 801.2(h) – (j).

CHAPTER 9 FOOD MANUFACTURING OPERATIONS; STORAGE; TRANSPORTATION

900 FOOD MANUFACTURING OPERATIONS – GENERAL PROVISIONS

- 900.1 Food manufacturing operations shall be conducted in accordance with 21 CFR 110.80 (b) – Processes and controls.
- 900.2 Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated by maintaining cold, potentially hazardous foods at forty-one degrees Fahrenheit (41° F) (five degree Centigrade (5° C)) or below, except when the food is received and stored at temperatures specified in another law, such as laws governing milk, molluscan shellfish, and shell eggs.
- 900.3 Frozen foods shall be maintained in a frozen state and stored at thirty-two degrees Fahrenheit (32° F) (zero degrees Centigrade (0° C)) or below.
- 900.4 Frozen foods shall not be refrozen after having been thawed unless the products are to be further processed by the processor, as necessary to control microbial growth.
- 900.5 Frozen foods during transportation shall remain frozen and at thirty-two degrees Fahrenheit (32° F) (zero degrees Centigrade (0° C)) or below.

- 900.6 Foods refrigerated during transportation shall be at forty-one degrees Fahrenheit (41° F) (five degree Centigrade (5° C)) or below unless a federal law governing the food's distribution applies, such as temperature requirements for shellfish or shell eggs.
- 900.7 The licensee of a food processing operation shall report to the Department within twenty-four (24) hours after receiving positive test results, any microbiological test or other laboratory analysis that shows the likelihood that any ready-to-eat food produced by that operator contains pathogenic organisms, undeclared allergens, or other health hazards. The licensee may report orally, electronically, or in writing.
- 900.8 A licensee is not required to report test results if:
- (a) A product code or production date identifies the ready-to-eat food lot number; and
 - (b) The licensee has not sold or distributed any of the food represented by the product code or production lot number.

901 FOOD MANUFACTURING OPERATIONS – ICE

- 901.1 When ice is used as an ingredient or in contact with food, it shall be made from water that is safe and meets the quality standards specified in section 1303. Ice shall be used only if it has been manufactured in accordance with this Code.
- 901.2 When ice is used as an ingredient or in contact with food, it shall be processed, handled, packed, and held under sanitary conditions in accordance with the criteria referenced in 21 CFR 110.5 – Current good manufacturing practices.
- 901.3 Ice used in the processing of food shall be protected from contamination during its manufacture, storage, transportation and use by taking necessary precautions which include but are not limited to ensuring that:
- (a) Storage bins and containers of water are covered;
 - (b) All storage and packaging containers, including ice house or storage room contact surfaces, are sanitary, readily cleanable, and do not impart deleterious materials to the ice. Wooden totes shall not be used to transport or hold ice;

- (c) Scoops, shovels and other utensils used in the handling of ice are in a sanitary condition, properly stored, readily cleanable, and do not impart deleterious materials to the ice;
- (d) The ice does not come into contact with floor areas where foot traffic is possible; and
- (e) Equipment used to manufacture ice is in a sanitary condition, readily cleanable and does not impart any deleterious or other foreign substances to the ice.

902 FOOD MANUFACTURING OPERATIONS – BOTTLED DRINKING WATER AND BEVERAGES

- 902.1 Bottled drinking water and beverages shall be processed in accordance with the criteria referenced in 21 CFR 129.1 – Current good manufacturing practice and 21 CFR 165.110 – Bottled water.
- 902.2 Bottled drinking water, manufactured, used, or sold, shall meet the requirements of the criteria referenced in 21 CFR 129.1 – Current good manufacturing practice and 21 CFR 165.110 – Bottled water.

903 FOOD MANUFACTURING OPERATIONS – STORAGE AND TRANSPORTATION – CONTROL OF CONTAMINATION

- 903.1 Storage and transportation of finished food shall be performed as stated in federal law, specifically 21 CFR 110.93 – Warehousing and distribution.
- 903.2 Potentially hazardous foods shall be transported at the temperatures specified in sections 900.2 through 900.6, and as required under subtitle H of this Code.

CHAPTER 10 FOOD LABELING

1000 FOOD LABELING

- 1000.1 Food packaged or stored in a food processing operation shall be labeled in accordance with 21 CFR 101.3 – Identity labeling of food in packaged form, and 9 CFR 317.345 – Guidelines for voluntary nutrition labeling of single ingredient, raw product.
- 1000.2 Labels shall include all information required by federal laws, except when exemptions exist, such as those documented in section 403(Q)(3)-(5) of the Federal Food Act, 21 CFR 101.3 – Identity labeling of food in packaged

form, and 9 CFR 317.345 – Guidelines for voluntary nutrition labeling of single ingredient, raw product.

1001 LABELING — STANDARDS OF IDENTITY

1001.1 Packaged food shall comply with the standard of identity requirements in 21 CFR 130.10 – Requirements for foods named by use of a nutrient content claim and a standardized term.

1002 LABELING — ACCURATE REPRESENTATION

1002.1 Food shall be labeled and offered for human consumption in a way that does not mislead or misinform the consumer.

1002.2 Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of the food.

1003 FOOD LABELING — FOOD EXEMPT IN TRANSIT FOR COMPLETION PURPOSES

1003.1 Food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where it was originally processed or packed, is exempt from the affirmative labeling requirements of this chapter, while it is in transit from the one establishment to the other, if such transit is made in good faith for such completion purposes only; but it is otherwise subject to all the applicable provisions of this Code.

1004 BOTTLED WATER LABELING STANDARDS

1004.1 All bottled water must conform to applicable federal labeling laws and state labeling laws in the jurisdiction in which the bottled water plant operates, and be labeled in compliance with the following standards:

- (a) Mineral water may be labeled "mineral water". Bottled water to which minerals are added shall be labeled so as to disclose that minerals are added, and may not be labeled "natural mineral water";
- (b) Spring water may be labeled "spring water" or "natural spring water";
- (c) Water containing carbon dioxide that emerges from the source and is bottled directly with its entrapped gas or from which the gas is mechanically separated and later reintroduced at a level not higher than naturally occurring in the water may bear on its label the words "naturally carbonated" or "naturally sparkling";

- (d) Bottled water that contains carbon dioxide other than that naturally occurring in the source of the product shall be labeled with the words "carbonated", "carbonation added", or "sparkling" if the carbonation is obtained from a natural or manufactured source;
- (e) Well water may be labeled "well water" or "natural well water";
- (f) Artesian water may be labeled "artesian water" or "natural artesian water";
- (g) Purified water may be labeled "purified water" and the method of preparation shall be stated on the label, except that purified water produced by distillation may be labeled as "distilled water";
- (h) Drinking water may be labeled "drinking water";
- (i) The use of the word "spring" or any derivative of "spring" other than in a trademark, trade name, or company name, to describe water that is not spring water is prohibited; and
- (j) Supplemental printed information and graphics may appear on the label but shall not imply properties of the product or preparation methods that are not factual.

1004.2 Bottled soft drinks, soda, or seltzer products commonly recognized as soft drinks and identified on the product identity panel with a common or usual name other than one of those specified in section 9901 are exempt from the requirements of this section.

1004.3 Water that is not in compliance with the requirements of this section shall not be identified, labeled, or advertised as "artesian water", "bottled water", "distilled water", "natural water", "purified water", "spring water", or "well water".

CHAPTER 11 RECALL PROCEDURES

1100 GENERAL PROVISIONS

1100.1 Food processing operations shall develop and implement written recall procedures in accordance with 21 CFR 7.42 – Recall strategy, and 21 CFR 107.230 – Elements of an infant formula recall.

1100.2 Shellfish dealers shall develop and implement written procedures for conducting recalls of adulterated and misbranded shellfish products in accordance with 21 CFR 7.42 – Recall strategy.

1100.3 Recall procedures shall include timely notification to the Department of the following information:

- (a) The situation requiring the recall; and
- (b) The consignees or distributors who received the affected product, and the effective removal or correction of the affected product.

SUBTITLE D: EQUIPMENT, UTENSILS, FOOD CONTACT SURFACES AND FOOD-PACKAGING MATERIALS

CHAPTER 12 DESIGN, CONSTRUCTION, AND MAINTENANCE OF EQUIPMENT, UTENSILS, FOOD-CONTACT SURFACES AND FOOD-PACKAGING MATERIALS

1200 EQUIPMENT AND UTENSILS — DESIGN, CONSTRUCTION, DURABILITY AND STRENGTH

1200.1 All food processing equipment, utensils, and fixtures shall be designed and constructed of such material and workmanship to be durable, cleanable, and properly maintained in accordance with 21 CFR 110.40 – Equipment and utensils, and the requirements in this chapter.

1200.2 The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

1200.3 Food processing equipment and utensils that are certified or classified for sanitation either by the National Sanitation Foundation (NSF) International, the Underwriters Laboratories (UL), or the American National Standards Institute (ANSI) shall be deemed in compliance with this Code.

1201 EQUIPMENT AND UTENSILS — DESIGN, CONSTRUCTION, DURABILITY AND STRENGTH, FOOD TEMPERATURE MEASURING DEVICES*

1201.1 Food temperature measuring devices shall not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.

1202 EQUIPMENT AND UTENSILS — CLEANING

1202.1 Equipment and utensils used in food processing shall be cleaned as frequently as necessary to protect against contamination of food as follows:

- (a) Food-contact surfaces of equipment and utensils used for manufacturing or holding low moisture food shall be in a dry, clean and sanitary condition at the time of use. When the food-contact surfaces are wet cleaned, they shall be sanitized and thoroughly dried before subsequent use.
- (b) In wet processing, when cleaning is performed to protect against the introduction of microorganisms into food, food-contact surfaces of equipment and utensils shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated.
- (c) Where equipment and utensils are used in a continuous production operation, food-contact surfaces of the equipment shall be cleaned and sanitized as necessary to prevent contamination.
- (d) Nonfood-contact surfaces of equipment used in food processing operations shall be cleaned as frequently as necessary to protect against contamination of food.
- (e) Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and sanitized.
- (f) Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010 – Sanitizing solutions.

1203 EQUIPMENT AND UTENSILS — STORAGE, PREVENTING CONTAMINATION

1203.1 Equipment and utensils used in the processing of foods, such as knives, scrapers, scoops, shovels, cutters, and other hand tools and equipment shall be placed or stored in a manner that prevents food contact surfaces from physical, biological or chemical contamination.

1203.2 Cleaned and sanitized portable equipment and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination.

1203.3 Food contact equipment and utensils shall not be stored in the following manner:

- (a) In contact with the floor, dirty equipment frames, or other unsanitary nonfood contact surfaces;
- (b) In contact with containers of nonpotable water (other than sterilizing solutions); or
- (c) In contact with other contaminants.

1204 EQUIPMENT — TEMPERATURE MEASURING DEVICES, ACCURACY

1204.1 Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to plus or minus one degree Centigrade ($\pm 1^{\circ}\text{C}$) (plus or minus two degrees Fahrenheit ($\pm 2^{\circ}\text{F}$)) in the intended range of use.

1204.2 Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to plus or minus two degrees Fahrenheit ($\pm 2^{\circ}\text{F}$) (plus or minus one degree Centigrade ($\pm 1^{\circ}\text{C}$)) in the intended range of use.

1205 EQUIPMENT — TEMPERATURE MEASURING DEVICES, AMBIENT AIR AND WATER, ACCURACY

1205.1 Ambient air and water temperature measuring devices that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to plus or minus one and one half degrees Centigrade ($\pm 1.5^{\circ}\text{C}$) (thirty-four and seven tenths degrees Fahrenheit ($\pm 34.7^{\circ}\text{F}$)) in the intended range of use.

1205.2 Ambient air and water temperature measuring devices that are scaled only in Fahrenheit shall be accurate to plus or minus three degrees Fahrenheit ($\pm 3^{\circ}\text{F}$) (plus or minus two degrees Centigrade ($\pm 2^{\circ}\text{C}$)) in the intended range of use.

1206 EQUIPMENT — FOOD TEMPERATURE MEASURING DEVICES, ACCURACY, INSTALLATION*

1206.1 Each freezer and refrigeration unit, including vehicles used to store, hold or transport food shall be fitted with an indicating thermometer, temperature measuring device or temperature recording device so installed as to show the temperature accurately within the compartment and shall be fitted with

an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

1206.2 The licensee shall:

- (a) Record the temperature shown by each measuring device installed in the unit, with the date on which the temperature reading was taken. Temperature shall be monitored and recorded at least weekly.
- (b) Retain and have available for inspection the temperature records for the last six (6) months.

1206.3 The amount of food stored in a refrigerator or frozen food storage unit shall not exceed the designed capacity of that unit.

1207 EQUIPMENT — REFRIGERATED UNITS, CONTROLS, TEMPERATURES

1207.1 Every operator of a refrigerated unit operation shall provide a complete temperature control system with adequate capacity and accurate and reliable controls for the maintenance of the following uniform temperatures of the various refrigerated units under extreme conditions of outside temperatures and under peak load conditions in the food processing operation. Unit temperatures shall be maintained as follows:

- (a) Chill room: Air temperature shall be maintained at forty-one degrees Fahrenheit (41° F) (five degrees Centigrade (5 ° C)) or below with accuracy within three degrees Fahrenheit (3 ° F) (two degrees Centigrade (2 ° C)).
- (b) Deep freezing room: Air temperature of a deep freezing room shall be maintained at minus ten degrees Fahrenheit (-10° F) (minus twenty-three degrees Centigrade (-23° C)) or below. When forced air circulation is employed, the maximum air temperature shall be maintained at zero degrees Fahrenheit (0 ° F) (minus seventeen degrees Centigrade (-17° C)) with a tolerance of ten degrees Fahrenheit (10 ° F) (minus twelve degrees Centigrade (-12° C)).
- (c) Locker room: Air temperatures of a locker room shall be maintained at zero degrees Fahrenheit (0° F) (minus seventeen degrees Centigrade (-17° C)) with a tolerance of twelve degrees Fahrenheit (12° F) (minus eleven degrees Centigrade (-11° C)).

**1208 EQUIPMENT — PRESSURE MEASURING DEVICES,
MECHANICAL WAREWASHING EQUIPMENT, COMPRESSED
AIR**

1208.1 Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse shall have increments of seven (7) kilopascals (1 pound per square inch) or smaller and shall be accurate to plus or minus fourteen (± 14) kilopascals (± 2 pounds per square inch) in the range indicated on the manufacturer's data plate.

1208.2 Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

1209 EQUIPMENT — GOOD REPAIR, COMPLIANCE

1209.1 All equipment shall be in good repair and shall be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces between the equipment.

1209.2 Existing cooling, heating, or temperature holding equipment that does not comply with this Code shall be replaced as specified in sections 3108.7 and 3108.8.

**1210 EQUIPMENT — GOOD REPAIR AND CALIBRATION,
TEMPERATURE AND PRESSURE MEASURING DEVICES**

1210.1 Instruments and controls used for measuring, regulating, or recording temperatures, acidity, water activity, humidity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, sufficient in number for their designated uses, and calibrated at the frequency recommended by the manufacturer of the device.

1211 FOOD-CONTACT SURFACES — CHARACTERISTICS*

1211.1 Food-contact surfaces shall be made of nontoxic and non-harmful materials and designed to withstand the environment of their intended use, the action of food, and, if applicable, cleaning compounds and sanitizing agents.

1211.2 Food-contact surfaces shall be corrosion-resistant when in contact with food.

1212 FOOD-CONTACT SURFACES – CLEANABILITY*

1212.1 Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives, by the following means:

- (a) Seams and edges on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
- (b) Equipment that is in the food processing or food-handling area that does not come into contact with food shall be so constructed that it can be maintained in a clean condition.
- (c) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

1213 NONFOOD-CONTACT SURFACES – CLEANABILITY

1213.1 Nonfood-contact surfaces shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

1214 FOOD-PACKAGING MATERIALS – DESIGN, CONSTRUCTION, DURABILITY AND STRENGTH

1214.1 All food-packaging materials that are in direct contact with food shall be designed and constructed of material appropriate for their intended use in accordance with 21 CFR 181.22 – Certain substances employed in the manufacture of food-packaging materials and 9 CFR 317.24 – Packaging Materials. .

1215 FOOD-PACKAGING MATERIALS – HANDLING AND STORAGE, PREVENTING CONTAMINATION

1215.1 Food packaging materials shall be stored in appropriate containers and locations, and shall be handled and disposed of in a manner that protects against contamination of food or food-contact surfaces.

1215.2 The food contact surfaces of food packaging materials shall be protected from potential sources of contamination during handling and storage by

taking necessary precautions which include but are not limited to ensuring that:

- (a) Boxes, liners and other primary containers are not stored on floors or other unsanitary surfaces;
- (b) Top containers in a nested stack of lined or primary containers are inverted or otherwise protected;
- (c) All single service containers, caps, roll stock, liner jars, bottles, jugs and other preformed containers are stored in closed sanitary tubes, wrappings, boxes or cartons prior to use;
- (d) The forming, make-up or other package assembly is conducted in a manner that precludes contamination; and
- (e) The handling of packaging material and containers prior to filling or wrapping is conducted so that they are not exposed to contamination by dust, foreign material or other contaminants.

SUBTITLE E: WATER, PLUMBING, AND WASTE

CHAPTER 13 WATER

1300 SOURCE — APPROVED SYSTEM*

- 1300.1 The only approved system for drinking water is the District of Columbia public water system.
- 1300.2 A food processing operation shall not obtain water for its operations from a water system that is not the District of Columbia public water system.

1301 SOURCE — SYSTEM FLUSHING AND DISINFECTION*

- 1301.1 A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

1302 SOURCE — BOTTLED DRINKING WATER*

- 1302.1 Bottled drinking water used in a food processing operation shall be obtained from approved sources in accordance with 21 CFR 129.1 – Current good manufacturing practice.

1303 QUALITY — STANDARDS*

- 1303.1 Water from a public water system or potable water shall meet the requirements of the applicable provisions of 40 CFR Part 141 – National Primary Drinking Water Regulations, and District of Columbia drinking water quality standards.
- 1303.2 Potable water shall be used for drinking; cooking; washing of food, equipment, food contact surfaces, and utensils; and food preparation.
- 1303.3 Any steam used in a food processing operation or that comes in contact with food contact surfaces shall be free from additives or deleterious substances.

1304 QUALITY — NONDRINKING WATER*

- 1304.1 A nondrinking water or nonpotable water supply may be used only if its use is approved by the Department.
- 1304.2 Nondrinking water may be used for purposes unrelated to food processing including, but not limited to, air conditioning, nonfood equipment cooling, fire protection, irrigation, plant and equipment cleanup, and other sanitary purposes.

1305 QUANTITY AND AVAILABILITY — CAPACITY*

- 1305.1 The water source and system shall be of sufficient capacity to meet the water demands of the food processing operation.
- 1305.2 Hot water generation and distribution systems shall be sufficient to meet the hot water demands throughout the food processing operation.

1306 QUANTITY AND AVAILABILITY — PRESSURE

- 1306.1 Hot or cold water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use hot or cold water.

1307 DISTRIBUTION, DELIVERY, AND RETENTION — SYSTEM

- 1307.1 Water shall be received from the source through the use of an approved public water main, or through one or more of the following, which shall be constructed, maintained, and operated according to the applicable provisions of 40 CFR Part 141 – National Primary Drinking Water Regulations, and District of Columbia drinking water quality standards:

- (a) Water transport vehicles; or
- (b) Water containers.

1308 DISTRIBUTION, DELIVERY, AND RETENTION – ALTERNATIVE WATER SUPPLY

- 1308.1 Water meeting the requirements specified in sections 1300 through 1307 shall be made available for a mobile facility, for a temporary food processing operation without a permanent water supply, and for a food processing operation with a temporary interruption of its water supply through:
- (a) A supply of containers of commercially bottled drinking water;
 - (b) One or more closed portable water containers;
 - (c) An enclosed vehicular water tank;
 - (d) An on-premises water storage tank; or
 - (e) Piping, tubing, or hoses connected to an adjacent approved source.

CHAPTER 14 PLUMBING SYSTEM

1400 MATERIALS – APPROVED MATERIALS, USE *

- 1400.1 A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to the ICC International Plumbing Code/2000 as amended by the D.C. Plumbing Code Supplement/2003 (Title 12F of the District of Columbia Municipal Regulations), and subsequent amendments, hereinafter referred to as the “Plumbing Code”.
- 1400.2 A water filter shall be made of safe materials.

1401 DESIGN, CONSTRUCTION, AND INSTALLATION – APPROVED SYSTEM AND CLEANABLE FIXTURES*

- 1401.1 A plumbing system shall be designed, constructed, and installed according to the Plumbing Code.
- 1401.2 A plumbing system shall be of sufficient size and shall be designed, constructed, installed and maintained according to the Plumbing Code to:
- (a) Carry sufficient quantities of water to required locations throughout the food processing operation;

- (b) Properly convey sewage and liquid disposable waste from the food processing operation;
- (c) Avoid constituting a source of contamination to food, potable water, food contact surfaces, equipment, utensils or food packaging materials, or creating any unsanitary condition; and
- (d) Provide sufficient floor drainage to prevent excessive pooling of water or other disposable waste in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

1401.3 A plumbing fixture such as a handwashing facility, toilet, or urinal shall be easily cleanable.^N

1401.4 Each food processing operation shall be equipped with effective plumbing and sewage facilities and adequate accommodations.

**1402 DESIGN, CONSTRUCTION, AND INSTALLATION —
HANDWASHING SINKS, WATER TEMPERATURE, AND FLOW**

1402.1 All handwashing sinks, including those in toilet rooms, shall be equipped to provide water at a temperature of at least one hundred degrees Fahrenheit (100° F) (thirty-eight degrees Centigrade (38°C)) through a mixing valve, a combination faucet, or tempered water and a single faucet.

1402.2 A steam mixing valve shall not be used at a handwashing sink.

1402.3 A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least fifteen (15) seconds without the need to reactivate the faucet.

1402.4 An automatic handwashing facility shall be installed in accordance with the manufacturer's instructions.

**1403 DESIGN, CONSTRUCTION AND INSTALLATION – TOILETS AND
URINALS**

1403.1 Toilet facilities shall be provided in accordance with section 1908 and the Plumbing Code.

1404 DESIGN, CONSTRUCTION AND INSTALLATION – SERVICE SINKS

1404.1 Service sinks and curbed cleaning facilities shall be provided in accordance with section 1907 and the Plumbing Code.

1405 DESIGN, CONSTRUCTION, AND INSTALLATION – BACKFLOW PREVENTION, AIR GAP*

1405.1 An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than twenty-five millimeters (25 mm) or one inch (1 in).

1406 DESIGN, CONSTRUCTION, AND INSTALLATION – BACKFLOW PREVENTION DEVICE, DESIGN STANDARD

1406.1 A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering standards for construction, installation, maintenance, inspection, and testing for that specific application and type of device.

1407 DESIGN, CONSTRUCTION, AND INSTALLATION – CONDITIONING DEVICE, DESIGN

1407.1 A water filter, screen, or other water-conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

1408 NUMBERS AND CAPACITIES – BACKFLOW PREVENTION DEVICE, WHEN REQUIRED*

1408.1 A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food processing operation, including on a hose bibb if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by the Plumbing Code by:

- (a) Providing an air gap as specified in section 1405; or
- (b) Installing an approved backflow prevention device as specified in section 1406.

1409 NUMBERS AND CAPACITIES — BACKFLOW PREVENTION DEVICE, CARBONATOR*

- 1409.1 If an air gap is not provided as specified in section 1405, a double check valve with an intermediate vent preceded by a screen of not less than one hundred (100) mesh to twenty-five and four tenths millimeters (25.4 mm) (100 mesh to 1 inch) shall be installed upstream from a carbonating device and downstream from any copper in the water supply line.
- 1409.2 A single or double check valve attached to the carbonator need not be of the vented type if an air gap or vented backflow prevention device has been otherwise provided as specified in section 1408.1.

1410 LOCATION AND PLACEMENT — BACKFLOW PREVENTION DEVICE

- 1410.1 A backflow prevention device shall be located so that it may be serviced and maintained.

1411 LOCATION AND PLACEMENT — CONDITIONING DEVICE

- 1411.1 A water filter, screen, or other water-conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

1412 OPERATION AND MAINTENANCE — PROHIBITING A CROSS CONNECTION*

- 1412.1 A person shall not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.
- 1412.2 The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.^N

1413 OPERATION AND MAINTENANCE — SCHEDULING INSPECTION AND SERVICE FOR A WATER SYSTEM DEVICE

- 1413.1 A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with the manufacturer's instructions and as necessary to prevent device failure based on local water conditions. Records demonstrating inspection and service shall be maintained by supervisors.

1414 OPERATION AND MAINTENANCE — WATER RESERVOIR OF FOGGING DEVICES, CLEANING*

1414.1 A reservoir that is used to supply water to a device such as a produce fogger shall be cleaned and maintained in accordance with the manufacturer's specifications, or according to the procedures specified in section 1414.2, whichever is more stringent.

1414.2 Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:

- (a) Draining and complete disassembly of the water and aerosol contact parts;
- (b) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;
- (c) Flushing the complete system with water to remove the detergent solution and particulate accumulation; and
- (d) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least fifty (50) mg/L hypochlorite solution.

1415 OPERATION AND MAINTENANCE — SYSTEM MAINTAINED IN GOOD REPAIR*

1415.1 A plumbing system shall be:

- (a) Repaired according to the Plumbing Code; and
- (b) Maintained in good repair.

**CHAPTER 15 SEWAGE, OTHER LIQUID WASTE,
AND RAINWATER****1500 RETENTION, DRAINAGE, AND DELIVERY — DRAINAGE SYSTEM**

1500.1 Food operation drainage systems, including grease traps, that convey sewage shall be designed, constructed and installed in accordance with the Plumbing Code.

1501 RETENTION, DRAINAGE, AND DELIVERY — BACKFLOW PREVENTION*

1501.1 Except as specified in this section, a direct connection shall not exist between the sewage system and a drain originating from equipment in which food, potable water, portable equipment, utensils, or food packaging materials are placed.

1501.2 Section 1501.1 shall not apply to floor drains that originate in refrigerated spaces that are constructed as an integral part of the building.

1501.3 If allowed by the Plumbing Code, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within one and one-half meters (1.5m) or five feet (5 ft.) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

1501.4 If allowed by the Plumbing Code, a warewashing or culinary sink may have a direct connection.

1502 RETENTION, DRAINAGE, AND DELIVERY — GREASE TRAP

1502.1 A grease trap shall be easily accessible for cleaning.

1503 RETENTION, DRAINAGE, AND DELIVERY — CONVEYING SEWAGE*

1503.1 Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated in accordance with the Plumbing Code.

1504 RETENTION, DRAINAGE, AND DELIVERY — REMOVING FOOD OPERATION WASTES

1504.1 Removal of liquid waste, including grease collections, shall comply with the provisions of this chapter. The licensee shall maintain a copy of the food processing operation's waste service contract on the premises of the food processing operation indicating approved waste servicing areas, and the:

- (a) Name and address of the licensed sewage and liquid waste transport contractor;
- (b) Duration of the contract; and

- (c) Frequency of sewage and liquid waste removal services provided under the contract.

1504.2 Sewage and other liquid wastes shall be removed from a food processing operation by a sewage transport vehicle in such a way that the waste does not constitute a source of contamination in areas where food is exposed, and in such a way that a public health hazard or nuisance is not created.

1505 RETENTION, DRAINAGE, AND DELIVERY — FLUSHING A WASTE RETENTION TANK

1505.1 A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

1506 DISPOSAL FACILITY — APPROVED SYSTEM*

1506.1 Sewage shall be disposed through an approved facility that is a public sewage treatment plant or an individual sewage disposal system that is sized, constructed, maintained, and operated according to the Plumbing Code.

1507 DISPOSAL FACILITY — OTHER LIQUID WASTES AND RAINWATER

1507.1 Condensate drainage and other nonsewage liquids and rainwater shall be drained from point of discharge to disposal according to applicable District laws and regulations.

CHAPTER 16 RECEPTACLES AND WASTE HANDLING UNITS

1600 FACILITIES ON PREMISES — INDOOR STORAGE AREA

1600.1 If located within a food processing operation, storage areas for refuse, recyclables, and returnables shall meet the requirements specified in section 1608.

1601 FACILITIES ON PREMISES — OUTDOOR STORAGE SURFACE

1601.1 An outdoor storage surface for refuse, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be smooth, durable, and sloped to drain.

1602 FACILITIES ON THE PREMISES — OUTDOOR ENCLOSURE

1602.1 If used, an outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials.

1603 FACILITIES ON PREMISES — RECEPTACLES

1603.1 Receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, nonabsorbent and maintained in good repair.

1603.2 Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the food processing operation, or within closed outside receptacles.

1604 FACILITIES ON PREMISES — OUTSIDE RECEPTACLES

1604.1 Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the food processing operation shall be designed and constructed to have tight-fitting lids, doors, or covers.

1604.2 Receptacles and waste handling units for refuse and recyclables such as an on-site compactor shall be installed so that accumulation of debris, insect, and rodent attraction and harborage are minimized, and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

1605 NUMBERS AND CAPACITIES — STORAGE AREAS, ROOMS, AND RECEPTACLES

1605.1 An inside storage room and area, outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold the refuse, recyclables, and returnables that accumulate.

1605.2 A receptacle shall be provided in each area of the food processing operation or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.

1605.3 If disposable towels are used at handwashing sinks, a waste receptacle shall be located at each sink or group of adjacent sinks.

1606 NUMBERS AND CAPACITIES — TOILET ROOM RECEPTACLE, COVERED

1606.1 A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

1607 NUMBERS AND CAPACITIES — CLEANING IMPLEMENTS AND SUPPLIES

1607.1 Except as specified in section 1607.2, suitable cleaning implements and supplies such as high-pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.

1607.2 If approved by the Department, off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.

1608 LOCATION AND PLACEMENT — STORAGE AREAS, REDEEMING MACHINES, RECEPTACLES AND WASTE HANDLING UNITS

1608.1 An area designated for refuse, recyclables, returnables, and a redeeming machine for recyclables or returnables shall be located so that it is separate from food processing, storage and packaging areas and a public health hazard or nuisance is not created.

1608.2 The location of receptacles and waste handling units for refuse, recyclables, and returnables shall not create a public health hazard or nuisance or interfere with the cleaning of adjacent space.

1609 OPERATION AND MAINTENANCE — STORAGE OF REFUSE, RECYCLABLES, AND RETURNABLES

1609.1 Refuse, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

1610 OPERATION AND MAINTENANCE — AREAS, ENCLOSURES, AND RECEPTACLES, GOOD REPAIR

1610.1 Storage areas, enclosures, and receptacles for refuse, recyclables, and returnables shall be maintained in good repair.

1611 OPERATION AND MAINTENANCE – OUTSIDE STORAGE PROHIBITIONS

1611.1 Except as specified in section 1611.2, refuse receptacles not meeting the requirements specified in section 1603, such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue shall not be stored outside.

1611.2 Cardboard or other packaging material that does not contain food residue and is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.

1612 OPERATION AND MAINTENANCE – COVERING RECEPTACLES

1612.1 Receptacles and waste handling units for refuse, recyclables, and returnables located inside the food procession operation shall be kept covered after they are filled or if they contain food residue and are not in continuous use. If located outside the food processing operation, receptacles and units shall be kept covered with tight-fitting lids or doors.

1613 OPERATION AND MAINTENANCE – USING DRAIN PLUGS

1613.1 Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place.

1614 OPERATION AND MAINTENANCE – REFUSE AREAS AND ENCLOSURES

1614.1 Storage areas and enclosures for refuse, recyclables, or returnables shall be kept clean, and maintained free of unnecessary items, as specified in section 2000.

1615 OPERATION AND MAINTENANCE – LOCATION

1615.1 Storage areas and enclosures for receptacles and waste handling equipment shall be located at a distance from the building that minimizes the entrance of pests and other vermin.

1616 OPERATION AND MAINTENANCE – CLEANING RECEPTACLES

1616.1 Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, utensils, equipment, food-contact surfaces, or food-packaging materials, and waste water shall be disposed of as specified in sections 1503 and 1504.

- 1616.2 Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

1617 REMOVAL — FREQUENCY

- 1617.1 Refuse, recyclables, and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents and that protects against contamination of food, utensils, equipment, food-contact surfaces, food packaging materials, water supplies, and ground surfaces.
- 1617.2 The licensee shall maintain a copy of the facility's professional service contract which documents the following information:
- (a) Name and address of its licensed trash or solid waste contractor;
 - (b) Duration of the contract; and
 - (c) Frequency of trash or solid waste collection services provided under the contract.
- 1617.3 Trash or solid waste collection shall comply with title 21, chapter 7 of the DCMR.

1618 REMOVAL — RECEPTACLES OR VEHICLES

- 1618.1 Refuse, recyclables, and returnables shall be removed from the premises by way of:
- (a) Portable receptacles that meet District law; or
 - (b) A transport vehicle that is maintained and operated according to District law.

SUBTITLE F: PHYSICAL FACILITIES

**CHAPTER 17 MATERIALS FOR CONSTRUCTION AND
REPAIR OF PHYSICAL FACILITIES**

1700 INDOOR AREAS — SURFACE CHARACTERISTICS

- 1700.1 Materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

- (a) Smooth, durable, and easily cleanable for areas where food operations are conducted;
- (b) Closely woven and easily cleanable carpet for carpeted areas; and
- (c) Nonabsorbent for areas subject to moisture, such as food processing areas, walk-in refrigerators, toilet rooms, and areas subject to flushing or spray cleaning methods.

1701 OUTDOOR AREAS — SURFACE CHARACTERISTICS

- 1701.1 The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel, or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.
- 1701.2 Exterior surfaces of buildings shall be of weather-resistant materials, and shall comply with applicable District laws and regulations.
- 1701.3 Outdoor storage areas for refuse, recyclables, or returnables shall be constructed of materials specified in sections 1601 and 1602.

CHAPTER 18 DESIGN, CONSTRUCTION, AND INSTALLATION OF PHYSICAL FACILITIES

1800 DESIGN AND CONSTRUCTION — PHYSICAL FACILITIES

- 1800.1 Physical facilities shall be adequate in size, construction, and design to facilitate maintenance and the sanitary operation of the food processing operation in accordance with 21 CFR 110.20 – Plant and grounds, 21 CFR 110.35 – Sanitary operations, 21 CFR 110.37 – Sanitary facilities and controls, and this Code.
- 1800.2 The floor of every workroom shall be maintained, as far as practicable, in a dry condition. Where wet processes are used, drainage shall be maintained and false floors, platforms, mats, or other dry standing places shall be provided. Where practicable and appropriate, waterproof footwear shall be provided.

1801 CLEANABILITY — FLOORS, WALLS, AND CEILINGS

- 1801.1 Except as specified in section 1804, the floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are smooth and easily cleanable, except that antislip floor coverings or applications may be used for safety reasons.

1801.2 To facilitate cleaning, floors, workrooms, and passageways shall be kept free from protruding nails, splinters, loose boards, and unnecessary holes and openings.

1802 CLEANABILITY — FLOORS, WALLS, CEILINGS, AND UTILITY LINES

1802.1 Utility service lines and pipes shall not be unnecessarily exposed.

1802.2 Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

1802.3 Exposed horizontal utility service lines and pipes shall not be installed on the floor.

1803 CLEANABILITY — FLOOR AND WALL JUNCTURES, COVERED, AND ENCLOSED OR SEALED

1803.1 In food processing operations in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be covered and closed to no larger than one millimeter (1 mm) or one thirty-second of an inch (1/32 in.).

1803.2 The floors in food processing operations in which water flush cleaning methods are used shall be provided with floor drains and be graded to drain. The floor and wall junctures shall be covered and sealed.

1804 CLEANABILITY — FLOOR CARPETING, RESTRICTIONS AND INSTALLATION

1804.1 A floor covering such as carpeting or similar material shall not be installed as a floor covering in food processing areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing sinks, toilets, or urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

1804.2 If carpeting is installed as a floor covering in areas other than those specified in section 1804.1, it shall be:

- (a) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another similar method; and
- (b) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with

the edges of the carpet secured by metal stripping or some other means.

1805 CLEANABILITY — FLOOR COVERING, MATS AND DUCKBOARDS

1805.1 Mats and duckboards shall be designed to be removable and easily cleanable.

1806 CLEANABILITY — WALL AND CEILING COVERINGS AND COATINGS

1806.1 Wall and ceiling covering materials shall be attached so that they are easily cleanable.

1806.2 Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and sealed to provide a smooth, nonabsorbent, easily cleanable surface.

1807 CLEANABILITY AND EXPOSURE — WALLS AND CEILINGS, ATTACHMENTS, STUDS, JOISTS, AND RAFTERS

1807.1 Except as specified in section 1807.2, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be easily cleanable.

1807.2 In public areas, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet the requirements of section 1807.1 if they are kept clean.

1807.3 Studs, joists, and rafters shall not be exposed in areas subject to moisture.

1808 FUNCTIONALITY – LIGHTING, INTENSITY

1808.1 The light intensity inside a food processing operation shall be:

- (a) At least one hundred and eight (108) lux or ten (10) foot candles at a distance of seventy-five centimeters (75 cm) or thirty inches (30 in.) above the floor in walk-in refrigeration units and dry food storage areas and in other areas and rooms during periods of cleaning;
- (b) At least two hundred and fifteen (215) lux or twenty (20) foot candles:
 - (1) Inside equipment such as reach-in and under-counter refrigerators; and

- (2) At a distance of seventy-five centimeters (75 cm) or thirty inches (30 in.) above the floor in areas used for handwashing, warewashing, storage of equipment, utensil or food-packaging materials, and in toilet rooms; and
- (c) At least five hundred and forty (540) lux or fifty (50) foot candles at the working surface of a food processing area where a food employee is working with food or working with utensils or equipment including knives, slicers, grinders, or saws where employee safety is a factor, and in areas used for warewashing.

1809 FUNCTIONALITY – LIGHT BULBS, PROTECTIVE SHIELDING

- 1809.1 Except as specified in section 1809.2, light bulbs shall be shielded, coated, or otherwise shatter-resistant in all areas where food is examined, processed, or stored, and where equipment or utensils are cleaned.
- 1809.2 Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages, if:
 - (a) The integrity of the packages cannot be affected by broken glass falling onto them; and
 - (b) The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.
- 1809.3 An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

1810 FUNCTIONALITY – VENTILATION, MECHANICAL

- 1810.1 All rooms shall have sufficient tempered make-up air and exhaust ventilation to keep them free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes.
- 1810.2 All ventilation systems, furnaces, gas- or oil-fired room heaters, and water heaters shall be designed, installed, and operated in accordance with the Plumbing Code.
- 1810.3 Each room in which food or drink is prepared, or in which utensils are washed, shall be provided with facilities for at least eight (8) air changes per hour. Recirculation of air is not permitted.

1810.4 Each food processing operation that creates smoke, steam, gases, fumes, odors, vapors, or excessive heat shall be hooded and vented, or locally vented to the outside air by forced draft, in a manner that will effectively remove the conditions.

**1811 FUNCTIONALITY – HEATING, VENTILATING, AIR
CONDITIONING SYSTEM VENTS**

1811.1 Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, food packaging materials, equipment, or utensils.

1811.2 Adequate ventilation or control equipment shall be provided to minimize odors and vapors, including steam and noxious fumes, in areas where they may contaminate food; and fans and other air blowing equipment shall be located and operated in a manner that minimizes the potential for contaminating food, utensils, equipment, food-packaging materials, and food-contact surfaces.

1811.3 Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

1811.4 Ventilation systems may not create a public health hazard or nuisance or unlawful discharge, if vented to the outside.

**1812 FUNCTIONALITY – INSECT CONTROL DEVICES, DESIGN AND
INSTALLATION**

1812.1 Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

1812.2 Insect control devices shall be installed so that:

- (a) The devices are not located over a food preparation area; and
- (b) Dead insects and insect fragments are prevented from being impelled onto or falling onto exposed food, clean equipment, utensils and food-contact surfaces, or food-packaging materials.

1813 FUNCTIONALITY – OUTER OPENINGS, PROTECTED

1813.1 Except as otherwise specified in this section, the outer openings of a food processing operation shall be protected against the entry of insects, rodents or other vermin by:

- (a) Filling or closing holes and other gaps along floors, walls, and ceilings;
 - (b) Closed, tight-fitting windows; and
 - (c) Solid, self-closing, tight-fitting doors, except that dock doors need not be self-closing.
- 1813.2 Section 1813.1 shall not apply if a food processing operation opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.
- 1813.3 Exterior doors used as exits need not be self-closing if they are:
 - (a) Solid and tight-fitting;
 - (b) Designated only for emergency by the Fire Department; and
 - (c) Restricted so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.
- 1813.4 Except as specified sections 1813.2 and 1813.5, if the windows or doors of a food processing operation are kept open for ventilation or other purposes, the openings shall be protected against the entry of insects and rodents by:
 - (a) Sixteen (16) mesh to twenty-five and four tenths millimeters (25.4 mm) or sixteen (16) mesh to one inch (1 in.) screens;
 - (b) Properly designed and installed air curtains to control flying insects; or
 - (c) Other effective means that prohibit the entry of insects and rodents to a similar degree.
- 1813.5 Section 1813.4 does not apply if flying insects and other pests are absent due to the location of the food processing operation, the weather, or other limiting conditions.
- 1814 FUNCTIONALITY – EXTERIOR WALLS AND ROOFS, PROTECTIVE BARRIER**
- 1814.1 Perimeter walls and roofs of a food processing operation shall effectively protect the food processing operation from the weather and the entry of insects, rodents, and other animals.

1815 FUNCTIONALITY – OUTDOOR FOOD VENDING AREAS, OVERHEAD PROTECTION

1815.1 If located outside, a machine used to vend food shall be provided with overhead protection, except that a machine vending canned beverages need not meet this requirement.

1816 FUNCTIONALITY – OUTDOOR SERVICING AREAS, OVERHEAD PROTECTION

1816.1 Servicing areas shall be provided with overhead protection, except that areas used only for the loading of water or the discharge of sewage and other liquid waste through the use of a closed system of hoses need not be provided with overhead protection.

1817 FUNCTIONALITY – OUTDOOR WALKING AND DRIVING SURFACES, GRADED TO DRAIN

1817.1 Exterior walking and driving surfaces shall be graded to drain.

1818 FUNCTIONALITY – OUTDOOR REFUSE AREAS, CURBED AND GRADED TO DRAIN

1818.1 Outdoor refuse areas shall be constructed, curbed and graded to drain to collect and dispose of liquid waste that results from the refuse and from cleaning the area and waste receptacles.

1819 FUNCTIONALITY – PRIVATE HOMES AND LIVING OR SLEEPING QUARTERS, USE PROHIBITION

1819.1 A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters shall not be used for food-handling or conducting food operations.

1820 FUNCTIONALITY – LIVING OR SLEEPING QUARTERS, SEPARATION

1820.1 Living or sleeping quarters located on the premises of a food processing operation, such as those provided for security personnel, shall be separated from rooms and areas used for food operations by complete partitioning and solid, self-closing doors.

1820.2 Access to any place designed, intended, or used for human habitation shall not be through a food processing operation, but shall be by means of a separate entrance.

**CHAPTER 19 NUMBER, CAPACITY, LOCATION, AND OPERATION
OF PHYSICAL FACILITIES****1900 HANDWASHING SINKS – NUMBER, AND LOCATION**

1900.1 Handwashing sinks shall be located to allow convenient use by employees in food processing areas, and in, or immediately adjacent to, toilet rooms.

1900.2 Handwashing sinks located in the toilet rooms, or within an anteroom or vestibule serving a toilet room, do not meet the requirements for handwashing sinks in operating areas for persons working in any capacity the activities of which include contact with unprotected food for human consumption, or the care and use of food contact surfaces.

1900.3 Any area of food operation in which open food is handled shall have its own handwashing sink, other than a toilet room, which shall be located not more than twenty feet (20 ft.) from where the food is handled; provided, that the Department shall have the discretion to require that this handwashing sink be located closer than twenty feet (20 ft.) from the area where food is handled.

1900.4 The Department may permit the continuing use of existing handwashing sinks to meet the requirements of this section if the sinks:

- (a) Are immediately adjacent to the operational areas they are intended to serve;
- (b) Are not available to or used by the public; and
- (c) Do not serve more than three (3) persons when the activities of any person involve contact with unprotected food for human consumption or the care and use of food contact surfaces.

1900.5 If approved and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing sinks in a food processing operation that has at least one (1) handwashing sink.

1901 HANDWASHING SINKS -- USE

1901.1 A handwashing sink shall be maintained so that it is accessible at all times for employees' use.

1901.2 A handwashing sink shall not be used for purposes other than handwashing.

1901.3 An automatic handwashing facility shall be used in accordance with the manufacturer's instructions.

1902 HANDWASHING SINKS — HANDWASHING CLEANSER, AVAILABILITY

1902.1 Each handwashing sink or group of two (2) adjacent sinks shall be provided with hand cleaning liquid or powder.

1903 HANDWASHING SINKS — HAND DRYING PROVISION

1903.1 Each handwashing sink or group of adjacent sinks shall be provided with:

- (a) Individual, disposable towels; or
- (b) A heated-air hand-drying device, except that a heated-air hand-drying device shall not be the only device provided at a sink used by employees in a food processing area.

1904 HANDWASHING SINKS — HANDWASHING AIDS AND DEVICES, USE RESTRICTIONS

1904.1 A sink used for food preparation or utensil washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, shall not be provided with the handwashing aids and devices required for a handwashing sink as specified in sections 1902, 1903, and 1906.1.

1905 HANDWASHING SINKS — HANDWASHING SIGNAGE

1905.1 A sign or poster that notifies food employees to wash their hands shall be provided at all handwashing sinks used by food employees and shall be clearly visible to food employees.

1905.2 Food processing operations shall provide signs directing food employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces where to wash and, where appropriate, to sanitize their hands.

1905.3 Handwashing signs shall be posted in food processing areas and in all other areas where employees handle food, food-packaging materials, or food-contact surfaces. If necessary, the signs shall be multilingual.

1906 HANDWASHING SINKS — DISPOSABLE TOWELS, WASTE RECEPTACLE

- 1906.1 A handwashing sink or group of adjacent sinks that is provided with disposable towels or suitable drying devices shall be provided with a waste receptacle as specified in section 1605.3.

1907 SERVICE SINKS – NUMBERS AND CAPACITIES

- 1907.1 At least one (1) service sink or one (1) curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

1908 TOILETS AND URINALS — NUMBER, CAPACITY, CONVENIENCE AND ACCESSIBILITY*

- 1908.1 Each food processing operation shall maintain toilet facilities for employees, which shall consist of a toilet room or toilet rooms with proper and sufficient water closets and lavatories. Toilet facilities shall be conveniently located and readily accessible to all operating personnel.
- 1908.2 Toilets and urinals provided for employees' use shall be in accordance with the Plumbing Code. Urinals may be substituted for toilets if the substitution is approved by the Department of Consumer and Regulatory Affairs and the Department.
- 1908.3 The licensee shall, at a minimum:
- (a) Maintain the toilet facilities in a sanitary condition that is clean and free of trash and litter;
 - (b) Keep the facilities in good repair at all times;
 - (c) Provide self-closing doors; and
 - (d) Provide doors that do not open into areas where food is exposed to airborne contamination except where alternate means have been taken to protect against contamination, such as double doors or positive airflow systems.
- 1908.4 A food processing operation that employs both males and females shall have separate toilet facilities for each sex; provided, that a food operation with five (5) or fewer employees may allow employees of both sexes to use a single toilet facility.

1908.5 Toilet facilities shall be deemed conveniently located and accessible to employees during all hours of operation if they are:

- (a) Located within the same building as the business they serve; and
- (b) Accessible during working hours without going outside the building.

1909 TOILETS AND URINALS — TOILET ROOMS ENCLOSED

1909.1 A toilet room located on the premises shall be completely enclosed and provided with a tight-fitting and self-closing door, except that this requirement does not apply to a toilet room that is located outside a food processing operation and does not open directly into the food processing operation.

1909.2 Toilet room doors shall be kept closed except during cleaning and maintenance operations.

1910 TOILETS AND URINALS — TOILET TISSUE, RECEPTACLE AVAILABILITY

1910.1 A supply of toilet tissue shall be available at each toilet.

1910.2 A covered receptacle for sanitary napkins shall be provided, as appropriate, in accordance with section 1606.1.

1911 EMPLOYEE ACCOMMODATIONS — DESIGNATED AREAS, CHANGING ROOMS, SHOWERS FACILITIES

1911.1 Areas designated for employees to eat, drink, and use tobacco shall be located so that food, equipment, utensils, food-contact surfaces, or food-packaging materials are protected from contamination.

1911.2 Locker rooms shall be used by employees if employees regularly change their clothes in the establishment

1911.3 Lockers or other suitable facilities shall be provided for the orderly storage of employees' clothing, either personal or supplied by management, and other possessions in a designated room or area where contamination of food, equipment, utensils, food contact surfaces, or food-packaging materials can not occur.

1911.4 A food operation that requires employees to wear protective clothing because of the possibility of contamination shall provide changing rooms

equipped with storage facilities for street clothes and separate storage facilities for the protective clothing

1911.5 When a food operation provides work clothes that become wet or are washed between shifts, clothes drying facilities shall be provided to insure that such clothing is dry before reuse.

1911.6 A food operation that requires employees to shower because of a particular food processing standard shall provide one shower for every ten (10) employees of each sex, or numerical fraction thereof, who are required to shower during the same shift.

1911.7 Each shower shall be conveniently equipped with:

- (a) Body soap or other appropriate cleansing agents;
- (b) Hot and cold water feeding a common discharge line; and
- (c) A supply of individual clean towels for employees who use the showers.

1912 DISTRESSED MERCHANDISE — SEGREGATION AND LOCATION

1912.1 Products that are returned to the distributor for credit or redemption, including damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from food, equipment, utensils, food-contact surfaces, and food-packaging materials.

CHAPTER 20 MAINTENANCE OF PHYSICAL FACILITIES

2000 PHYSICAL FACILITIES — MAINTAINING PREMISES, UNNECESSARY ITEMS AND LITTER

2000.1 The grounds surrounding a food processing operation under the control of the licensee shall be kept in a condition that will protect against the contamination of food, equipment, utensils, food-contact surfaces, or food-packaging materials.

2000.2 The methods for adequate maintenance of grounds include, but are not limited to, the following:

- (a) Properly storing or removing unnecessary equipment that is nonfunctional or no longer used, removing litter and waste, and cutting

weeds or grass within the immediate vicinity of the physical facility that may constitute an attractant, breeding place or harborage for pests.

- (b) Maintaining roads and parking lots so that they do not constitute a source of contamination in areas where food, equipment, utensils, food-contact surfaces, or food-packaging materials are exposed.
- (c) Adequately draining areas that may contribute contamination to food, equipment, utensils, food-contact surfaces, or food-packaging materials by seepage, foot-borne filth or providing a breeding place for pests.

2000.3 If the food processing operation's grounds are bordered by grounds not under the operator's control and not maintained in the manner described in section 2000.2, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of contamination to food, equipment, utensils, food-contact surfaces, or food-packaging materials.

2000.4 Methods for maintaining a sanitary operation include, but are not limited to, the following:

- (a) Providing sufficient space for placement of equipment and storage of materials; and
- (b) Taking precautions to reduce the potential for contamination of food, equipment, utensils, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination shall be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

2001 PHYSICAL FACILITIES — REPAIRING

2001.1 The physical facilities shall be maintained in good repair.

2002 PHYSICAL FACILITIES — CLEANING FREQUENCY AND RESTRICTIONS

2002.1 The physical facilities shall be cleaned as often as necessary to keep them clean.

2002.2 Except for cleaning that is necessary due to a spill or other accident, cleaning shall be done during periods when the least amount of food is exposed, such as after closing.

2003 PHYSICAL FACILITIES — CLEANING FLOORS, DUSTLESS METHODS

2003.1 Except as provided in section 2003.2, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops or sweeping using a broom and dust-arresting compounds. If mops or similar wet floor cleaning tools are used, at least one (1) service sink or one (1) curbed cleaning facility equipped with a floor drain and supplied with hot and cold water under pressure shall be provided and conveniently located.

2003.2 Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:

- (a) Without the use of dust-arresting compounds; and
- (b) In the case of liquid spills or drippage, with the use of a small amount of absorbent compound, such as sawdust or diatomaceous earth, applied immediately before spot cleaning.

2004 PHYSICAL FACILITIES — CLEANING VENTILATION SYSTEMS, NUISANCE, AND DISCHARGE PROHIBITION

2004.1 Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

2004.2 If vented to the outside, ventilation systems shall not create a public health hazard or nuisance, or unlawful discharge.

2005 PHYSICAL FACILITIES — CLEANING MAINTENANCE TOOLS, PREVENTING CONTAMINATION*

2005.1 Food preparation sinks, handwashing sinks, and warewashing equipment shall not be used to clean maintenance tools, to prepare or hold maintenance materials, or for the disposal of mop water and similar liquid wastes.

2006 PHYSICAL FACILITIES — DRYING MOPS

2006.1 After use, mops shall be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies.

2007 PHYSICAL FACILITIES — ABSORBENT MATERIALS ON FLOORS, USE LIMITATION

2007.1 Except as specified in section 2003.2, sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials shall not be used on floors.

2008 PHYSICAL FACILITIES — CLEANING OF PLUMBING FIXTURES

2008.1 Plumbing fixtures such as handwashing sinks, toilets, and urinals shall be cleaned as often as necessary to keep them clean and well-maintained.

2009 PHYSICAL FACILITIES — CONTROLLING PESTS*

2009.1 The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by:

- (a) Routinely inspecting incoming shipments of food and supplies;^N
- (b) Routinely inspecting the premises for evidence of pests;^N
- (c) Using methods, if pests are found, such as trapping devices or other means of pest control as specified in sections 2202, 2211 and 2212; and
- (d) Eliminating harborage conditions.^N

2009.2 The licensee shall maintain a copy of the establishment's professional service contract and service schedule, which documents the following information:

- (a) Name and address of its licensed pest exterminator / contractor;
- (b) Frequency of pest extermination services provided under the contract; and
- (c) Date pest extermination services were last provided to the establishment.

2010 PHYSICAL FACILITIES — REMOVING DEAD OR TRAPPED BIRDS, INSECTS, RODENTS, AND OTHER PESTS

2010.1 Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition or the attraction of pests.

2011 PHYSICAL FACILITIES — STORING MAINTENANCE TOOLS

2011.1 Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

- (a) Stored so they do not contaminate food, equipment, utensils, food-contact surfaces, or food-packaging materials; and
- (b) Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

2012 PHYSICAL FACILITIES — PROHIBITING ANIMALS*

2012.1 Patrol dogs accompanying police or security officers and sentry dogs running loose in outside fenced areas may be allowed in some areas of a food processing operation if the presence of the animals cannot result in contamination of food, equipment, utensils, food-contact surfaces, or food-packaging materials.

SUBTITLE G: POISONIOUS OR TOXIC MATERIALS**CHAPTER 21 LABELING AND IDENTIFICATION OF POISONOUS OR TOXIC MATERIALS****2100 ORIGINAL CONTAINERS — IDENTIFYING INFORMATION, PROMINENCE***

2100.1 Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label.

2101 WORKING CONTAINERS — COMMON NAME*

2101.1 Working containers used for storing poisonous or toxic materials, such as cleaners and sanitizers taken from bulk supplies shall be clearly and individually identified with the common name of the material.

CHAPTER 22 OPERATIONAL SUPPLIES AND APPLICATIONS OF POISONOUS OR TOXIC MATERIALS**2200 STORAGE — SEPARATION***

2200.1 Poisonous or toxic materials shall be stored and transported so they can not contaminate food, equipment, utensils, food-contact surfaces, or food-packaging materials by:

- (a) Separating the poisonous or toxic materials by spacing or partitioning; and
- (b) Locating the poisonous or toxic materials in an area that is not above food processing areas, equipment, utensils, or food-packaging materials. This paragraph does not apply to equipment and cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, food-contact surfaces, and food-packaging materials.

2201 PRESENCE AND USE — RESTRICTION*

- 2201.1 Restricted-use pesticides shall be applied only by a certified applicator as defined in section 2 of the Pesticide Operations Act of 1977, effective April 18, 1978 (D.C. Law 2-70; D.C. Official Code § 8-401).
- 2201.2 Only the following toxic materials may be used or stored in a food processing operation where food is processed or exposed:
- (a) Chemicals required for maintaining clean and sanitary conditions;
 - (b) Chemicals necessary for use in laboratory testing procedures;
 - (c) Chemicals necessary for plant and equipment maintenance and operation; and
 - (d) Chemicals necessary for use in the plant's operations.
- 2201.3 Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, equipment, utensils, food-contact surfaces, and food-packaging materials.

2202 PRESENCE AND USE — CONDITIONS OF USE*

- 2202.1 Poisonous or toxic materials shall be used according to:
- (a) The Pesticide Operations Act of 1977, effective April 18, 1978 (D.C. Law 2-70; D.C. Official Code § 8-401 *et seq.*), and this Code;
 - (b) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state use is allowed in a food processing operation; and

- (c) The conditions of certification, if certification is required, for use of the pest control materials.

2202.2 Poisonous or toxic materials shall be applied so that:

- (a) A hazard to employees or other persons is not constituted;
- (b) Contamination including toxic residues due to drip, drain, fog, splash, or spray on food, equipment, utensils, food-contact surfaces, and food-packaging materials is prevented; and
- (c) For restricted-use pesticides, contamination is prevented by:
 - (1) Removing items listed in paragraph (b);
 - (2) Covering items listed in paragraph (b) with impermeable covers;
 - (3) Taking other appropriate preventive actions; and
 - (4) Cleaning and sanitizing equipment, utensils, food-contact surfaces, and food-packaging materials after the application.

2203 CONTAINER PROHIBITIONS — POISONOUS OR TOXIC MATERIAL CONTAINERS*

2203.1 A container previously used to store poisonous or toxic materials shall not be used to store, transport, or dispense food.

2204 CHEMICALS — SANITIZERS, CRITERIA*

2204.1 Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements of 40 CFR 180.940 – Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

2205 CHEMICALS — CLEANING COMPOUNDS, SANITIZERS*

2205.1 Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use.

2205.2 Compliance with this requirement may be verified by an effective means including, but not limited to, purchase of substances under a supplier's guarantee or certification, or examination of the substances for contamination.

2206 CHEMICALS — WASHING FRUITS AND VEGETABLES, CRITERIA*

2206.1 Chemicals used to wash or peel whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 – Chemicals used in washing or to assist in the peeling of fruits and vegetables.

2207 CHEMICALS — BOILER WATER ADDITIVES, CRITERIA*

2207.1 Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310 – Boiler water additives.

2208 CHEMICALS — DRYING AGENTS, CRITERIA*

2208.1 Drying agents used in conjunction with sanitization shall contain only components that are listed as one of the following:

- (a) Generally recognized as safe for use in food as specified in 21 CFR Part 182 – Substances Generally Recognized as Safe or 21 CFR Part 184 – Direct Food Substances Affirmed as Generally Recognized as Safe;
- (b) Generally recognized as safe for the intended use as specified in 21 CFR Part 186 – Indirect Food Substances Affirmed as Generally Recognized as Safe;
- (c) Approved for use as a drying agent under a prior sanction specified in 21 CFR Part 181 – Prior Sanctioned Food Ingredients;
- (d) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175 – 178 – Indirect Food Additives: Adhesives and Components of Coatings; Indirect Food Additives: Paper and Paperboard Components; Indirect Food Additives: Polymers; Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; or
- (e) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 – Threshold of regulation for substances used in food-contact articles.

2208.2 When sanitization is used with chemicals, the approval required in section 2208.1(c) or 2208.1(e) or the regulation as an indirect food additive required in section 2208.1(d) shall be specifically for use with chemical sanitizing solutions.

2209 LUBRICANTS — INCIDENTAL FOOD CONTACT, CRITERIA*

- 2209.1 Lubricants shall meet the requirements specified in 21 CFR 178.3570 — Lubricants with incidental food contact, if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces.

2210 PESTICIDES — RESTRICTED USE PESTICIDES, CRITERIA*

- 2210.1 Restricted use pesticides shall meet the requirements specified in 40 CFR 152.170 — Criteria for restriction to use by certified applicators.

2211 PESTICIDES — RODENT BAIT STATIONS*

- 2211.1 Rodent bait shall be contained in a covered, tamper-resistant bait station.

2212 PESTICIDES — TRACKING POWDERS, PEST CONTROL AND MONITORING*

- 2212.1 A tracking powder pesticide may not be used in a food processing operation, except as specified in section 2212.2.
- 2212.2 If used, a nontoxic tracking powder such as talcum or flour may not contaminate food, equipment, utensils, food-contact surfaces, or food-packaging materials.

2213 FIRST AID SUPPLIES — STORAGE*

- 2213.1 First aid supplies that are in a food processing operation for the employees' use shall be:
- (a) Labeled as specified in section 2100 of this Code; and
 - (b) Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, food-contact surfaces, and food-packing materials.

2214 OTHER PERSONAL CARE ITEMS — STORAGE

- 2214.1 Employees shall store their personal care items in separate cabinets or storage lockers specified in section 1911.3, except as specified in section 2213.

**SUBTITLE H: SHELLFISH PROCESSING
OPERATIONS**

CHAPTER 23 ADMINISTRATION AND CERTIFICATION

2300 ADMINISTRATION — DEPARTMENT RECORDKEEPING

2300.1 The Department shall maintain records to demonstrate the effective administration of a District-wide shellfish safety and sanitation program to regulate:

- (a) Shellfish processing procedures and facilities;
- (b) Product labeling;
- (c) Storage, handling and packing;
- (d) Shellfish shipment in interstate commerce; and
- (e) Shellfish dealers.

2300.2 These records shall be maintained in a central file and made available to any interested person upon request, consistent with applicable District and federal law.

2301 CERTIFICATES — PREREQUISITE FOR OPERATION

2301.1 No person shall act as a shellfish dealer prior to obtaining a certificate from the Department.

2301.2 A person who wants to be a certified as a shellfish dealer shall:

- (a) Apply to the Department for certification or recertification pursuant to section 2302;
- (b) Have and implement a HACCP plan, have a program of sanitation monitoring and record keeping, and conform to all other requirements listed in the most recent edition of the Interstate Shellfish Sanitation Conference Guide for the Control of Molluscan Shellfish;
- (c) Have a permanent business address at which inspections of facilities, activities, or equipment can be conducted and records are maintained; and
- (d) Pay the appropriate license fee.

2302 CERTIFICATES — APPLICATION PROCEDURE

2302.1 Any person who engages in the wholesale handling, shipping, or repacking of shellfish shall be deemed to be a shellfish dealer (hereinafter “dealer”) and shall apply for certification or renewal of certification as a shellfish dealer in writing on a form supplied by the Department. The certification shall authorize the dealer to conduct a shellfish operation at a specified location. Applicants shall provide all information required on the form, including:

- (a) Name of the owner of the business;
- (b) Mailing address and telephone number of the owner of the business;
- (c) Address of the shellfish operation;
- (d) Trade name of the shellfish operation;
- (e) Name and address of corporate officers;
- (f) Name and country of registered agent, if applicable;
- (g) Type and source of shellfish to be handled;
- (h) Type of operation to be carried out; and
- (i) Whether shellfish will be sold in interstate commerce.

2303 GENERAL REQUIREMENTS — TYPES OF SHELLFISH DEALER CERTIFICATIONS

2303.1 Any dealer who shucks and packs shellfish shall be certified as a shucker-packer. A shucker-packer may act as a shellstock shipper, or reshipper, or may repack shellfish originating from other dealers.

2303.2 Any dealer who repacks shucked shellfish shall be certified as a repacker. A repacker may act as a shellstock shipper or reshipper.

2303.3 Any dealer who buys, repacks, or sells shellstock shall be certified as a shellstock shipper. A shellstock shipper may also ship shellfish shucked by a certified shucker-packer.

2303.4 Any dealer who only purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers, or retailers shall be certified as a reshipper.

2304 DEALER CERTIFICATION – GENERAL REQUIREMENTS

- 2304.1 An applicant requesting an initial certification or a dealer seeking to renew an existing certification shall be subject to a comprehensive, onsite inspection and shall meet the requirements specified in section 2305.1.
- 2304.2 Inspection of shellfish operations shall be conducted only by the Department's shellfish standardization inspector. The inspection shall be documented on the appropriate inspection form within one hundred and twenty (120) business days immediately prior to the issuance of an initial or renewal certification.
- 2304.3 The Department shall issue one (1) certification to a dealer for each location. An applicant or dealer may obtain more than one (1) certification if each shellfish operation:
- (a) Is operated as a separate entity; and
 - (b) Is not found at the same location.
- 2304.4 The Department may permit separate certified dealers to share a facility. A unique certification shall be issued by the Department to each dealer.

2305 DEALER CERTIFICATION – INITIAL REQUIREMENTS

- 2305.1 An initial certification shall be issued by the Department only when the applicant has met the following requirements:
- (a) The applicant has an HACCP plan approved by the Department; and
 - (b) Not more than two (2) critical violations and two (2) noncritical violations are cited during an inspection of the dealer's operation in accordance with section 2304.1.
- 2305.2 If the dealer's operation contains violations, the initial certification shall include a compliance schedule to correct any violations not corrected by the dealer during the inspection.

2306 DEALER CERTIFICATION – RENEWAL REQUIREMENTS

- 2306.1 A dealer shall make application for certification renewal annually in accordance with section 2302. The Department shall not renew the certification for any dealer unless the dealer:
- (a) Meets the requirements specified in section 2305.1; and

- (b) Agrees to a compliance schedule to address any new violations not corrected by the dealer during the inspection.

2306.2 The number of violations allowed for renewal applications shall include carry over violations from an existing compliance schedule approved by the Department and new violations identified during the certification renewal inspection.

2307 CERTIFICATES — RESPONSIBILITIES OF THE DEPARTMENT

2307.1 The Department shall issue a shellfish certification upon receipt of the application and upon approval of the facilities and sanitary condition of the shellfish operation.

2307.2 When the Department certifies an applicant to become a dealer, the Department shall notify the FDA for the purpose of having the dealer listed in the Interstate Certified Shellfish Shippers List (ICSSL). The notice shall be in the format of FDA Form 3038.

2307.3 The Department shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certification is suspended or revoked.

2307.4 The Department shall inspect current certifications, which the dealer shall keep on file at the shellfish operation.

2308 DEALER CERTIFICATION — RECORDKEEPING REQUIREMENTS

2308.1 Each dealer shall maintain adequate records documenting compliance with certification requirements for at least three (3) years. These records shall include:

- (a) Inspection reports of dealers;
- (b) Notification letters and enforcement actions;
- (c) Shellfish sample results and follow-up actions taken;
- (d) Records of complaints or inquiries and follow-up actions taken; and
- (e) Administrative hearing transcripts and records.

2309 CERTIFICATES — EXPIRATION DATE

2309.1 All shellfish certifications shall expire on June 30th of each year and shall be renewed annually. In no case shall a dealer conduct a shellfish operation without a valid certification issued by the Department.

2310 CERTIFICATES — NOT TRANSFERABLE

2310.1 A shellfish certification shall not be transferable with respect to persons or locations.

2311 CERTIFICATES — DISCONTINUANCE OF OPERATION

2311.1 A certified dealer shall submit a “Statement of Discontinuance of Operations” to the Department at least thirty (30) calendar days before discontinuing its operations in accordance with section 3104.2.

2312 DEALER CERTIFICATION — REVOCATION OR SUSPENSION OF CERTIFICATES

2312.1 A dealer whose certification has been suspended or revoked in accordance with section 3521.1, or whose certification is automatically withdrawn from the ICSSL on the date of expiration shall not conduct shellfish operations at any facility that no longer has a valid certification until the dealer meets the requirements of section 2305 or 2306, obtains a new certification from the Department for the facility, and is listed on the ICSSL pursuant to section 2307.2.

**CHAPTER 24 TAGS, LABELING
& RECORDKEEPING****2400 GENERAL REQUIREMENTS –DEALER TAGS FOR SHELLFISH**

2400.1 A dealer shall buy shellfish only from sources certified by the Department or listed in the current ICSSL.

2400.2 A dealer shall receive shellfish with the dealer’s tag or label affixed to each container of shellfish and the dealer’s tag or label shall remain affixed until the container is:

- (a) Shipped;
- (b) Emptied to wash, grade, or pack the shellfish; or
- (c) Emptied for repacking of shellfish.

2400.3 The dealer shall affix a dealer tag or label in accordance with sections 2401 and 2403 on each new container in which the shellfish is placed.

2400.4 The dealer's tags shall be:

- (a) Durable, waterproof, and sanctioned by the Department prior to use; and
- (b) At least two and five eighths inches ($2 \frac{5}{8}$ in.) by five and one-fourth inches ($5 \frac{1}{4}$ in.) in size.

2401 DEALER TAGS -- SHELLSTOCK

2401.1 The dealer's tag on shellstock shall contain the following indelible, legible information in the order specified below:

- (a) The dealer's name and address;
- (b) The dealer's certification number as assigned by the Department and the original shellstock shipper's certification number;
- (c) The date of harvest;
- (d) The most precise identification of the harvest location as is practicable, including the initials of the state of harvest and the designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed, then an appropriate geographical or administrative designation shall be used;
- (e) If the shellstock has been transported across state lines and placed in wet storage in a dealer's operation, the statement:

"This product is a product of (name of state) and
was wet stored at (facility certification number)
from (date) to (date)";

- (f) The type and quantity of shellstock; and
- (g) The following statement in bold capitalized type on each tag:

"This tag is required to be attached until
container is empty or is retagged and
thereafter kept on file for ninety (90)
days";

- (h) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, or an equivalent statement, shall be included on all shellstock:

“Retailers, inform your customers ‘Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.’ ”

- 2401.2 If the shellstock is removed from the original container, the tag on the new container shall meet the requirements specified in section 2400.4 and this section.

2402 LOT TAGGING – DURING INTERMEDIATE PROCESSING

- 2402.1 When the shellstock is removed from the original container, the dealer shall:

- (a) Keep the dealer’s tag that was affixed to the original container on file for ninety (90) days;
- (b) Keep track of the growing area and date of harvest for the shellstock by identifying and recording this information from the lot containers of shellstock commingled during intermediate processing; and
- (c) Maintain the lot identity of all shellstock during any intermediate stage of processing.

- 2402.2 A dealer receiving bulk tagged lots of shellstock must have an intermediate processing plan approved by the Department to ensure that each lot of shellstock is kept separate and identified in a way that prevents misidentification.

- 2402.3 A dealer may tag a lot container of shellstock in lieu of meeting the requirements specified in sections 2400.2 and 2400.3 for a dealer tag on each individual container, if the dealer has an intermediate processing plan which establishes the procedures for tagging lots during the washing, packing or staging of shellfish and the plan is approved by the Department..

- 2402.4 If shellstock are sold in bulk, the dealer shall prepare a transaction record prior to shipment. This transaction record shall contain all the information required in section 2405 in addition to the name of the consignee.

2403 SHUCKED SHELLFISH LABELING

- 2403.1 If a dealer stores shucked shellfish under refrigerated conditions using in-plant re-usable containers, the dealer shall maintain lot integrity.
- 2403.2 If a shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:
- (a) The original shucker-packer's name and certification number;
 - (b) The shucking date; and
 - (c) The quantity of shellfish per container and the total number of containers shipped.
- 2403.3 If a dealer uses master shipping cartons, the master cartons are exempt from the labeling requirements in this section when the individual containers within the carton are properly labeled.
- 2403.4 At a minimum, a dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with 21 CFR 101.3 – Identity labeling of food in packaged form; and 16 CFR 502.3 – Prohibited acts.
- 2403.5 Each individual package containing less than sixty-four fluid ounces (64 fl. oz.) of fresh or frozen shellfish shall be labeled with the following information:
- (a) The shucker-packer's or repacker's certification number; and
 - (b) A "Sell by" date which provides a reasonable subsequent shelf-life or the words "Best if used by" followed by a date when the product would be expected to reach the end of its shelf-life. The date shall consist of the abbreviation for the month and number of the day of the month. For fresh frozen shellfish, the year shall be added to the date.
- 2403.6 Each individual package containing sixty-four or more fluid ounces (64 fl. oz.) of fresh or frozen shellfish shall be labeled with the following information:
- (a) The shucker-packer's or repacker's certification number; and

- (b) The words "DATE SHUCKED" followed by the date shucked located on both the lid and sidewall or bottom of the container;
 - (1) The date shall consist of either the abbreviation for the month and number of the day of the month or in Julian format (YDDD), the last digit of the four digit year and the three digit number corresponding the day of the year; and
 - (2) For fresh frozen shellfish, the year shall be added to the date (for non-Julian format).

- 2403.7 If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as "previously frozen".
- 2403.8 If the dealer freezes fresh shucked shellfish, the dealer shall label all frozen shellfish as frozen using type of equal size and prominence immediately adjacent to the type of the shellfish and shall add the year to the date (for non-Julian format).
- 2403.9 If the dealer uses lot codes to track shellfish containers, the lot codes shall be distinct and set apart from any date listed on the container.
- 2403.10 If the dealer elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with this section except that the original date of shucking shall be added to the new repacked container pursuant to section 2403.6 or the original date of shucking shall be used in establishing the "Sell by date" pursuant to section 2403.5.

2404 SHIPPING DOCUMENTS AND RECORDS

- 2404.1 Each shellfish shipment shall be accompanied by a shipping document.
- 2404.2 The shipping document shall contain:
 - (a) The name, address, and certification number of the shipping dealer;
 - (b) The name and address of the major consignee; and
 - (c) The kind and quantity of the shellfish product.
- 2404.3 The receiving dealer shall:
 - (a) Maintain in a file a copy of the completed shipping document; and

- (b) Make the shipping document available to the Department upon request.

2404.4 If the shipment is subdivided and shipped to different dealers, each receiving dealer shall maintain records sufficient to trace the portion received back to the original shipment.

2405 TRANSACTION RECORDS

2405.1 Each dealer shall have a business address at which transaction records are maintained.

2405.2 Each dealer shall maintain complete, accurate, and legible records of information required to comply with this section in a form authorized by the Department.

2405.3 Transaction records shall be sufficient to:

- (a) Document that the shellfish are from a source authorized under this chapter;
- (b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
- (c) Permit a lot of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, and if possible, the harvester or group of harvesters.

2405.4 Purchase and sales shall be recorded:

- (a) In a permanently bound ledger book; or
- (b) Using other recording methods acceptable to and authorized by the Department.

2405.5 The transaction records shall be retained:

- (a) In the case of fresh shellfish, for a minimum of one (1) year; and
- (b) In the case of frozen shellfish, for at least two (2) years or the shelf-life of the product, whichever is longer.

2405.6 If computer records are maintained, the Department shall approve the format and its use.

CHAPTER 25 HACCP PLAN**2500 HACCP PLAN — GENERAL REQUIREMENTS**

- 2500.1 Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventive measures that the dealer can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest.
- 2500.2 Each dealer shall have and implement a written HACCP Plan. The HACCP Plan shall be specific to:
- (a) Each location where shellfish products are processed by that dealer; and
 - (b) Each kind of shellfish product processed by the dealer, except as specified in section 2500.3;
- 2500.3 The plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in section 2501.1 are identical for all shellfish products so grouped or for all production methods so grouped.

2501 HACCP PLAN — MINIMUM REQUIREMENTS

- 2501.1 The HACCP Plan shall, at a minimum, comply with the requirements of section 704 and:
- (a) List the food safety hazards that are reasonably likely to occur for:
 - (1) Natural toxins;
 - (2) Microbiological contamination;
 - (3) Chemical contamination;
 - (4) Pesticides;
 - (5) Drug residues;
 - (6) Unapproved use of direct or indirect food or color additives; and

- (7) Physical hazards;
- (b) List the critical control points for each of the identified food safety hazards, including as appropriate:
 - (1) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest. At a minimum, the critical control points shall include those identified in chapter 27, as applicable; and
 - (2) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment. At a minimum, the critical control points shall include those identified in chapter 27, as applicable;
- (c) List the critical limits that must be met at each of the critical control points. At a minimum, the critical limits shall include those listed in chapter 27, as applicable. These limits shall be met as components of good manufacturing practice;
- (d) List the procedures, and frequency thereof, that shall be used to monitor each of the critical control points to ensure compliance with the critical limits;
- (e) Include any corrective action plans that have been developed to be followed in response to deviations from critical limits at critical control points;
- (f) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring; and
- (g) List the verification procedures, and frequency thereof, that the dealer shall use in accordance with section 2503.

2502 HACCP PLAN – CORRECTIVE ACTIONS

- 2502.1 Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:
- (a) Following a corrective action plan that is appropriate for the particular deviation; or
 - (b) Following the procedures in section 2502.2.

2502.2 When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall:

- (a) Segregate and hold the affected product, at least until the requirements of paragraphs (b) and (c) of this subsection are met;
- (b) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who are qualified through training or experience, in accordance with section 2505, to perform such a review;
- (c) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
- (d) Take corrective action, when necessary, to correct the cause of the deviation; and
- (e) Perform or obtain a timely reassessment of the HACCP Plan by an individual or individuals qualified in accordance with section 2505 to determine whether the HACCP Plan requires modification to reduce the risk of a recurrence of the deviation, and modify the HACCP Plan as necessary.

2502.3 All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with section 2503 and the record keeping requirements of section 2504.

2503 HACCP PLAN—VERIFICATION

2503.1 Every dealer shall verify that the HACCP Plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

- (a) A reassessment of the adequacy of the HACCP Plan, which shall be conducted at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP Plan. An individual or individuals who are qualified in accordance with section 2505 shall perform the reassessment. The HACCP Plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of section 2501;
- (b) Ongoing verification activities including:

- (1) A review of any consumer complaints that have been received by the dealer to determine whether they relate to performance at critical control points or reveal the existence of unidentified critical control points;
 - (2) The calibration of process-monitoring instruments; and
 - (3) At the option of the dealer, the performance of periodic end product or in-process testing; and
 - (c) A review, including signing and dating, by an individual who is qualified in accordance with section 2505, of the records that document:
 - (1) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that documented values are within the critical limits. This review shall occur within one (1) week after the day that the records are made;
 - (2) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with section 2502. This review shall occur within one (1) week after the day that the records are made; and
 - (3) The calibrating of any process monitoring instruments used at critical control points and the performance of any periodic end-product or in-process testing that is part of the dealer's verification activities. The purpose of these reviews shall be to ensure that the records are complete, and that these activities occurred in accordance with the dealer's written procedures. These reviews shall occur within a reasonable time after the records are made.
- 2503.2 Dealers shall immediately follow the procedures in section 2502 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.
- 2503.3 The calibration of process-monitoring instruments, and the performance of any periodic end-product and in-process testing in accordance with section 2503.1(b)(2) and 2503.1(b)(3) shall be documented in records that are subject to the record keeping requirements of section 2504.

2504 HACCP PLAN —RECORDKEEPING

2504.1 All records required by this chapter shall include:

- (a) The name and location of the dealer;
- (b) The date and time of the activity that the record reflects;
- (c) The signature or initials of the person performing the operation; and
- (d) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

2504.2 All records required by chapters 24 and 25 of this subtitle shall be retained at the shellfish operation for at least one (1) year after the date they were prepared in the case of refrigerated products and for at least two (2) years after the date they were prepared in the case of frozen products.

2504.3 Records that relate to the general adequacy of equipment or processes being used by at a shellfish operation, including the results of scientific studies and evaluations, shall be retained at the shellfish operation for at least two (2) years after the scientific data has been produced.

2504.4 If the processing facility is closed for a prolonged period between seasonal operations, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to another reasonably accessible location at the end of the seasonal operations but shall be immediately returned to the processing facility for review by the Department upon request.

2504.5 All records required by chapters 24 and 25 of this subtitle and HACCP Plans required by chapter 25 shall be available for official review and copying at reasonable times.

2504.6 Reused shellstock containers shall be retagged and are subject to the requirements of sections 2401 through 2403.

2504.7 The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.

2505 HACCP PLAN –TRAINING

- 2505.1 At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to shellfish processing:
- (a) Development of a HACCP Plan, which may include adapting a model or generic-type HACCP plan that is appropriate for a specific shellfish operation, in order to meet the requirements of section 2501.1;
 - (b) Reassessment and modification of the HACCP plan in accordance with the corrective action procedures specified in section 2502.2(e) and the verification activities specified in section 2503.1(a);
 - (c) Performance of the record review required by sections 2502.2(b) and 2503.1(c).
- 2505.2 An individual who performs the functions described in section 2505.1 shall provide the Department, upon request, with a copy of their certificate of completion of training for the application of HACCP principles for shellfish processing.
- 2505.3 Job experience may qualify an individual to perform the functions specified in section 2505.1. The individual performing these functions need not be an employee of the dealer.

CHAPTER 26 TRANSPORTATION**2600 SHIPMENT ACCEPTABILITY**

- 2600.1 Shellfish shipments shall be considered acceptable when:
- (a) Shipments are properly identified with tags or labels and shipping documents;
 - (b) Shellstock is alive and cooled to an internal shellstock body temperature of fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) or less;
 - (c) Shucked shellfish is cooled to a temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less; and
 - (d) All other conditions of shipment in this chapter are met.

- 2600.2 Shellfish shall be rejected when:
- (a) Shellfish are not properly identified with tags or labels, or shipping documents;
 - (b) The internal shellstock body temperature exceeds sixty degrees Fahrenheit (60° F) (fifteen and six tenths degrees Centigrade (15.6° C));
 - (c) Shucked shellfish exceeds fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)); or
 - (d) The Department determines that the product is adulterated or unsafe for human consumption.
- 2600.3 The Department shall notify the shipping dealer, the receiving dealer, and the state where the shipment originated of the shipment's rejection.
- 2601 VEHICLES USED TO TRANSPORT SHELLFISH**
- 2601.1 Any dealer who transports shellfish shall ensure that all trucks used to transport shellfish are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellfish.
- 2601.2 Storage bins on trucks or other vehicles used in the transport of shellstock for direct marketing shall be kept clean with potable water and provided with effective drainage.
- 2601.3 Shellfish shall be transported in refrigerated trucks when the shellfish has been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.
- 2601.4 Pre-chilling of trucks or other vehicles is required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.
- 2601.5 When mechanical refrigeration units are used, the units shall be:
- (a) Equipped with automatic controls; and
 - (b) Capable of maintaining the ambient air temperature in the storage area at temperatures of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less.

2601.6 Any ice used to cool shellfish during transport shall meet the requirements of section 901 of this Code.

2601.7 Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where shellfish is stored.

2602 RECEIVING SHELLFISH

2602.1 The dealer shall reject or discard any shellfish shipments that:

- (a) Do not originate from a licensed harvester or dealer; or
- (b) Are unwholesome or adulterated, inadequately protected, or whose source cannot be identified.

2602.2 Transportation agents or common carriers used by a dealer are not required to be certified by the Department but must be properly registered with the appropriate federal regulatory agency.

2602.3 The dealer shall:

- (a) Inspect incoming shellfish shipments to ensure that the shipments are received under the conditions required in this chapter;
- (b) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) or less for more than two (2) hours at points of transfer such as loading docks;
- (c) Ensure that shucked shellfish are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less; and
- (d) Ensure that frozen shellfish remain frozen.

2603 TRANSPORTATION — CONTAINERS CONSTRUCTION AND CLEANING

2603.1 All containers used to transport shellfish shall be:

- (a) Constructed to allow for easy cleaning; and
- (b) Operated and maintained to prevent product contamination.

2603.2 All containers shall be cleaned with:

- (a) Potable water; and
- (b) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

2603.3 All containers used for storing shellfish shall be clean and fabricated from safe materials.

2604 TRANSPORTATION — PROTECTION FROM CONTAMINATION

2604.1 When the entire cargo consists of shellfish products only, except for bulk shipments, shellstock shipments shall be shipped on pallets. If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.

2604.2 When the conveyance has mixed cargos, the shellfish shall be shipped as part of a mixed cargo of seafood or other food products only when:

- (a) Shellfish products are protected from contamination by the other cargo;
- (b) All cargo is placed on pallets; and
- (c) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.

2605 TRANSPORTATION — SHIPPING TIME

2605.1 When the shipping time is four (4) hours or less:

- (a) The dealer shall ship the shellfish well iced or using other acceptable means of refrigeration;
- (b) When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be capable of maintaining the ambient air in the storage area at temperatures of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less;
- (c) The dealer shall not be required to provide thermal recorders during shipment; and

- (d) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.
- 2605.2 When the shipping time is greater than four (4) hours, the dealer shall ship all shellfish in:
- (a) Mechanically refrigerated conveyances that are equipped with automatic controls and are capable of maintaining the ambient air in the storage area at temperatures of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less; or
 - (b) Containers with an internal ambient air temperature maintained at or below temperatures of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less.
- 2605.3 Unless the dealer has an approved HACCP Plan with an alternate means of monitoring time-temperature, any dealer who transports shellfish shall ensure that a suitable time-temperature recording device accompanies each shipment of shellfish.
- 2605.4 Dealers who transport shellfish shall note on the temperature-indicating device the date and time the shellfish was loaded for transport and the date and time the shellfish was unloaded upon reaching its destination.
- 2605.5 Each receiving dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.
- 2605.6 The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature on file and shall make it available to the Department upon request.
- 2605.7 An inoperative temperature-indicating device shall be considered as no recording device.

CHAPTER 27 SPECIFIC CRITICAL CONTROL POINTS

2700 SHUCKING AND PACKING REQUIREMENTS — SHELLSTOCK SOURCES & STORAGE

- 2700.1 The dealer shall shuck and pack only shellstock that is from a source certified by the Department or listed in the ICSSL; and identified with a tag on each container or a transaction record for each bulk shipment.

2700.2 The dealer shall ensure that, once placed under temperature control and until sale to a subsequent dealer or the final consumer, shellstock is:

- (a) Iced or placed and stored in a storage area or conveyance maintained at forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less;
- (b) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration for more than two (2) hours at points of transfer such as loading docks; and
- (c) Not placed in wet storage.

2700.3 The dealer that processes the shellstock shall ensure that:

- (a) For shellstock that has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less within three (3) hours of shucking;
- (b) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less within four (4) hours of removal from refrigeration;
- (c) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats are cooled to forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less within two (2) hours after the heat shock process; and
- (d) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock are cooled to an internal temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) within two (2) hours from time of heat shock.

2700.4 The dealer shall store shucked and packed shellfish in covered containers at an ambient air temperature in the storage area of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less or covered with ice.

2701 SHUCKED SHELLFISH REPACKING REQUIREMENTS

2701.1 The dealer receiving shellfish shall repack only shellfish that:

- (a) Originated from a dealer; and
- (b) Are identified with a tag or label as specified in sections 2401 through 2403.

2701.2 The dealer processing shellfish shall ensure that repacked shellfish:

- (a) Do not exceed an internal temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) for more than two (2) hours; and
- (b) Are maintained at a temperature less than forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) in any portion of frozen shellfish thawed for repacking.

2701.3 The dealer shall store repacked, shucked shellfish in covered containers at an ambient temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less or covered in ice.

2702 SHELLSTOCK SHIPPER RECEIVING REQUIREMENTS

2702.1 The dealer receiving shellstock shall ship or repack only shellstock obtained from:

- (a) Sources certified by the Department or listed in the most recent or current ICSSL;
- (b) A licensed harvester who has:
 - (1) Harvested the shellstock from an approved or conditionally approved area in the open status as identified by the tag; and
 - (2) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or
- (c) A dealer who has identified the shellstock with a tag on each container.

2702.2 The dealer storing shellstock shall ensure that, once placed under temperature control and until sale to the processor or final consumer, the shellstock is:

- (a) Iced or placed in a storage area or conveyance maintained at forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less;

- (b) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration for more than two (2) hours at points of transfer, including but not limited to loading docks; and
- (c) Not placed in wet storage.

2703 RESHIPPING REQUIREMENTS

2703.1 The dealer shall reship only shellfish received that is:

- (a) From a source certified by the Department or listed in the ICSSL;
- (b) Identified with a tag as specified sections 2400, 2401, and 2402, or a label as specified in section 2403; and
- (c) At a temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less.

2703.2 The dealer shall ensure that, once placed under temperature control and until sale to the processor or final consumer, shellfish is:

- (a) Iced or placed in a storage area or conveyance maintained at forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less;
- (b) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than two (2) hours at points of transfer such as loading docks; and
- (c) Not placed in wet storage.

2703.3 The dealer shall store shucked shellfish at a temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2 ° C)) or less.

CHAPTER 28 REQUIREMENTS FOR SANITATION AND PREVENTION OF CONTAMINATION

2800 SAFETY OF WATER SUPPLY

2800.1 The dealer shall provide a water supply that meets the requirements of sections 1300 through 1303.

2800.2 Any steam used in shellfish processing or that comes in contact with food contact surfaces shall be free from additives or deleterious substances.

2800.3 Ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:

- (a) Be made on-site from potable water in a commercial ice machine; or
- (b) Come from a licensed ice manufacturing plant.

2801 SHELLSTOCK WASHING

2801.1 Water from a potable water supply shall be used to wash shellstock.

2801.2 If the dealer uses any system to wash shellstock that recirculates water, the dealer shall:

- (a) Obtain approval from the Department for any construction or remodeling of the system;
- (b) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and
- (c) Test bacteriological water quality daily.

2801.3 The dealer may use ultra-violet disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed twenty (20) nephelometric turbidity units (NTUs) measured using the method in the APHA Standard Methods for the Examination of Water and Wastewater.

2802 STORAGE AND HANDLING – SHELLSTOCK AND OTHER SHELLFISH

2802.1 A dealer shall ensure that shellstock is:

- (a) Alive;
- (b) Reasonably free of sediment; and
- (c) Culled.

- 2802.2 The dealer shall inspect incoming shipments and shall reject dead or contaminated shellstock.
- 2802.3 A dealer that uses heat shock to prepare shellstock for shucking shall:
- (a) Post the schedule for the heat shock process in a conspicuous location;
 - (b) Ensure that all responsible persons are familiar with the requirements of the process; and
 - (c) Cool all hot dipped shellstock immediately after the heat shock process by:
 - (1) Dipping in an ice bath; or
 - (2) Using flowing potable water.
- 2802.4 If a heat shock water tank is used, the dealer shall completely drain and flush the tank at three (3) hour intervals or less so that all mud and debris that have accumulated in the dip tank are eliminated.
- 2802.5 The dealer shall not allow the use of dip buckets for hand or knife rinsing during shucking.
- 2802.6 The dealer shall completely empty shucking buckets at the packing room so that no overage is returned to the shucker.
- 2802.7 After shucking, the dealer shall wash, blow, and rinse all shellfish meats in accordance with the provisions required for oysters in 21 CFR 161.130 – Oysters.
- 2802.8 The dealer shall thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room.
- 2802.9 The dealer shall conduct packing activities so as to conform to applicable food additive regulations.
- 2802.10 A dealer who stores or repacks shellstock shall have a facility or make arrangements to use a facility that has been approved by the Department for the proper storage or repacking of shellstock.
- 2802.11 The dealer shall store packaged shellfish, if they are to be frozen, at an ambient temperature of zero degrees Fahrenheit (0° F) (negative seventeen and eight tenths degrees Centigrade (-17.8° C)) or less. The shellfish shall be frozen solid within twelve (12) hours following the initiation of freezing.

- 2802.12 The dealer shall not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless the dealer is able to verify through the ICSSL the legitimate source of the containers and the containers contain shellfish from that source.
- 2802.13 The dealer shall repack shucked shellfish meats only into containers labeled with the dealer's authorized certification number.
- 2802.14 The dealer shall not commingle, sort, or repack shellstock or shucked shellfish from different lots during shucking, packing or repacking unless the dealer is included in a commingling plan that has been approved by the Department, and shall not remove or alter any existing tag or label during reshipping.

2803 EQUIPMENT AND UTENSILS

- 2803.1 The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers, that comply with section 1200 and are:
- (a) Constructed in a manner and with materials that can be cleaned, sanitized, maintained and replaced in a manner that prevents contamination of shellfish products; and
 - (b) Free from exposed screws, bolts, or rivet heads on food contact surfaces; and
 - (c) Fabricated from food grade materials.
- 2803.2 Shucking blocks shall be:
- (a) Easily cleanable;
 - (b) Fabricated from safe material;
 - (c) Solid, one piece construction; and
 - (d) Easily removed from the shucking bench, unless the block is an integral part of the bench.
- 2803.3 All equipment used in heat shock processing shall meet the requirements of this section.

2803.4 All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in sections 2803.1 and 2803.2.

2803.5 The dealer shall provide a temperature measuring device accurate to plus or minus two degrees Fahrenheit ($\pm 2^{\circ}$ F) (plus or minus one degree Centigrade ($\pm 1^{\circ}$ C)) for use in monitoring product temperatures.

2804 CLEANING AND SANITIZING OF EQUIPMENT, UTENSILS, CONTAINERS, FOOD CONTACT SURFACES, AND NON-FOOD CONTACT SURFACES

2804.1 The dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks to construct:

- (a) Shucking benches and contiguous walls;
- (b) Stands or stalls and stools for shuckers; and
- (c) Any other non-food contact surfaces in shellfish storage or handling areas.

2804.2 Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches.

2804.3 The dealer shall ensure that all joints on food contact surfaces have smooth, easily cleanable surfaces and are welded.

2804.4 Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces.

2804.5 All conveyances and equipment that come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.

2804.6 Food contact surfaces of equipment, utensils, and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall comply with section 1202 and shall:

- (a) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers and make hot water and pressure hoses available within the plant;

- (b) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated;
- (c) Wash and rinse equipment and utensils at the end of each day; and
- (d) Provide a test kit or other device that actually measures parts per million (ppm) concentration of the chemical sanitizing agent in use.

- 2804.7 Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling.
- 2804.8 Containers that may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded.
- 2804.9 Shucked shellfish shall be packed or repacked in clean containers that are fabricated from food grade materials and stored in a manner that ensures their protection from contamination.

2805 PREVENTING CROSS CONTAMINATION THROUGH STORAGE

- 2805.1 Shellstock shall be stored in a manner that protects shellstock from contamination in dry storage and at points of transfer.
- 2805.2 Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment.
- 2805.3 Equipment and utensils shall be stored in a manner that prevents splash, dust, and contamination in accordance with section 1203.

2806 PREVENTING CROSS CONTAMINATION FROM HANDS & SEWAGE

- 2806.1 The dealer shall ensure that where the same employees work in both shucking and packing activities, the employees maintain a high level of personal hygiene and cleanliness in accordance with chapter 4.
- 2806.2 The dealer shall require all employees in accordance with sections 401 and 402 to wash their hands thoroughly with hand cleaning liquid or powder and water, and sanitize their hands in an adequate handwashing sink in accordance with section 403.

2806.3 The dealer shall provide:

- (a) Handwashing sinks with warm water at a minimum temperature of one hundred degree Fahrenheit (100°F) (thirty-eight degrees Centigrade (38°C)) dispensed through a hot and cold mixing valve, a combination faucet, or tempered water and a single faucet in accordance with section 1402.1;
- (b) Proper disposal of sewage and liquid disposable wastes from the facility in accordance with sections 1506 and 1507;
- (c) An adequate number of conveniently located toilets in accordance with section 1908;
- (d) An adequate supply of toilet paper in a suitable holder in each toilet facility in accordance with section 1910.

2807 PREVENTING CONTAMINATION BY EMPLOYEES

2807.1 In accordance with chapter 4, in any area where shellfish are shucked or packed and in any area that is used for cleaning or storage of utensils, employees shall not:

- (a) Store clothing or other personal belongings;
- (b) Eat or drink;
- (c) Spit; or
- (d) Use tobacco in any form.

2807.2 Any employee handling shucked shellfish shall:

- (a) Wear effective hair restraints;
- (b) Remove any hand jewelry that cannot be sanitized or secured;
- (c) Wear finger cots or gloves if jewelry cannot be removed; and
- (d) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean.

- 2807.3 The dealer shall ensure that supervisors, in accordance with chapter 2:
- (a) Are trained in proper food handling techniques and food protection principles;
 - (b) Are knowledgeable about personal hygiene and sanitary practices;
 - (c) Train employees and monitor employee compliance with required hygiene practices, including hand washing, the prohibition on eating and smoking at work stations, and the requirement that personal items and clothing be stored in accordance with chapter 4; and
 - (d) Comply with chapter 3 through employee training and monitoring of employees' health.

2807.4 In accordance with section 303.1, the dealer shall exclude or restrict an employee who exhibits or reports a symptom or who reports a diagnosed illness as specified in sections 300.3 through 300.5.

2807.5 An employee with a lesion containing pus such as a boil or infected wound that is open or draining shall report it to his or her supervisor and keep it covered in accordance with section 300.3.

2807.6 If used, finger cots or gloves shall be:

- (a) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done;
- (b) Sanitized at least twice daily;
- (c) Cleaned more often, if necessary;
- (d) Properly stored until used; and
- (e) Maintained in a clean, intact, and sanitary condition.

2808 PREVENTING CROSS CONTAMINATION FROM ADULTERANTS

2808.1 Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing.

2808.2 In accordance with section 1809, lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage.

2808.3 Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with manufacturer label directions and sections 2204 and 2205.

2809 PREVENTING CROSS CONTAMINATION FROM ICE

2809.1 Ice that is not made on site in the shellfish operation facility shall be inspected upon receipt and rejected if the ice has not been delivered in a manner that is protected from contamination.

2809.2 Ice shall be stored in a safe and sanitary manner to prevent contamination.

2810 PROPER LABELING, STORAGE, AND USE OF TOXIC COMPOUNDS

2810.1 When pesticides are used in the shellfish operation, the dealer shall ensure that they are applied in accordance with section 2201 and 2202 and in a manner that prevents the contamination of shellfish or packaging materials with residues.

2810.2 Cleaning compounds and sanitizing agents shall be properly labeled and used only in accordance with the manufacturer's label directions.

2810.3 Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

2810.4 The dealer shall ensure that only toxic substances necessary for plant activities are present in the shellfish operation.

2810.5 Each of the following categories of toxic substances shall be stored separately:

- (a) Insecticides and rodenticides;
- (b) Detergents, sanitizers, and related cleaning agents; and
- (c) Caustic acids, polishes, and other chemicals.

2810.6 The dealer shall not store toxic substances above shellfish, food contact surfaces, or food packaging materials.

2811 PLUMBING AND RELATED FACILITIES

2811.1 The dealer shall, in accordance with chapters 14 and 15, design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

- (a) Prevent contamination of water supplies; and
- (b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.

2811 .2 Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall:

- (a) Be easily accessible for cleaning and inspection;
- (b) Be self-draining; and
- (c) Meet the requirements for food contact surfaces contained in subtitle D.

2812 HANDWASHING SINKS, PLUMBING, AND VENTILATION

2812.1 Handwashing sinks shall be provided in accordance with sections 1900 through 1905; and shall be directly plumbed to an approved sewage disposal system in accordance with section 1401.

2812.2 The dealer shall provide at least one (1) handwashing sink in the packaging room.

2812.3 Adequate floor drainage, including backflow prevention devices such as air gaps, shall be provided where floors are:

- (a) Used in shellstock storage;
- (b) Used for food holding units;
- (c) Cleaned by hosing, flooding, or similar methods; and
- (d) Subject to the discharge of water or other liquid waste on the floor during normal activities.

2812.4 A safe, effective means of sewage disposal for the facility shall be provided in accordance with sections 1400 and 1401.

2812.5 Drainage or waste pipes shall not be installed over food processing or food storage areas, or over areas in which containers and utensils are washed or stored.

- 2812.6 Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.
- 2812.7 Ventilation shall be provided to minimize condensation in areas where food is stored, processed, or packaged.
- 2812.8 Air pump intakes shall be located in a protected place and installed with air filters installed on all blower air pump intake systems.

2813 PHYSICAL SEPARATION OF ACTIVITIES

- 2813.1 Facilities for shucking and packing activities shall be separated by physical barriers such as rooms, partitions, or spacing to prevent contamination.
- 2813.2 Manufacturing activities, which could result in the contamination of the shellfish, shall be separated by physical barriers such as rooms or partitions.

2814 PLANT AND GROUNDS

- 2814.1 The physical facilities of a shellfish operation shall be maintained in good repair.
- 2814.2 Grounds around the facility shall be maintained in a manner that prevents rodent attraction and harborage, and provides adequate drainage to avoid shellfish contamination.
- 2814.3 In accordance with section 2012, animals shall not be allowed in areas where shellfish are stored, handled, processed, or packaged or where food handling equipment, utensils, and packaging materials are cleaned or stored.

2815 PLANT INTERIOR

- 2815.1 Sanitary conditions shall be maintained throughout the facility.
- 2815.2 All dry area floors shall be hard, smooth, easily cleanable, and in good repair.
- 2815.3 All wet area floors used in areas to store shellstock, process food, or clean equipment or utensils shall be constructed of easily cleanable, impervious, and corrosion-resistant materials and shall:
- (a) Be graded to provide adequate drainage;
 - (b) Have even surfaces and be free from cracks that create sanitary problems and interfere with drainage; and

- (c) Have sealed junctions between floors and walls to render them impervious to water.
- 2815.4 Walls, ceilings, and interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials.
- 2815.5 The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices.
- 2815.6 The dealer shall ensure that toilet room doors are tight fitting, self-closing, and do not open directly into a processing area in accordance with section 1908.3.
- 2815.7 The dealer shall operate the facility to minimize the presence of pests on the premises in accordance with sections 1812 and 1813.
- 2815.8 The dealer shall protect the facility against the entry of insects, rodents or other vermin by employing necessary internal and external insect and vermin control measures including but not limited to tight fitting, self-closing doors in accordance with section 1813.

2816 WASTE DISPOSAL

- 2816.1 Disposal of waste materials shall not create a public health hazard or nuisance.
- 2816.2 All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent the attraction, harborage, or breeding of insects, rodents, and vermin in accordance with chapter 16.

SUBTITLE I: COMPLIANCE, ENFORCEMENT, AND DEFINITIONS

CHAPTER 29 CODE APPLICABILITY

2900 USE FOR INTENDED PURPOSE — PUBLIC HEALTH PROTECTION

- 2900.1 The Department shall use this Code to promote the safeguarding of public health to ensure the safe manufacturing, processing, and packing of food, and the safe shipping and receiving of shellfish.
- 2900.2 In enforcing the provisions of this Code, the Department shall assess existing facilities or equipment that were in use before the effective date of this Code based on the following considerations:

- (a) Whether the facilities and equipment are in good repair and capable of being maintained in a sanitary condition;
- (b) Whether food-contact surfaces comply with sections 1200, 1203 1209, 1211, 1212, 1214, 2803, and 2804;
- (c) Whether the capacities for cooling equipment are sufficient to comply with sections 900.2 through 900.6, sections 1204, 1205, 1206, 1207, 2600, 2601.3, 2601.4, 2601.5, 2602.3, 2605.1, 2605.2, 2700.2, 2700.3, 2700.4, 2701.2, 2701.3, 2702.2, 2703.1(c), 2703.2, and 2703.3; and
- (d) The existence of a documented agreement with the licensee or dealer that the facilities or equipment will be replaced so as to comply with this Code or be upgraded or replaced to comply with the requirements stated in paragraph (c) of this subsection by December 30, 2011, as specified in section 3108.7 and 3108.8.

**2901 PREVENTING HEALTH HAZARDS — PROVISION FOR
CONDITIONS NOT ADDRESSED**

- 2901.1 If necessary to protect against public health hazards or nuisances, the Department may impose specific requirements in addition to the requirements contained in this Code that are authorized pursuant to An Act To authorize the Commissioners of the District of Columbia to make regulations to prevent and control the spread of communicable and preventable diseases, approved August 11, 1939 (53 Stat. 1408; D.C. Official Code § 7-131 *et seq.*).
- 2901.2 The Department shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the applicant, licensee or dealer and a copy shall be maintained in the Department's files.

CHAPTER 30 PLAN SUBMISSIONS AND APPROVAL

3000 FACILITY AND OPERATING PLANS — WHEN REQUIRED

- 3000.1 An applicant, licensee or dealer shall submit to the Department for review and approval properly prepared plans and specifications as specified in section 704, section 801.2 or chapter 25, and this chapter before:
- (a) Opening a new food processing operation;
 - (b) Beginning the construction of a food processing operation;

- (c) Converting an existing structure for use as a food processing operation;
- (d) Conducting a major renovation, remodeling or alteration of a food processing operation; or
- (e) Changing the type of food processing operation or the food processing methods used at the food processing operation.

3000.2 The applicant, licensee or dealer shall submit plans, specifications, an application form, and the applicable fee to the Department at least thirty (30) calendar days before beginning construction, remodeling, or conversion of a food processing operation.

3000.3 In addition to HACCP plans required under section 704 and section 801.2 or chapter 25, plans required by this section shall include specifications showing layout, arrangement, and construction materials to be used in the food processing operation and the location, size, and type of fixed equipment and facilities.

3000.4 The Department may require an applicant, licensee or dealer to submit facility and operating plans for review and approval when the Department makes a determination pursuant to an inspection that such plans and specifications are necessary to ensure compliance with this Code and to protect the public.

3000.5 The Department shall approve the completed plans and specifications if they meet the requirements of this Code, and the Department shall report its findings to the applicant, licensee or dealer within thirty (30) days of the date the completed plans are received.

3000.6 Plans and specifications that are not approved as submitted shall be changed to comply with the Department's requirements or this Code or be deleted from the project.

3001 FACILITY AND OPERATING PLANS — CONTENTS AND SPECIFICATIONS

3001.1 Plans and specifications for a food processing operation shall include the following information to demonstrate conformance with this Code:

- (a) Type of foods that are potentially hazardous to be produced, stored, held, repacked, relabeled, distributed, or transported;

- (b) Proposed layout, mechanical schematics, construction materials, and finish schedules;
- (c) Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
- (d) A complete set of elevations and drawings for all custom fabricated equipment;
- (e) A functional flow plan indicating how food will be handled;
- (f) Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed;
- (g) Evidence of an established food safety program such as an employee training manual, and standard operating procedures that ensure compliance with this Code; and
- (h) Other information that may be required before the Department may approve proposed plans for the construction, conversion, or modification, including but not limited to approvals by other District agencies.

3001.2 Used equipment shall satisfy the standards specified in chapter 12, and sections 2601, 2603, 2803, and 2804, and shall be approved by the Department before use.

3002 FACILITY AND OPERATING PLANS — WHEN MUST A HACCP PLAN BE SUBMITTED

3002.1 An applicant, licensee or dealer shall submit a HACCP Plan to the Department for approval when:

- (a) An HACCP Plan is required under section 801.2 or chapter 25, and an initial application for a license or certification is filed with the Department in accordance with chapter 31; or
- (b) An HACCP Plan is required under section 801.2 or chapter 25, and a renewal application for a license or certification is filed with the Department in accordance with chapter 31.

3002.2 If a food processing operation is required under section 3002.1 to have a HACCP plan, the plan must be prepared in accordance section 704, section 801.2 or chapter 25, and this section.

3003 FACILITY AND OPERATING PLANS — COMPLIANCE WITH HACCP PLAN

3003.1 A licensee or dealer shall maintain and provide to the Department, on request, records that demonstrate that the following are routinely employed:

- (a) Procedures for monitoring critical control points;
- (b) Monitoring of the critical control points;
- (c) Verification of the effectiveness of an operation or process; and
- (d) Necessary corrective actions if there is failure at a critical control point.

3004 CONFIDENTIALITY — TRADE SECRETS

3004.1 The Department shall treat as confidential, information that is contained in the plans and specifications submitted pursuant to section 3001.

3005 CONSTRUCTION, INSPECTION, AND APPROVAL — PREOPERATIONAL INSPECTIONS

3005.1 The Department shall conduct one (1) or more preoperational inspections to verify that the food processing operation is constructed and equipped in accordance with approved plans and approved modifications to those plans, has established standard operating procedures for food processing methods that will be used, and is in compliance with applicable laws and this Code.

**CHAPTER 31 LICENSE / CERTIFICATION
TO OPERATE****3100 LICENSE / CERTIFICATION REQUIREMENT — PREREQUISITE FOR OPERATION**

3100.1 No person shall operate a food processing operation, including owning, operating or offering the services of any refrigerated locker or lockers, in the District without a valid license or dealer certification issued by the Department.

3100.2 All food processing operations doing business in the District shall be in compliance with federal regulations requiring food facilities to register with FDA in accordance with 21 CFR 1.225 – Who must register under this subpart? before beginning operations.

3101 APPLICATION PROCEDURE — PERIOD FOR SUBMISSION

- 3101.1 An applicant shall submit an application for a license or dealer certification at least thirty (30) calendar days before the date planned for opening a food processing operation or the expiration date of the current license or dealer certification for an existing operation.
- 3101.2 Licenses shall be valid for a two (2) year period except that shellfish certifications shall be valid for a one (1) year period in accordance with section 2309.
- 3101.3 Fees shall be prorated for licenses and dealer certifications issued after beginning of the license or dealer certification period.

3102 APPLICATION PROCEDURE — FORM OF SUBMISSION

- 3102.1 An applicant shall submit a written application for a license or dealer certification on a form provided by the Department.

3103 APPLICATION PROCEDURE — CONTENTS OF THE APPLICATION

- 3103.1 The application for a license for a food processing operation shall include the name, address, and signature of the applicant, and the following information, in addition to any information required for shellfish operations under section 2302.1:
- (a) Name, mailing address and telephone number of the owner of the business;
 - (b) Trade name;
 - (c) Name and address of corporate officers;
 - (d) Name and country of registered agent, if applicable;
 - (e) Address of the food processing operation;
 - (f) Type of food processing method(s) that will be in use in the food processing operation; and
 - (g) Whether product will be sold in interstate commerce.

3104 ISSUANCE OF LICENSE, CERTIFICATION – NOTICE OF OPENING, DISCONTINUANCE OF OPERATION, AND POSTING

- 3104.1 A food processing operation shall provide notice to the Department of its intent to operate at least thirty (30) calendar days before beginning operations.
- 3104.2 A food processing operation shall provide notice to the Department of its intent to shut down permanently or temporarily at least thirty (30) calendar days before discontinuing operations.
- 3104.3 All licenses, certifications and current inspection results shall be conspicuously posted within the food processing operation.

3105 ISSUANCE OF LICENSE, CERTIFICATION – NEW, CONVERTED, OR REMODELED FOOD PROCESSING OPERATIONS

- 3105.1 For food processing operations that are required to submit plans as specified in section 3000, the Department shall issue a license or dealer certification to an applicant after:
- (a) A properly completed application is submitted;
 - (b) The required fee is submitted;
 - (c) The required plans, specifications, and information are reviewed and approved; and
 - (d) A preoperational inspection as specified in section 3005 has been conducted that shows the operation is built or remodeled in accordance with the approved plans and specifications and that the operation is in compliance with this Code.

3106 ISSUANCE OF LICENSE, CERTIFICATION – EXISTING OPERATIONS, AND CHANGE OF OWNERSHIP OR LOCATION

- 3106.1 The Department shall renew a license or dealer certification to an existing food processing operation after a properly completed application is submitted, reviewed and approved, applicable fees are paid, and an inspection shows that the operation is in compliance with this Code.
- 3106.2 The Department shall issue a new license or dealer certification to an existing food processing operation that has changed ownership or changed location after a properly completed application is submitted, reviewed and

approved, applicable fees are paid, and an inspection shows that the operation is in compliance with this Code.

3107 ISSUANCE — DENIAL OF APPLICATION FOR LICENSE OR DEALER CERTIFICATION, NOTICE

3107.1 If an application for a license or dealer certification or a renewal of a license or dealer certification is denied, the Department shall provide the applicant with written notice that includes:

- (a) The specific reasons and legal authority for denial of the license or certification;
- (b) The actions, if any, that the applicant must take to qualify for a new license or certification or to renew a license or certification; and
- (c) Notice of the applicant's right to a hearing and the process and timeframes for appeal as prescribed in chapter 37.

3108 CONDITIONS OF RETENTION — RESPONSIBILITIES OF THE LICENSEE OR DEALER

3108.1 Upon receipt of a license or dealer certification issued by the Department, the licensee or dealer, in order to retain the license or dealer certification, shall comply with sections 3108.2 through 3108.8.

3108.2 The licensee or dealer shall post the license or dealer certification and current inspection results in a conspicuous location within the food processing operation as specified in section 3104.3.

3108.3 The licensee or dealer shall comply with the provisions of this Code and approved plans as specified in section 3000.

3108.4 The licensee or dealer shall immediately contact the Department to report an illness of an employee as specified in section 301.

3108.5 The licensee or dealer shall immediately discontinue operations and notify the Department if an imminent health hazard exists as specified in section 3210.

3108.6 The licensee or dealer shall allow representatives of the Department access to its food processing operation as specified in section 3200.1 and 3200.2.

3108.7 The licensee or dealer shall replace existing facilities and equipment approved for use before the effective date of this Code pursuant to a documented agreement with the Department requiring that the facilities or

equipment be replaced with facilities and equipment that comply with this Code, except the Department may direct the replacement of existing facilities and equipment because the facilities and equipment constitute a public health hazard or nuisance.

- 3108.8 The licensee or dealer shall upgrade or replace refrigeration equipment to comply with the requirements specified in section 2900.2(c) by December 30, 2011.

**3109 CONDITIONS OF RETENTION — LICENSE OR DEALER
CERTIFICATION NOT TRANSFERABLE**

- 3109.1 A license or dealer certification shall not be transferred from one person to another person, or from one type of food processing operation to another if the operation changes from the type of processing operation stated in the application, as specified in section 3103, and the change in operation is not approved.

**CHAPTER 32 INSPECTION AND CORRECTION
OF VIOLATIONS**

3200 ACCESS — DEPARTMENT RIGHT OF ENTRY, DENIAL

- 3200.1 After representatives of the Department present official credentials and provide notice of the purpose and intent to conduct an inspection in accordance with this Code, the applicant, licensee or dealer shall allow the Department access to any part, portion or area of a food processing operation.

- 3200.2 The Department may enter and inspect all aspects of a food processing operation, including, but not limited to its vehicles, equipment, refrigerated lockers, finished and unfinished materials, containers, labeling, and advertisements, at any time for one or more of the following purposes:

- (a) To determine if the food processing operation is in compliance with this Code;
- (b) To investigate an emergency affecting the public health if the food processing operation is or may be involved in the matter causing the emergency;
- (c) To investigate, examine and sample food; and
- (d) To obtain information, and examine and copy all records on the premises relating to food purchased, received, processed, packaged, or used by a food processing operation.

- 3200.3 If a person denies the Department access to any part, portion, or area of a food processing operation, the Department shall inform the individual that:
- (a) The applicant, licensee or dealer is required to allow access to the Department as specified in section 3200.1;
 - (b) Access is a condition of the receipt and retention of a license or dealer certification as specified in section 3108.6;
 - (c) If access is denied, an inspection order allowing access may be obtained in accordance with District law; and
 - (d) The Department is making a final request for access.
- 3200.4 If the Department presents credentials and provides notice as specified in section 3200.1, explains the authority upon which access is requested, and makes a final request for access as specified in section 3200.3, and the applicant, licensee or dealer continues to refuse access, the Department shall provide details of the denial of access on the inspection report.
- 3200.5 If the Department is denied access to a food processing operation for an authorized purpose, after complying with sections 3200.1 through 3200.3, the Department may:
- (a) Summarily suspend a license or dealer certification issued to the food processing operation in accordance with sections 3516;
 - (b) Revoke or suspend a license or certification issued to the food processing operation in accordance with section 3521; or
 - (c) Request that the Office of the Attorney General for the District of Columbia commence an appropriate civil action in the Superior Court of the District of Columbia to secure a temporary restraining order, a preliminary injunction, a permanent injunction, or other appropriate relief from the court, to enforce this Code in accordance with section 8a(l) of An Act Relating to the adulteration of food and drugs in the District of Columbia, effective May 2, 2002 (D.C. Law 14-116; D.C. Official Code § 48-108.01(l)).

3201 FREQUENCY — RISK-BASED INSPECTION SCHEDULE

- 3201.1 The Department shall inspect a food processing operation based on a written risk-based inspection schedule that is uniformly applied throughout the District.

3201.2 The Department shall prioritize the inspection frequency for each food processing operation based on the potential health hazard associated with each establishment's operations and its compliance history as follows:

- (a) HIGH-RISK (Shellstock Processing): Wholesale handling, shipping, receiving, shucking, packing, repacking, selling, or purchasing of shellstock or shucked shellstock;
- (b) HIGH-RISK: Manufacturers of acidified foods, low acid foods in hermetically sealed containers, by methods of canning, packaging, or bottling operations; wholesale manufacturers of potentially hazardous foods such as cream-filled pastries, filled macaroni products, and smoked/cured fish; manufacturers of high risk ready-to-eat foods; food salvagers; and vacuum packers;
- (c) MODERATE-RISK: Processing or altering of food. Processing includes but is not limited to acidifying, smoking, drying, fermenting, curing, deboning, filleting, reduced oxygen packaging, and other operations and processes that significantly alter the finished product. Extensive repacking or repackaging of food products also constitutes significant processing;
- (d) LOW-RISK: Sale of food products without processing or repackaging of food products such as occurs in supermarkets, grocery stores or refrigerated warehouses and food warehouses; or sale of wholesale products offered to the public without any additional processing by the establishment. Processing is limited to labeling and presentation of the food product, such as reselling processed foods to a distributor.

3202 FREQUENCY — PERFORMANCE AND RISK-BASED FACTORS

3202.1 Within the parameters specified in section 3201, the Department shall prioritize and conduct more frequent inspections based upon its assessment of a food processing operation's history of compliance with this Code and its potential as a vector of foodborne illness by evaluating:

- (a) Past performance for numerous or repeat critical violations of this Code or HACCP Plan requirements;
- (b) Past performance for numerous or repeat violations of this Code or HACCP Plan requirements that are noncritical violations;
- (c) Past performance, for complaints investigated and found to be valid;

- (d) The hazards associated with particular foods that are processed, prepared, stored, purchased, transported, held, shipped, packaged, or received; and
- (e) The type of operation.

3203 FREQUENCY — SHELLFISH-PROCESSING OPERATIONS

3203.1 In addition to section 3202.1, the Department shall inspect shellfish-processing operations identified in section 3201.2(a) for compliance with subtitle H and the most recent edition of the Interstate Shellfish Sanitation Conference Guide for the Control of Molluscan Shellfish.

3203.2 After an applicant is certified as specified in section 2307, the Department shall make unannounced inspections of the dealer's facilities:

- (a) During hours of operation; and
- (b) At the following minimum frequencies:
 - (1) Within thirty (30) business days of beginning operations if the dealer was certified on the basis of a pre-operational inspection;
 - (2) At least quarterly for dealer operations certified as shucker-packers or repackers; and
 - (3) At least semiannually for other dealer operations.

3204 FREQUENCY — SHELLFISH-PROCESSING OPERATIONS, PERFORMANCE BASED INSPECTION PROGRAM (PIP)

3204.1 A performance based inspection program (PIP) may be instituted by the Department for any dealer who meets the requirements of this section.

3204.2 The minimum frequency of inspection under a PIP shall be no less than one (1) inspection per certification period. The recertification inspection may qualify as the required minimum inspection frequency.

3204.3 To be eligible for a PIP, the dealer shall have demonstrated a history of satisfactory compliance for the previous three (3)-year period. The previous three (3)-year period shall demonstrate:

- (a) Full compliance with inspections conducted under the minimum inspection frequency specified in section 3203.2(b);

- (b) Recertification of the dealer by the Department each year;
- (c) Verification that no more than one (1) critical violation and no more than two (2) noncritical violations have occurred in any one inspection;
- (d) Correction of all identified violations in accordance with the compliance schedule approved by the Department; and
- (e) No repetition of the identified violations.

3205 REPORT OF FINDINGS — DOCUMENTING INFORMATION AND OBSERVATIONS

3205.1 The Department shall document on an inspection report form:

- (a) Administrative information about the food processing operation's legal identity, street and mailing addresses, type of operation, and food processing method, inspection date, and other information such as type of water supply and sewage disposal, status of the license or dealer certification and personnel certificates that may be required; and
- (b) Specific factual observations of Code violations that require correction by the licensee or dealer including:
 - (1) Failure of the licensee or dealer to ensure that supervisors are certified by an FDA and USDA approved institution, have obtained a District-issued Certified Supervisor Identification Card as specified in section 200.9, or monitor compliance with the requirements stated in section 201;
 - (2) Failure of food employees and supervisors to demonstrate their knowledge of their responsibility to report a disease or medical condition as specified in sections 300 and 301;
 - (3) Nonconformance with critical items of this Code; and
 - (4) Failure of a licensee or dealer to meet an approved compliance schedule as specified in sections 3212 and 3214.

3206 REPORT OF FINDINGS — SPECIFYING TIME FRAME FOR CORRECTIONS

3206.1 The Department shall specify on the inspection report form the time frame for correction of violations as specified in sections 3212, and 3214.

3207 REPORT OF FINDINGS — ISSUING REPORT AND OBTAINING ACKNOWLEDGMENT OF RECEIPT

3207.1 At the conclusion of the inspection, the Department shall provide a copy of the completed inspection report and the notice to correct violations to the licensee or dealer, and request a signed acknowledgment of receipt. The inspection report shall contain a listing of violations by area in the operation and inspection item with corresponding citations to applicable Code provisions.

3208 REPORT OF FINDINGS — REFUSAL TO SIGN ACKNOWLEDGMENT

3208.1 The Department shall inform a person who declines to sign an acknowledgment of receipt of inspection findings that:

- (a) An acknowledgment of receipt is not an agreement with the finding;
- (b) Refusal to sign an acknowledgment of receipt will not affect the licensee's or dealer's obligation to correct the violations noted in the inspection report within the time frames specified; and
- (c) A refusal to sign an acknowledgment of receipt will be noted in the inspection report for the food processing operation.

3209 DEPARTMENT RECORDS REQUIREMENTS

3209.1 The Department shall keep and maintain a record of each inspection made of any food processing operation within the District for a period of three (3) years.

3209.2 The Department shall maintain annual records of the following information:

- (a) Total number of licensed or certified food processing operations by category;
- (b) Number of inspections by category;
- (c) Number of reinspections by category;
- (d) Number of hearings;
- (e) Number of license or dealer certification suspensions by category;
- (f) Number of license or dealer certification revocations by category;

- (g) Number and types of adulterated or misbranded foods or foods originating from unapproved sources that were officially tagged or marked subject to embargo orders;
- (h) Number and types of equipment, utensils, or food-packing materials that did not meet the requirements of this Code and were officially tagged or marked subject to condemnation orders; and
- (i) Number of general complaints investigated and the outcomes.

3210 IMMINENT HEALTH HAZARD – CEASING OPERATIONS AND EMERGENCY REPORTING

3210.1 A licensee or dealer shall immediately discontinue operations and notify the Department if an imminent health hazard may exist because of an emergency, such as:

- (a) A fire;
- (b) A flood;
- (c) An extended interruption of electrical or water service;
- (d) A sewage backup;
- (e) A misuse of poisonous or toxic materials;
- (f) The onset of an apparent foodborne illness outbreak;
- (g) A gross unsanitary occurrence or condition; or
- (h) Other circumstances that may endanger public health.

3211 IMMINENT HEALTH HAZARD – RESUMPTION OF OPERATIONS

3211.1 If operations are discontinued as specified in section 3210 or otherwise according to District laws and regulations, the licensee or dealer shall obtain approval from the Department before resuming operations.

3211.2 A licensee or dealer need not discontinue operations in a food processing area that is unaffected by the imminent health hazard as determined by the Department or other District agency.

3212 CRITICAL VIOLATION – TIME FRAME FOR CORRECTION

- 3212.1 A licensee or dealer shall, at the time of inspection, correct a critical violation of this Code and implement corrective action for a HACCP Plan requirement that is not in compliance with its critical limit(s) in accordance with sections 801.2, 2501 and 2502, except as specified in section 3212.3 and 3501.3.
- 3212.2 A dealer shall correct a critical violation at the time of the inspection, or shall cease production of the contaminated or adulterated product affected by the violation in accordance with section 3501.3.
- 3212.3 The Department may consider the nature of the potential hazard involved and the complexity of the corrective action needed and agree to specify a longer timeframe, not to exceed five (5) business days after the inspection, for the licensee or dealer to correct a critical violation of this Code or HACCP Plan deviations.
- 3212.4 Failure to correct violations in accordance with this section may subject a licensee or dealer to an embargo order pursuant to section 3503, a condemnation order pursuant to section 3510, summary suspension of a license or dealer certification pursuant to section 3516, revocation or suspension of a license or dealer certification pursuant to section 3521, civil penalties pursuant to section 3522, and judicial remedies pursuant to section 3525.

3213 CRITICAL VIOLATION – VERIFICATION AND DOCUMENTATION OF CORRECTION

- 3213.1 After observing at the time of inspection a correction of a critical violation, the Department shall enter the violation and information about the corrective action on the inspection report.
- 3213.2 After receiving notification that the licensee or dealer has corrected a critical violation, the Department shall verify correction of the violation, document the information on an inspection report, and enter the report in the Department's records.

3214 NONCRITICAL VIOLATION – TIME FRAME FOR CORRECTION

- 3214.1 The licensee or dealer shall correct noncritical violations by a date and time agreed to or specified by the Department but no later than thirty (30) business days after the inspection, except as specified in section 3214.2.

3214.2 The Department may approve a compliance schedule that extends beyond the time limits specified in section 3214.1 if the licensee or dealer submits a written schedule of compliance and no health hazard exists or will result from allowing an extended schedule for compliance.

3214.3 Failure to correct violations in accordance with this section may result in the revocation or suspension of a license or certification pursuant to section 3521, issuance of civil penalties pursuant to section 3522, and the imposition of judicial remedies pursuant to section 3525.

3215 REQUEST FOR REINSPECTION

3215.1 If a license or dealer certification is summarily suspended pursuant to section 3516 or suspended or revoked pursuant to 3521 because of violations of this Code, the licensee or dealer shall submit a written request for reinspection.

3215.2 Upon receipt of a request for reinspection, the Department shall perform the reinspection of the food processing operation within three (3) business days of receipt of the request.

3215.3 A food processing operation shall not resume operations or remove from public view any warning or current inspection results as specified in sections 3104.3 and 3108.2 until the Department has reinspected the food processing operation and certified that it is in compliance with this Code.

CHAPTER 33 PREVENTION OF FOODBORNE DISEASE TRANSMISSION BY EMPLOYEES

3300 INVESTIGATION AND CONTROL — OBTAINING INFORMATION, ILLNESSES

3300.1 The Department shall, when it has probable cause to believe that a food employee has transmitted a disease, is infected with a disease in a communicable form that is transmissible through food, is a carrier of an infectious agent that causes a disease that is transmissible through food, or is affected with a boil, an infected wound, or acute respiratory infection:

- (a) Secure a confidential medical history of the employee or make other investigations as deemed appropriate; and
- (b) Require appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected employee and other employees.

3301 INVESTIGATION AND CONTROL — RESTRICTION OR EXCLUSION OF FOOD EMPLOYEE OR SUMMARY SUSPENSION OF LICENSE OR DEALER CERTIFICATION

3301.1 Based on the findings of an investigation related to a food employee who is suspected of being infected or diseased, or a carrier of an infectious agent that causes a disease that is transmissible through food, the Department may issue an order to the suspected employee, or licensee or dealer instituting one (1) or more of the following control measures:

- (a) Restricting the food employee's services to specific areas and tasks in a food processing operation that present no risk of transmitting the disease;
- (b) Excluding the food employee from a food processing operation; or
- (c) Closing the food processing operation by summarily suspending a license or dealer certification in accordance with this Code.

3302 INVESTIGATION AND CONTROL — RESTRICTION OR EXCLUSION ORDER

3302.1 Based on the findings of the investigation specified in section 3300 and to control disease transmission, the Department may issue an order of restriction or exclusion to a suspected food employee or the licensee or dealer without prior warning, notice of a hearing, or a prior hearing if the order recites:

- (a) The reasons for the restriction or exclusion that is ordered;
- (b) The requirement that the food employee or the licensee or dealer shall provide evidence demonstrating that the reasons for the restriction or exclusion have been eliminated;
- (c) That the suspected food employee or the licensee or dealer may request a hearing by submitting a timely request as provided in section 3700 of this Code; and
- (d) The name and address of the Department representative to whom a request for a hearing may be made.

3303 INVESTIGATION AND CONTROL — RELEASE OF FOOD EMPLOYEE FROM RESTRICTION OR EXCLUSION

3303.1 The Department shall release a food employee who was infected with *Salmonella* Typhi from restriction or exclusion if the food employee's stools are negative for *Salmonella* Typhi based on testing of at least three (3) consecutive stool specimen cultures that are taken:

- (a) Not earlier than one (1) month after onset;
- (b) At least forty-eight (48) hours after discontinuance of antibiotics; and
- (c) At least twenty-four (24) hours apart.

3303.2 If one (1) of the cultures taken as specified in section 3303.1 is positive, repeat cultures are to be taken at intervals of one (1) month until at least three (3) consecutive negative stool specimen cultures are obtained.

3303.3 The Department shall release a food employee who was infected with *Shigella* spp. or Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli* from restriction or exclusion according to this Code if the food employee's stools are negative for *Shigella* spp. or Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli* based on testing of two (2) consecutive stool specimen cultures that are taken:

- (a) Not earlier than forty-eight (48) hours after discontinuance of antibiotics; and
- (b) At least twenty-four (24) hours apart.

3303.4 The Department shall release a food employee who was infected with hepatitis A virus from restriction or exclusion if:

- (a) Symptoms cease; or
- (b) At least two (2) blood tests show falling liver enzymes.

CHAPTER 34 NOTICES**3400 SERVICE OF NOTICE — PROPER METHODS**

3400.1 A notice issued in accordance with this Code shall be deemed properly served if it is served by one of the following methods:

- (a) The notice is personally served by the Department, a law enforcement officer, or person authorized to serve civil process and service is made to the licensee, dealer, or person operating a food processing operation without a license or dealer certification;
- (b) The notice is sent by the Department to the last known address of the licensee, dealer, or person operating a food processing operation without a license or dealer certification by other public means so that a written acknowledgment of receipt may be acquired; or
- (c) For civil infraction penalties, the notice is provided by the Department in accordance with the procedures stated in section 3102 of Title 16 of the District of Columbia Municipal Regulations.

3401 SERVICE OF NOTICE — RESTRICTION OR EXCLUSION, EMBARGO, CONDEMNATION, OR SUMMARY SUSPENSION ORDERS

3401.1 An employee restriction or exclusion order, embargo order, condemnation order, or a summary suspension order shall be:

- (a) Served as specified in section 3400.1(a); or
- (b) Clearly posted by the Department at a public entrance to the food processing operation and a copy of the notice sent by first class mail to the licensee, dealer, or the owner or custodian of the food processing operation, as appropriate.

3402 SERVICE OF NOTICE — WHEN NOTICE IS EFFECTIVE

3402.1 Service is effective at the time of the notice's receipt or if service is made as specified in section 3401.1(b), at the time of the notice's posting.

3403 SERVICE OF NOTICE — PROOF OF PROPER SERVICE

3403.1 Proof of proper service may be made by certificate of service signed by the person making service or by admission of a return receipt, certificate of mailing, or a written acknowledgment signed by the licensee, dealer, the person operating a food processing operation without a license or dealer certification, or an authorized agent.

CHAPTER 35 REMEDIES**3500 CRITERIA FOR SEEKING REMEDIES — CONDITIONS WARRANTING REMEDY**

3500.1 The Department may seek an administrative or judicial remedy to achieve compliance with the provisions of this Code if a licensee, dealer, or person operating a food processing operation, or employee:

- (a) Fails to have a valid license or dealer certification as specified in section 3100;
- (b) Violates any term or condition of a license or dealer certification as specified in section 3108;
- (c) Fails to allow the Department access to a food processing operation as specified in section 3200;
- (d) Fails to comply with directives of the Department including time frames for corrective actions specified in inspection reports, orders, or warnings issued by the Department as specified in sections 3212 and 3214;
- (e) Fails to comply with a Department order issued as specified in section 3302 concerning an employee suspected of having a disease transmissible through food by an infected person;
- (f) Engages in prohibited conduct or practices as specified in chapter 36;
- (g) Fails to comply with an embargo or condemnation order as specified in this chapter;
- (h) Fails to comply with a summary suspension order by the Department as specified in this chapter; or
- (i) Fails to comply with an order issued as a result of an administrative hearing.

3500.2 The Department may simultaneously use one or more of the remedies listed in this chapter to address a violation of this Code.

3501 CRITERIA FOR SEEKING REMEDIES — CONDITIONS WARRANTING REMEDY, SHELLFISH-PROCESSING OPERATIONS

- 3501.1 The Department may seek an administrative or judicial remedy, or any combination thereof, to achieve compliance with the provisions of this Code if a person operating a shellfish-processing operation or employee fails to comply with sections 3500 or 3501.2 through 3501.4.
- 3501.2 When a dealer has failed to meet a compliance schedule as specified in sections 3212 and 3214, the Department shall determine whether it is appropriate to:
- (a) Revise an existing compliance schedule;
 - (b) Close the shellfish-processing operation by summarily suspending a dealer's certification; or
 - (c) Take action to revoke or suspend a dealer's certification.
- 3501.3 When any inspection detects a critical violation:
- (a) The violation shall be corrected during that inspection; or
 - (b) The dealer shall cease production of the contaminated or adulterated product affected by the violation.
- 3501.4 When a dealer fails to comply with section 3501.3, the Department shall summarily suspend the dealer's certification and immediately begin action to suspend or revoke the dealer's certification.
- 3501.5 The Department shall prevent the release of contaminated or adulterated products affected by a critical violation by:
- (a) Detaining or seizing any undistributed lots of shellfish that may have been adulterated in accordance with section 3503;
 - (b) Requiring the dealer to initiate a recall of any distributed shellfish in accordance with section 1100.2; and
 - (c) Notifying immediately the enforcement officials for FDA and any other jurisdiction where the product was distributed.
- 3501.6 Except for critical violations described in section 3501.3, when new violations that were not included in a compliance schedule are observed

during an inspection, the Department shall work with the dealer to develop a compliance schedule to correct the new violations.

- 3501.7 When four (4) or more new critical violations are observed during an inspection, the Department may:
- (a) Revise an existing compliance schedule;
 - (b) Close the shellfish-processing operation by summarily suspending a dealer's certification; or
 - (c) Take action to revoke or suspend a dealer's certification.
- 3501.8 The Department shall document its reasons for revising a compliance schedule or imposing other administrative remedies.
- 3502 ADMINISTRATIVE — EXAMINING, SAMPLING, AND TESTING FOOD**
- 3502.1 The Department may collect samples, without cost, and examine them as necessary to determine compliance with this Code.
- 3503 ADMINISTRATIVE — EMBARGO ORDER, JUSTIFYING CONDITIONS AND REMOVAL OF FOOD**
- 3503.1 A duly authorized agent of the Department may embargo and forbid the sale of, or cause to be destroyed, any food it finds or has probable cause to believe:
- (a) May be unsafe, adulterated, or not honestly presented;
 - (b) Is not prepared, processed, handled, packaged, transported, held, or stored in compliance with this Code;
 - (c) Originated from an unapproved source;
 - (d) Is not labeled according to law, or if raw molluscan shellfish, is not tagged or labeled, and documented and recorded as specified in chapter 24; or
 - (e) Is otherwise not in compliance with this Code.
- 3503.2 The Department shall permit storage of the embargoed food under conditions specified in section 3506.2, unless storage is not possible without risk to the public health, in which case immediate destruction shall be ordered and accomplished.

3504 ADMINISTRATIVE — EMBARGO ORDER, CONTENTS

3504.1 The embargo order notice shall:

- (a) State that food subject to the order may not be used, sold, moved from the food processing operation, or destroyed without a written release of the order from the Department;
- (b) State the specific reasons for placing the food under the embargo order with reference to the applicable provisions of this Code and the hazard or adverse effect created by the observed condition;
- (c) Completely identify the food subject to the embargo order by the common name, the label information, a container description, the quantity, the Department's tag or identification information, and location;
- (d) State that the licensee or dealer has the right to a hearing and may request a hearing by submitting a timely request in accordance with chapter 37, which shall not stay the Department's imposition of the embargo;
- (e) State that the Department may order the destruction of the food if a timely request for a hearing is not received; and
- (f) Provide the name and address of the Department representative to whom a request for a hearing may be made.

3505 ADMINISTRATIVE — EMBARGO ORDER, OFFICIAL TAGGING OR MARKING OF FOOD

3505.1 The Department shall affix an official tag, label, or other appropriate marking on the food or containers or otherwise conspicuously identify food subject to the embargo order.

3505.2 The official tag, label, or marking required in section 3505.1 shall:

- (a) Give notice that the food is or is suspected of being adulterated or misbranded;
- (b) Give notice that the food has been detained or embargoed for a period not to exceed five (5) business days; and
- (c) Contain a warning to all persons not to remove or dispose of the food, except as specified in section 3506.

3505.3 The tag or other method used to identify a food that is the subject of an embargo order shall include a summary of the provisions specified in section 3504 and shall be signed and dated by the Department.

3506 ADMINISTRATIVE — EMBARGO ORDER, FOOD MAY NOT BE USED OR MOVED

3506.1 A food placed under an embargo order may not be used, sold, served, or moved from the establishment by any person, except as specified in section 3506.2.

3506.2 The Department may allow the licensee or dealer to store the food in an area of the food processing operation if the food is protected from subsequent deterioration and the storage does not restrict operations of the establishment.

3507 ADMINISTRATIVE — EMBARGO ORDER, REMOVING THE OFFICIAL TAG OR MARKING

3507.1 Only the Department may remove embargo order tags, labels, or other appropriate markings from food subject to an embargo order.

3508 ADMINISTRATIVE — EMBARGO ORDER, DESTROYING OR DENATURING FOOD

3508.1 If an embargo order is sustained pursuant to a hearing, or if a timely request for a hearing is not filed, the Department may order the licensee, dealer, or other person who owns or has custody of the food to bring the food into compliance with this Code or to destroy or denature the food under the Department's supervision.

3509 ADMINISTRATIVE — EMBARGO ORDER, WARNING OR HEARING NOT REQUIRED

3509.1 The Department may issue an embargo order to a licensee or dealer, or to a person who owns or controls the food, as specified in section 3503, without prior warning, notice of a hearing, or a prior hearing on the embargo order.

3509.2 The licensee or dealer shall have a right to request a hearing within five (5) business days of receiving an embargo order. The Department shall hold a hearing within seventy-two (72) hours of receipt of a timely request, and shall issue a decision within seventy-two (72) hours after the hearing. The request for a hearing shall not act as a stay of the embargo action.

**3510 ADMINISTRATIVE — CONDEMNATION ORDER, JUSTIFYING
CONDITIONS AND REMOVAL OF EQUIPMENT, UTENSILS AND
FOOD PACKAGING MATERIALS**

3510.1 The Department may condemn and cause to be removed any equipment, utensils, or food packaging materials found in a food processing operation the use of which does not comply with this Code, or that is being used in violation of this Code, or that because of dirt, filth, extraneous matter, insects, corrosion, open seams, or chipped or cracked surfaces is unfit for use.

3511 ADMINISTRATIVE — CONDEMNATION ORDER, CONTENTS

3511.1 The condemnation order shall:

- (a) State that the equipment, utensils or food packaging materials subject to the order may not be used, sold, moved from the food processing operation, or destroyed without a written release of the order from the Department;
- (b) State the specific reasons for placing the equipment, utensils or food packaging materials under the condemnation order with reference to the applicable provisions of this Code and the hazard or adverse effect created by the observed condition;
- (c) Completely identify the equipment, utensils, or food packaging materials subject to the condemnation order by the common name, the label or manufacturer's information, description of the item, the quantity, the Department's tag or identification information, and location;
- (d) State that the licensee or dealer has the right to a hearing and may request a hearing by submitting a timely request in accordance with chapter 37, which request does not stay the Department's imposition of the condemnation order;
- (e) State that the Department may order the destruction, replacement or removal of the equipment, utensils or food packaging materials if a timely request for a hearing is not received; and
- (f) Provide the name and address of the Department representative to whom a request for a hearing may be made.

**3512 ADMINISTRATIVE — CONDEMNATION ORDER, OFFICIAL
TAGGING OR MARKING OF EQUIPMENT, UTENSILS, AND
FOOD PACKAGING MATERIALS**

- 3512.1 The Department shall place a tag, label, or other appropriate marking to indicate the condemnation of equipment, utensils, or food packaging materials that do not meet the requirements of this Code.
- 3512.2 The tag or other method used to identify the equipment, utensils, or food packaging materials that is the subject of a condemnation order shall include a summary of the provisions specified in section 3511 and shall be signed and dated by the Department.

**3513 ADMINISTRATIVE — CONDEMNATION ORDER, EQUIPMENT,
UTENSILS, AND FOOD PACKAGING MATERIALS MAY NOT BE
USED OR MOVED**

- 3513.1 Equipment, utensils or food packaging materials that is subject to a condemnation order may not be used, sold, moved, or otherwise destroyed by any person, except as specified in section 3513.2.
- 3513.2 The Department may allow the licensee or dealer to store the equipment, utensils, or food packaging materials in an area of the food processing operation that does not restrict operations of the establishment.

**3514 ADMINISTRATIVE — CONDEMNATION ORDER, REMOVING
THE OFFICIAL TAG OR MARKING**

- 3514.1 No person shall remove the tag, label, or other appropriate marking except under the direction of the Department as specified in section 3514.2.
- 3514.2 The Department shall issue a notice of release from a condemnation order and shall remove condemnation tags, labels, or other appropriate markings from equipment, utensils and food packaging materials if:
- (a) The condemnation order is vacated; or
 - (b) The licensee or dealer notifies the Department that the equipment, utensils, and food packaging materials have been modified to meet NSF, UL, or ANSI standards and the requirements of this Code, and the Department has conducted a re-inspection.

3515 ADMINISTRATIVE — CONDEMNATION ORDER, WARNING OR HEARING NOT REQUIRED

3515.1 The Department may issue a condemnation order to a licensee or dealer, or to a person who owns or controls the equipment, utensils or food packaging materials as specified in section 3510, without prior warning, notice of a hearing, or a prior hearing on the condemnation order.

3515.2 The licensee or dealer shall have the right to request a hearing within fifteen (15) business days of receiving a Department condemnation order. The Department shall hold a hearing within seventy-two (72) hours of receipt of a timely request, and shall issue a decision within seventy-two (72) hours after the hearing. The request for a hearing shall not act as a stay of the condemnation action.

3516 ADMINISTRATIVE — SUMMARY SUSPENSION OF LICENSE OR DEALER CERTIFICATION, CONDITIONS WARRANTING ACTION

3516.1 The Department may summarily suspend a license or dealer certification to operate a food processing operation if it is denied access to the food processing operation to conduct an inspection, or determines through an inspection, or examination of employees, food, records, or other means as specified in this Code, that an imminent health hazard exists.

3517 ADMINISTRATIVE — CONTENTS OF SUMMARY SUSPENSION NOTICE

3517.1 A summary suspension notice shall state:

- (a) That the license or dealer certification of a food processing operation is immediately suspended and that all operations shall immediately cease;
- (b) The reasons for summary suspension with reference to the provisions of this Code that are in violation;
- (c) The name and address of the Department representative to whom a written request for reinspection may be made and who may certify that reasons for the suspension are eliminated; and
- (d) That the licensee or dealer may request a hearing by submitting a timely request in accordance with section 3700, which request does not stay the Department's imposition of the summary suspension.

3518 ADMINISTRATIVE — SUMMARY SUSPENSION, WARNING OR HEARING NOT REQUIRED

3518.1 The Department may summarily suspend a license or dealer certification as specified in section 3516 by providing written notice as specified in section 3517 of the summary suspension to the licensee or dealer, without prior warning, notice of a hearing, or prior hearing.

3518.2 The licensee or dealer shall have the right to request a hearing within fifteen (15) business days after receiving the Department's summary suspension notice. The Department shall hold a hearing within seventy-two (72) hours of receipt of a timely request, and shall issue a decision within seventy-two (72) hours after the hearing. The request for a hearing shall not act as a stay of the summary suspension.

3519 ADMINISTRATIVE — SUMMARY SUSPENSION, TIME FRAME FOR REINSPECTION

3519.1 After receiving a written request from the licensee or dealer stating that the conditions cited in the summary suspension order no longer exist, the Department shall conduct a reinspection of the food processing operation for which the license or dealer certification was summarily suspended within three (3) business days of receiving the request.

3520 ADMINISTRATIVE — SUMMARY SUSPENSION, TERM OF SUSPENSION, REINSTATEMENT

3520.1 A summary suspension shall remain in effect until the conditions cited in the notice of suspension no longer exist and the Department has confirmed, through re-inspection or other appropriate means, that the conditions cited in the notice of suspension have been eliminated.

3520.2 The suspended license or dealer certification shall be reinstated if the Department determines that the public health hazard or nuisance no longer exists. A notice of reinstatement shall be provided to the licensee or dealer.

3521 ADMINISTRATIVE — REVOCATION OR SUSPENSION OF LICENSE OR DEALER CERTIFICATION

3521.1 Failure to comply with any of the provisions of this Code shall be grounds for the revocation or suspension of any license or dealer certification issued for a food processing operation pursuant to section 8a(c) of the An Act Relating to the adulteration of food and drugs in the District of Columbia, approved May 2, 2002 (D.C. Law 14-116; D.C. Official Code § 48-108.01(c)). When there is a history of repeated violations or where a license

or dealer certification has been previously suspended, the Department may revoke a license or dealer certification, upon a showing of a subsequent violation.

- 3521.2 Before the Department revokes or suspends a license or dealer certification, the licensee or dealer shall be given an opportunity to answer and to be heard on the violations.

3522 ADMINISTRATIVE — CIVIL PENALTIES

- 3522.1 Civil fines, penalties, or related costs may be imposed against any food processing operation, owner, licensee, or dealer for violation of any provision of this Code.

- 3522.2 The Department may impose penalties for violations of any provision of this Code not to exceed \$10,000 for each violation. Each day of any failure to comply with this Code shall constitute a separate offense and the penalties prescribed in this section shall apply to each separate offense in accordance with section 9(b) of An Act Relating to the adulteration of food and drugs in the District of Columbia, approved February 17, 1898 (30 Stat. 248; D.C. Official Code § 48-109(b)).

- 3522.3 Civil fines or penalties imposed pursuant to section 3522.2 shall reflect the severity of the violation and the extent to which it creates an imminent threat to the public health. Maximum amounts shall be limited to egregious or flagrant violations involving gross negligence or carelessness, or violations involving the transmission of communicable diseases through foods, which do not meet the criminal penalty standards in section 3525.

3523 ADMINISTRATIVE — CIVIL PENALTIES, NOTICES OF VIOLATION OR INFRACTIONS

- 3523.1 The notice of violation shall state the nature of the violation and allow a reasonable time for performance of the necessary corrective action.

- 3523.2 If a person fails to comply with the time stated in the notice of violation issued pursuant to this section, the Department shall issue a proposed compliance order, or a proposed cease and desist order, which shall include a statement of the nature of the violation, afford the right to a hearing, allow a reasonable time for compliance with the order, and state any penalties to be assessed for failure to comply with the order.

3524 ADMINISTRATIVE – CIVIL PENALTIES, STORAGE & TRANSPORT OF FOOD

3524.1 A person who knowingly stores or transports food in violation of sections 900, 901, and 903, or chapters 26 and 27, or who knowingly causes food to be stored or transported in violation of sections 900, 901, and 903, or chapters 26 and 27 may be subject to civil or criminal penalties in accordance with sections 3522 or 3525.

3524.2 The Department shall, wherever practical, secure the assistance of other District agencies, including but not limited to the District's Metropolitan Police Department, in identifying and investigating potential violations of section 900, 901, and 903, or chapters 26 and 27.

3525 JUDICIAL – CRIMINAL PENALTIES, INJUNCTIVE RELIEF, IMPRISONMENT

3525.1 Any person who knowingly violates any provision of this Code shall, upon conviction, be punished by a fine not to exceed ten thousand dollars (\$10,000), imprisonment not to exceed one (1) year, or both, for each violation. Each day of any failure to comply with this Code shall constitute a separate offense and the penalties prescribed in this section shall apply to each separate offense in accordance with section 9(c) of the An Act Relating to the adulteration of food and drugs in the District of Columbia, approved February 17, 1898 (30 Stat. 248; D.C. Official Code § 48-109(c)).

CHAPTER 36 PROHIBITED CONDUCT AND PRACTICES**3600 PROHIBITED CONDUCT – GENERAL PROVISIONS**

3600.1 The following activities are prohibited within the District:

- (a) Selling a food or a food product that is adulterated or misbranded;
- (b) Adulterating or misbranding a food or a food product;
- (c) Receiving a food or a food product that is adulterated or misbranded, or selling such an item for pay or otherwise;
- (d) Refusing the Department entry into or inspection of a food processing operation, collection of samples, or copying of any record as specified in section 3200.2;

- (e) Refusing the Department access to any part, portion or area of a food processing operation as required by section 3200.2;
- (f) Using any mark, stamp, tag, label, or other identification device that is not authorized or not required by this Code;
- (g) Using, removing, selling, serving or otherwise disposing of any embargoed food in violation of section 3506, or using, removing or disposing of detained equipment, utensils or food packaging materials in violation of section 3513; and
- (h) Altering, mutilating, destroying, obliterating, or removing all or any part of the labeling of, or performing any other act with respect to a food if the act is done while the article is held for sale and results in the article being misbranded.

3600.2 It shall be unlawful to resell, to offer for resale, or to distribute for resale within the District any food processed in a food processing operation that has not obtained a license in accordance with section 3100.1 after receiving notice from the Department that the food is from an unlicensed food processing operation.

3601 PROHIBITED CONDUCT – EGG & EGG PRODUCTS

3601.1 No person shall buy, sell, or transport, offer to buy or sell, or offer or receive for transportation any restricted eggs capable of use as human food, except as authorized in accordance with section 702.

3601.2 No egg handler shall possess with intent to use, or use, any restricted eggs in the preparation of human food, except that such eggs may be so possessed and used in accordance with section 702.

3601.3 No person shall process any egg products, except in accordance with section 702.

3601.4 No person shall buy, sell, or transport, offer to buy or sell, or offer or receive for transportation any egg products required to be inspected under this Code unless they have been so inspected and the egg products are labeled and packaged in accordance with section 702.

3601.5 No person shall forge, alter, detach or destroy any official device, mark, or certificate relating to eggs or egg products.

3601.6 No person shall knowingly possess, without promptly notifying the Department, any official device or any counterfeit, simulated, forged, or

improperly altered official certificate or any device or label relating to eggs or egg products, or any eggs or egg products bearing any counterfeit, simulated, forged, or improperly altered official mark.

3601.7 No person shall knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate as prohibited under section 702.

3601.8 No person shall knowingly represent that any egg or egg product has been inspected or exempted under this Code when in fact it has not been so inspected or exempted.

3602 PROHIBITED PRACTICES – MISBRANDING, FALSE LABEL

3602.1 A food shall be deemed to be misbranded if:

- (a) Its labeling is false or misleading;
- (b) It is offered for sale under the name of another food;
- (c) It is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated; or
- (d) Its container is so made, formed or filled as to be misleading.

3603 PROHIBITED PRACTICES – PACKAGED FOOD, MISBRANDING

3603.1 If a food is in a packaged form it shall be deemed to be misbranded, unless it bears a label containing:

- (a) The name and place of business of the manufacturer, packer, or distributor; and
- (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that reasonable variations shall be permitted under this section.

3604 PROHIBITED PRACTICES – MISBRANDING, LACK OF PROMINENT LABEL

3604.1 A food shall be deemed to be misbranded if any word, statement, or other information required by this Code to appear on the food's label is not prominently placed on the label 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.

3605 PROHIBITED PRACTICES – MISBRANDING, FAILURE TO SHOW USUAL NAME AND INGREDIENTS

3605.1 A food shall be deemed to be misbranded unless its label bears:

- (a) The common or usual name of the food, if any; and
- (b) If the food is fabricated from two or more ingredients, the common or usual name of each ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each. Compliance with this section shall not be required if compliance is impractical or would result in deception or unfair competition.

3606 PROHIBITED PRACTICES – PERISHABLE PACKAGED FOOD, REPACKAGING TO SUBSTITUTE FOR ORIGINAL DATE, EXCEPTION

3606.1 No person shall sell, trade, or barter any perishable packaged food beyond the pull date appearing thereon.

3606.2 No person shall rewrap or repackage any packaged perishable food with the intention of placing a pull date on the food that is different from the original pull date.

CHAPTER 37 HEARING ADMINISTRATION

3700 ADMINISTRATIVE – NOTICE, REQUEST FOR HEARING, BASIS AND TIME FRAME

3700.1 A person who receives a notice of hearing for an administrative remedy as specified in this chapter and elects to respond to the notice shall file a response to the notice within seven (7) calendar days after service.

3700.2 In response to an adverse administrative action, a licensee or dealer may submit a written request for a hearing to the Department within fifteen (15) calendar days of the receipt of notice of adverse action.

3700.3 A hearing request shall not stay the Department's restriction or exclusion of employees specified in sections 3301 and 3302, an embargo order as specified in section 3503, a condemnation order as specified in section 3510, or the imposition of a summary suspension as specified in section 3516.

**3701 ADMINISTRATIVE — HEARINGS ADMINISTRATION —
CONTENTS OF RESPONSE TO HEARING NOTICE, OR HEARING
REQUEST**

- 3701.1 A response to a hearing notice shall be in writing and contain the following:
- (a) An admission or denial of each allegation of fact;
 - (b) A statement as to whether the respondent waives the right to a hearing;
 - (c) A statement of defense, mitigation, or explanation concerning any allegation of fact if any;
 - (d) A request to the Department for a settlement of the proceeding by consent agreement, (if the Department provides this opportunity); and
 - (e) The name and address of the respondent's legal counsel, if any.

- 3701.2 A request for hearing shall be in writing and contain the following:
- (a) An admission or denial of each allegation of fact;
 - (b) A statement of defense, mitigation, denial, or explanation concerning each allegation of fact; and
 - (c) The name and address of the requester's legal counsel, if any.

**3702 ADMINISTRATIVE — HEARINGS ADMINISTRATION,
TIMELINESS**

- 3702.1 The Department shall afford a hearing within seventy-two (72) hours after receiving a written request for a hearing from:
- (a) A person who is excluded by the Department from working in a food processing operation as specified in sections 3301 and 3302;
 - (b) A licensee, dealer, or person who is subject to an embargo order as specified in sections 3503 or a condemnation order as specified in sections 3510;
 - (c) A person whose license or certification is summarily suspended as specified in sections 3516; or
 - (d) A person whose license or certification is suspended or revoked as specified in section 3521.

- 3702.2 A licensee, dealer, or person who submits a request for a hearing as specified in section 3700.2 may waive the expedited hearing in a written request to the Department.

CHAPTER 38 JUDICIAL REVIEW

3800 JUDICIAL REVIEW — APPEALS

- 3800.1 Any person aggrieved by a final order or decision of the Department may seek judicial review in accordance section 9(e) of the An Act Relating to the adulteration of food and drugs in the District of Columbia, approved February 17, 1898 (30 Stat. 248; D.C. Official Code § 48-109(e)).

CHAPTER 39 SCHEDULE OF FEES & SERVICES

RESERVED

CHAPTER 99 DEFINITIONS

9900 GENERAL PROVISIONS

- 9900.1 The terms and phrases used in this title shall have the meanings set forth in this Chapter, unless the text or context of the particular chapter, section, subsection, or paragraph provides otherwise.

9901 DEFINITIONS

Acid foods – foods that have a natural pH of four and six tenths (4.6) or below.

Acidified foods – low-acid foods to which acid(s) or acid food(s) are added. Acidified foods include, but are not limited to beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish. Singly or in any combination they have water activity (a_w) greater than eighty-five hundredths (0.85) and have a finished equilibrium pH of four and six tenths (4.6) or below. These foods may be called pickled, such as "pickled cauliflower." Acidified foods do not include carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and non-standardized food dressings and condiment sauces) that contain small amounts of low-acid food and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, or foods that are stored, distributed, and retailed under refrigeration.

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

Adulterated food – consists of any of the following:

- (a) Food that:
 - (1) Has been manufactured under such conditions that it is unfit for food; or if the food has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health within the meaning of 9 CFR 331.5 – Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of products; application of regulations; or 21 CFR 114.5 – Current good manufacturing practice; and
 - (2) Is covered by specific regulations for good manufacturing practices; or
- (b) A food, including egg or egg product, that:
 - (1) Bears or contains any poisonous or deleterious substance which may render it injurious to health; but if the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;
 - (2) 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 9 CFR 301.2 – Definitions;
 - (3) Is, in whole or part, a raw agricultural commodity and bears or contains a pesticide chemical which is unsafe within the meaning of 9 CFR 301.2 – Definitions;
 - (4) Bears or contains any food additive which is unsafe within the meaning of 9 CFR 301.2 – Definitions;
 - (5) Consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for human food;

- (6) Consists in whole or in part of any damaged egg or eggs to the extent that the egg meat or white is leaking, or it has been contacted by egg meat or white leaking from other eggs;
- (7) Has been prepared, packaged, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health within the meaning of 21 CFR 114.5 – Current good manufacturing practice;
- (8) Is an egg or the product of any egg that has been subjected to incubation;
- (9) Has been in a container that is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;
- (10) Has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to 9 CFR 381.1 - Definitions; or
- (11) Has any valuable constituent that has been in whole or in part omitted or abstracted from the egg or egg product, or has any substance substituted, wholly or in part for the egg or egg product, or has damage or inferiority that has been concealed in any manner; or has had any substance added to or mixed or packed with the egg or egg product so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Advertisement – a representation made, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of food.

Air gap – the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, plumbing fixture or other device and the flood level rim of that receptacle.

Allergen – foods that are commonly known to cause serious allergenic responses, including, but not limited to, milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, and legumes, particularly peanuts and soybeans.

Anicteric – not accompanied or characterized by jaundice.

Applicant – any person or entity that has submitted an application to the Department for a license or certification to operate a food processing operation or a shellfish operation.

Approved – acceptable to the Department or other regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

Artesian water – bottled water from a well tapping a confined aquifer in which the water level stands above the water table. "Artesian water" shall meet the requirements of "natural water."

Asymptomatic – without obvious symptoms and not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice. An asymptomatic individual may not be showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

Backflow – the flow of water or other liquids, mixtures or substances into the distribution pipes of a potable water supply from any source or sources other than the intended source.

Back siphonage – the flowing back of used, contaminated or polluted water from a plumbing fixture, vessel or other source into potable water supply pipes because of negative pressure in the water supply pipes.

Bottled water – water that is placed in a sealed container or package and is offered for sale for human consumption or other consumer uses.

Capable of use as human food – applies to any egg or egg product unless it is denatured, or otherwise identified, as required by regulations prescribed by the Director, to deter its use as human food.

Certification – the approval issued by the Department to a Molluscan Shellfish Dealer according to the provisions of the NSSP for each location in which the dealer conducts a shellfish operation. Each certification shall contain a certification number that consists of a one to five digit Arabic number preceded by "DC" the two letter abbreviation for the District of Columbia, followed by a two letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this Code using the following terms:

- (a) Shellstock shipper (SS);
- (b) Shucker-packer (SP);
- (c) Repacker (RP); and
- (d) Reshipper (RS).

CFR – the Code of Federal Regulations. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers. For example, 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

Color additive – has the meaning stated in 21 CFR 70.3 Definitions.

Commingle or commingling – the act of combining different lots of shellstock or shucked shellfish.

Compliance schedule – a written schedule that provides a correction time period to eliminate critical and noncritical violations.

Conditional employee – a potential food employee to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food.

Confirmed disease outbreak – a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness; or when two (2) 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; or a single case of illness from botulism or chemical poisoning.

Consumer – a person, who is a member of the public, takes possession of food, does not operate a food processing operation, and does not offer the food for resale. A consumer also includes any person who purchases eggs for his or her own family use or consumption, or any restaurant, hotel, boarding house, bakery, or other institution or concern which purchases eggs for serving to guests or patrons thereof, or for its own use in cooking or baking.

Container – any box, can, tin, plastic, or other receptacle, wrapper, or cover or any bag, sack, tote, conveyance or other receptacle in which food is packaged.

Corrosion-resistant material – a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

Critical Control Point – a point, step or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.

Critical item – a provision of this Code that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or an environmental health hazard. Critical items are denoted in this Code with an asterisk (*).

Critical limit – the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard.

Critical violation – a condition or practice that violates this Code and results in the production of a product that is adulterated, decomposed, misbranded, or unwholesome; or presents a threat to the health or safety of the consumer.

Cross connection – an unprotected actual or potential connection between a potable water system and any source or system containing unapproved water or a substance that is not or cannot be approved as safe and potable. Examples are bypass arrangements, jumper connections, removable sections, swivel or change over devices, or other devices through which backflow could occur.

Cull – to remove dead or unsafe shellstock from a lot of shellstock.

Dealer – any person who engages in, or desires to engage or continue to engage in the activities of shellstock shipper, shucker-packer, repacker, or reshipper of molluscan shellfish according to the provisions of the NSSP.

Department – the District of Columbia Department of Health.

Distilled water – bottled water that has been produced by a process of distillation and meets the definition of purified water in the most recent edition of the United States Pharmacopeia.

Egg – The shell egg of the domesticated chicken, turkey, duck, goose, or guinea, or any other species of fowl. The term does not include a balut, the egg of reptile such as an alligator, or an egg product.

Egg handler – any person who produces, contracts for, or obtains possession or control of eggs for the purpose of sale to another dealer or retailer, or for processing and sale to a dealer, retailer or consumer: The term "sell" or "sale" includes to offer for sale, expose for sale, or to have in one's possession for sale, exchange, barter, trade, or as an inducement for the sale of another product.

Egg product – all or a portion of the contents found inside eggs separated from the shell and pasteurized in a food processing operation, with or without added ingredients, that are intended for human consumption, such as dried, frozen or liquid eggs. Egg products do not include food which contains eggs only in a relatively small proportion such as cake mixes.

Employee – the licensee, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food processing operation.

Enterohemorrhagic *Escherichia coli* (EHEC) – *E. coli* that cause hemorrhagic colitis, meaning bleeding enterically or bleeding from the intestine. The term is typically used in association with *E. coli* that have the capacity to produce Shiga toxins and to cause attaching and effacing lesions in the intestine. EHEC is a subset of Shiga Toxin-producing *E. coli*. (STEC), whose members produce additional virulence factors which include hemorrhagic colitis and hemolytic uremic syndrome (HUS). Examples of serotypes of EHEC include: *E. coli* O157:H7; *E. coli* O157:NM; *E. coli* O26:H11; *E. coli* O145:NM; *E. coli* O103:H2; and *E. coli* O111:NM.

EPA – the United States Environmental Protection Agency.

Equipment – an article that is used in a food processing operation such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine. The term does not include apparatuses used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, or skids.

Exclude – to prevent a person from working as an employee in a food processing operation.

FDA – the United States Food and Drug Administration.

Federal Safe Drinking Water Act – the Safe Drinking Water Act, approved December 16, 1974 (88 Stat. 1660; 42 U.S.C. § 300f *et seq.*).

Federal Food Act – the Federal Food, Drug, and Cosmetic Act, approved June 25, 1938 (52 Stat. 1040; 21 U.S.C. § 301 *et seq.*).

Food – shall have the meaning specified in section 201 of the Federal Food Act (21 U.S.C. § 321).

Food-contact surface – a surface of equipment or a utensil with which food normally comes into contact or a surface of equipment or a utensil from which food may drain, drip, or splash into a food or onto a surface normally in contact with food, including equipment or a surface or utensil that normally comes into direct or indirect contact with shucked shellfish.

Food employee – an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces. This could include the owner, an individual having

supervisory or management duties, person on payroll, family member, volunteer, person performing work under contractual agreement, or any other person working in a food processing plant.

Food operation – the premises, practices, and procedures associated with a specific type of activity within a food processing operation.

Food processing – the handling or processing of food in any manner of preparation for sale for human consumption, except that food processing does not include the handling of fresh fruits or vegetables that are merely washed or trimmed while being prepared or packaged for sale in their natural state.

Food processing operation – any of the following:

- (a) Any premises, plant, establishment, building, room, area, facility and the appurtenances thereto, in whole or in part, where food is prepared, handled or processed in any manner for distribution or sale for resale by retail outlets, restaurants, and any such other facility selling or distributing to the ultimate consumer;
- (b) A commercial operation that manufactures, processes, packages, labels, or stores food for human consumption or provides food for sale or distribution to business entities such as other food processing operations or food establishments as defined in 25 DCMR § 9901. A food processing operation includes a place used for or in connection with commercial food manufacturing, preparation, processing, packaging, canning, freezing, storing, distributing, labeling, or holding. The term includes, but is not limited to bakery plants, confectionery plants, egg processing plants, food manufacturing plants, frozen food manufacturing plants, fresh and frozen seafood processing operations, shellfish processing operations, food storage warehouses, refrigerated lockers, food distribution centers, ice manufacturing plants, soft drink manufacturing plants, bottled water manufacturing plants, breweries, wineries, distilleries, food transfer stations, and meat processing plants that are not subject to regulation by the United States Department of Agriculture; or
- (c) Any custom cannery or processing operation where raw food products, food, or food products are processed for the owner thereof, or the food processing facilities are made available to the owners or persons in control of raw food products or food or food products for processing in any manner.

Food safety hazard – any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

Food storage warehouse – any premise, establishment, building, room area, facility, or place, in whole or in part, where food is stored, kept, or held for wholesale distribution to other wholesalers or to retail outlets, restaurants, and any other facility selling or

distributing food to the ultimate consumer. The term does not include grain elevators or fruit and vegetable storage and packing houses that store, pack, and ship fresh fruit and vegetables.

HACCP – the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods.

HACCP Plan – a written document that delineates formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods, or that a shellfish dealer follows to implement the HACCP requirements set forth in 21 CFR 123.6 as adopted by the ISSC.

IgG – a class of immunoglobulins that include the most common antibodies circulating in the blood, that facilitate the phagocytic destruction of microorganisms foreign to the body, that bind to and activate complement, and that are the only immunoglobulins to cross over the placenta from mother to fetus; an immunoglobulin of the class of IgG.

Imminent health hazard – a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operations to prevent injury based on the number of potential injuries, and the nature, severity, and duration of the anticipated injury.

Inspection item – standard criteria under which single or multiple observations of specific critical or noncritical violations can be debited.

Interstate Certified Shellfish Shippers List (ICSSL) – a monthly FDA publication of shellfish dealers, domestic and foreign, who have been certified by a state or foreign Authority as meeting the public health control measures specified in this Code. An ICSSL Link is accessible through the ICSSL website at <http://www.issc.org/>.

Interstate Shellfish Sanitation Conference (ISSC) – the organization which consists of agencies from shellfish producing and receiving States, FDA, the shellfish industry, the National Marine Fisheries Service of the U.S. Department of Commerce, and the U.S. Environmental Protection Agency. The ISSC provides the formal structure wherein State regulatory authorities, with FDA concurrence, can establish updated guidelines and procedures for sanitary control of the shellfish industry.

Licensee – the holder of a license to operate a food processing operation.

Lot – the food produced during a period of time indicated by a specific code.

Low-acid food – any food, other than an alcoholic beverage, that has a finished equilibrium pH greater than four and six tenths (4.6) and a water activity (a_w) greater than eighty-five hundredths (0.85). Tomatoes and tomato products having a finished equilibrium pH less than four and seven tenths (4.7) are not classed as low-acid foods.

Mineral water – bottled water that contains not less than two hundred and fifty parts per million (250 ppm) total dissolved solids that originate from a geologically and physically protected underground water source. Mineral water is characterized by constant levels and relative proportions of minerals and trace elements at the source. No minerals may be added to mineral water.

National Shellfish Sanitation Program (NSSP) – a Federal, State, Industry voluntary cooperative program that relies on regulatory controls by the State Shellfish Authority to ensure safe molluscan shellfish. The NSSP was developed through a Memorandum of Understanding between the FDA and the ISSC, of which the District of Columbia is a member.

Natural water – bottled spring, mineral, artesian, or well water that is derived from an underground formation. Natural water may be derived from a public water system if that supply has a single source such as an actual spring, artesian well, or pumped well, and has not undergone any treatment that changes its original chemical makeup except ozonization or an equivalent disinfection process.

Person – an association, a corporation, individual, partnership, trustee, government or governmental subdivision, or other legal entity.

Pest – any objectionable animal or insect including, but not limited to birds, rodents, flies, and larvae.

Personal care items – an item or substance that may be poisonous, toxic, or a source of contamination that is used to maintain or enhance a person's health, hygiene or appearance. Personal care items include medicines, first aid supplies, cosmetics, and toiletries such as toothpaste and mouthwash.

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. Values between zero (0) and seven (7) indicate acidity and values between seven (7) and fourteen (14) indicate alkalinity. The value for pure distilled water is seven (7), which is considered neutral.

Physical facilities – the structure and interior surfaces of a food processing operation, including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

Plumbing fixture – a receptacle or device that is permanently or temporarily connected to the water distribution system of the premises and demands a supply from the system or discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

Plumbing system – the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their

respective connections, devices, and appurtenances within the premises; and water-treating equipment.

Poisonous or deleterious substance – a toxic substance occurring naturally or added to the environment for which a regulatory tolerance limit or action level has been established in shellfish to protect public health.

Poisonous or toxic materials – any of the following substances that are not intended for ingestion:

- (a) Cleaners and sanitizers, including cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
- (b) Pesticides, except sanitizers, including insecticides and rodenticides;
- (c) Substances necessary for the operation and maintenance of the food processing operation, such as nonfood grade lubricants and personal care items that may be deleterious to health; and
- (d) Substances that are not necessary for the operation and maintenance of the food processing operation, including but not limited to substances on the premises for retail sale, such as petroleum products and paints.

Potentially hazardous food – any of the following:

- (a) A food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation, including:
 - (1) An animal food that is raw or heat-treated; a plant FOOD that is heat-treated or consists of raw seed sprouts, cut melons, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and
 - (2) Except as specified in section (b)(4) of this definition, a food that because of the interaction of its a_w and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged			
a_w values	<u>pH values</u>		
	4.6 or less	> 4.6 – 5.6	> 5.6
≤ 0.92	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food
>0.92 - .95	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
* PHF means Potentially Hazardous Food ** TCS food means Time/Temperature Control for Safety Food *** PA means Product Assessment required			

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged				
a_w values	<u>pH values</u>			
	< 4.2	4.2 – 4.6	> 4.6 – 5.0	> 5.0
< 0.88	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food
0.88 – 0.90	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
> 0.90 - 0.92	non-PHF/non-TCS food	non-PHF/non-TCS food	PA	PA
> 0.92	non-PHF/non-TCS food	PA	PA	PA
* PHF means Potentially Hazardous Food ** TCS food means Time/Temperature Control for Safety Food *** PA means Product Assessment required				

- (b) The term does not include:
- (1) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled but has been pasteurized to destroy all viable salmonellae;
 - (2) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;
 - (3) A food that because of its pH or a_w value, or interaction of a_w value or pH values, is designated as a non-PHF/non-TCS food in Table A or B of this definition;
 - (4) A food that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:
 - (A) Intrinsic factors, including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;
 - (B) Extrinsic factors, including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use; or
 - (C) A combination of intrinsic and extrinsic factors; or
 - (5) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the sections in (b)(1) through (b)(4) of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

Potable water means a water supply that meets the requirements of 40 CFR Part 141 – National Primary Drinking Water Regulations and District of Columbia drinking water quality standards.

Premises – the physical facility of a food processing operation, its contents, and the contiguous land or property under the control of the licensee or dealer.

Processing – the canning, freezing, drying, dehydrating, cooking, pressing, powdering, packaging, baking, heating, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, jarring, or otherwise processing food, including:

- (a) Manufacturing egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing, drying, or packaging egg products;
- (b) Any operation or combination of operations, whereby poultry is slaughtered, eviscerated, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed but does not include freezing of poultry products, except when freezing is incidental to operations otherwise classed as "processing" under this paragraph;
- (c) Activities that are directly related to the production of juice products but do not include:
 - (1) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and
 - (2) The operation of a retail establishment; and
- (d) Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding of fish or fishery products but does not include:
 - (1) Harvesting or transporting fish or fishery products, without otherwise engaging in processing;
 - (2) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel; and
 - (3) The operation of a retail establishment.

Public health significance – the potential for causing diseases and symptoms, as specified in chapter 3 of this Code that include but are not limited to:

- (a) Diarrhea;
- (b) Fever;
- (c) Jaundice;
- (d) Vomiting

- (e) Sore throat with fever;
- (f) Boils;
- (g) *Salmonella* Typhi;
- (h) *Shigella* spp.;
- (i) Enterohemorrhagic or Shiga Toxin-Producing *Escherichia coli*;
- (j) Hepatitis A virus; or
- (k) Norovirus.

Public water system – a system for the provision to the public of water for human consumption through pipes or, after August 5, 1998, other constructed conveyances, if such system has at least fifteen (15) service connections or regularly serves an average of at least twenty-five (25) individuals daily at least sixty (60) days out of the year including any collection, treatment, storage, and distribution facilities under the control of the operator of such system and used primarily in connection with such system; and any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system.

Pull date – the latest date a packaged food product shall be offered for sale to the public.

Purified water – bottled water produced by distillation, deionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the most recent edition of the United States Pharmacopeia. Water that meets this definition and is vaporized, then condensed, may be labeled "distilled water."

Raw shellfish – shellfish that have not been thermally processed to an internal temperature of one hundred forty-five degrees Fahrenheit (145° F) (sixty-two degrees Centigrade (62 ° C)) or greater for fifteen seconds (15 sec.); or to alter organoleptic characteristics.

Recall – a licensee's or dealer's removal or correction of a marketed product that the FDA or other responsible agency, such as the United States Department of Agriculture, Federal Trade Commission, or United States Customs Service considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery, as defined in 21 CFR 7.3 – Definitions. A recall may be initiated: (1) voluntarily by the firm that has primary responsibility for the manufacture or marketing of the product; or (2) at the request of the FDA or other responsible agency. Information regarding recall activities is shared with state agencies and the Department through daily faxed Recall Notices or other government reports. The state agencies and the Department monitor recall activities

to ensure non-compliant products are removed from the market through recall audit checks.

Refrigerated locker – any place, premises or establishment where facilities for the cold storage and preservation of human food in separate and individual compartments are offered to the public upon a rental or other basis providing compensation to the person offering such services. The term includes chill rooms, sharp freeze rooms and compartments, and locker rooms.

Refuse – solid waste not carried by water through the sewage system.

Repacker – any person, other than the original certified shucker packer, who repackages shucked shellfish into other containers.

Represent – to hold out as or to advertise.

Reshipper – a person who purchases shucked shellfish or shellstock from dealers and sells the product without repacking or relabeling to other dealers, wholesalers, or retailers.

Restrict – to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment or utensils, food contact surfaces, or food-packaging materials.

Restricted egg – any check, dirty egg, incubator reject, inedible, leaker, or loss.

Restricted use pesticide – a pesticide product that contains the active ingredients specified in 40 CFR 152.175 – Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

Retailer or retail establishment – an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption directly to consumers; and includes any person in intrastate commerce who sells eggs to a consumer.

Rework – clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and is suitable for use as food.

Safe materials – articles manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of or otherwise adversely affect the characteristics of any food.

Sanitation control record – a record that documents the monitoring of sanitation practices and conditions during processing.

Sanitization – the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five (5) logs, which is equal to a ninety-nine and nine hundred, ninety-nine thousands of a percent (99.999%) reduction of representative disease microorganisms of public health importance.

Sanitize – the application of a bactericidal treatment which is approved as being effective in destroying microorganisms, including pathogens:

- (a) To adequately treat food contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance substantially reducing the numbers of other undesirable microorganisms and not adversely affecting the product or its safety for the consumer; or
- (b) To treat hands in accordance with the requirements in section 404.

Scheduled process – the process selected by a processor as adequate for use under food manufacturing conditions to achieve and maintain a food that will not permit the growth of microorganisms having public health significance.

Sealed – free of cracks or other openings that allow the entry or passage of moisture.

Service animal – an animal such as a guide dog, signal dog, or other animal trained to provide assistance to an individual with a disability.

Sewage – liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

Shelf life – the length of time during which a packaged food product will retain its safe consumption quality if stored under proper temperature conditions.

Shellfish – all aspects of:

- (a) Oysters, clams, or mussels, whether:
 - (1) Shucked or in the shell;
 - (2) Raw, including post harvest processed;
 - (3) Fresh or frozen; or
 - (4) Whole or in part; and
- (b) Scallops in any form, except when the final product form is the adductor muscle only.

Shellfish dealer – any person who engages in, or desires to engage or continue to engage in the wholesale handling, shipping, or repacking of molluscan shellfish according to the provisions of the NSSP.

Shellstock – live molluscan shellfish in the shell.

Shellstock Shipper (SS) – a dealer who grows, harvests, buys, or repacks and sells shellstock. A shellstock shipper may also ship shucked shellfish. A shellstock shipper is not authorized to shuck shellfish or to repack shucked shellfish.

Shiga toxin-producing *Escherichia coli* (STEC) – any *E. coli* capable of producing Shiga toxins (also called verocytotoxins or “Shiga-like” toxins). Examples of serotypes of STEC include both O157 and non-O157 *E. coli*.

Shucker-Packer (SP) – a person who shucks and packs shellfish. A shucker-packer may act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.

Smooth –

- (a) A food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100) grit number three (3) stainless steel;
- (b) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; or
- (c) A floor, wall, or ceiling having an even or level surface with no roughness or projections that renders it difficult to clean.

Spring water – water derived from an underground formation from which water flows naturally to the surface of the earth. "Spring water" shall meet the requirements of "natural water."

Standard of Identity – a government regulation which establishes the criteria which must be met before foods can be labeled in a certain way.

Supervisor – a licensee or an employee of a licensee who, when present at the food processing operation, is responsible for the food processing operation or for the food processing operation's compliance with some or all of the provisions of this Code.

Temperature measuring device – a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

Transaction record – the form or forms used to document each purchase or sale of shellfish at the wholesale level, including shellfish harvest and sales records, ledgers, purchase records, invoices and bills of lading.

USDA – the United States Department of Agriculture.

Utensil – a food-contact implement or container used in the storage, preparation, transportation; dispensing; sale or service of food including kitchenware or tableware that is multiuse, single-service, or single-use; gloves used in contact with food; temperature sensing probes or measuring devices; and probe-type price or identification tags used in contact with food.

Vehicle – a commercial vehicle or commercial vessel which has a gross weight of more than ten thousand pounds, is used to transport property, and is a motor vehicle, motor truck, trailer, railroad car, or vessel.

Warewashing – the cleaning and sanitizing of utensils and the food-contact surfaces of equipment.

All persons wishing to comment on these proposed rules should submit written comments no later than thirty (30) days after publication of this notice in the *D.C. Register*, to the Department of Health, Office of the General Counsel, 825 North Capitol Street, N.E., Room 4122, Washington, D.C. 20002. Copies of the proposed rules may be obtained, at cost, at the same address during the hours of 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays.