(C) If time without temperature control is used as the public health control up to a maximum of 6 hours:

Time – maximum up to 6 hours

(1) The FOOD shall have an initial temperature of 5ºC (41ºF) or less when removed from temperature control and the FOOD temperature may not exceed 21ºC (70ºF) within a maximum time period of 6 hours; P

(2) The FOOD shall be monitored to ensure the warmest portion of the FOOD does not exceed 21ºC (70ºF) during the 6-hour period, *unless an ambient air temperature is maintained that ensures the FOOD does not exceed 21ºC (70ºF) during the 6-hour holding period*; Pf

(3) The FOOD shall be marked or otherwise identified to indicate: Pf

(a) The time when the FOOD is removed from 5ºC (41ºF) or less cold holding temperature control, Pf and

(b) The time that is 6 hours past the point in time when the FOOD is removed from cold holding temperature control; Pf

(4) The FOOD shall be:

(a) Discarded if the temperature of the FOOD exceeds 21°C (70°F), P or

(b) Cooked and served, served at any temperature if READY-TO-EAT, or discarded within a maximum of 6 hours from the point in time when the FOOD is removed from 5ºC (41ºF) or less cold holding temperature control; P and

(5) The FOOD in unmarked containers or PACKAGES, or marked with a time that exceeds the 6-hour limit shall be discarded. P

(D) A FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION may not use time as specified under ¶¶ (A), (B) or (C) of this section as the public health control for raw EGGS.

Specialized Processing Methods

3-502.11 Variance Requirement.

A FOOD ESTABLISHMENT shall obtain a VARIANCE from the REGULATORY AUTHORITY as specified in § 8-103.10 and under § 8-103.11 before: Pf

(A) Smoking FOOD as a method of FOOD preservation rather than as a method of flavor enhancement; Pf

(B) Curing FOOD; Pf

(C) Using FOOD ADDITIVES or adding components such as vinegar: Pf

(1) As a method of FOOD preservation rather than as a method of flavor enhancement, Pf or

(2) To render a FOOD so that it is not POTENTIALLY HAZARDOUS (TIME/TEMPERATURE CONTROL OF SAFETY FOOD); Pf

(D) Packaging FOOD using a REDUCED OXYGEN PACKAGING method *except where the growth of and toxin formation by* ***Clostridium botulinum*** *and the growth of* ***Listeria monocytogenes*** *are controlled as specified under § 3-502.12*; Pf

(E) Operating a MOLLUSCAN SHELLFISH life-support system display tank used to store or display shellfish that are offered for human consumption; Pf

(F) Custom processing animals that are for personal use as FOOD and not for sale or service in a FOOD ESTABLISHMENT; Pf

(G) Preparing FOOD by another method that is determined by the REGULATORY AUTHORITY to require a VARIANCE; Pf or

(H) Sprouting seeds or beans. Pf

Clostridium botulinum and Listeria monocytogenes Controls

3-502.12 Reduced Oxygen Packaging Without a Variance, Criteria.

(A) Except for a FOOD ESTABLISHMENT that obtains a VARIANCE as specified under § 3-502.11, a FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall control the growth and toxin formation of ***Clostridium botulinum*** and the growth of ***Listeria monocytogenes***. P

(B) A FOOD ESTABLISHMENT that PACKAGES POTENTIALLY HAZARDOUS FOOD (TIME/TEMPERATURE CONTROL FOR SAFETY FOOD) using a REDUCED OXYGEN PACKAGING method shall have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and that: Pf

(1) Identifies the FOOD to be PACKAGED; Pf

(2) Except as specified under ¶¶ (C) - (E) of this section, requires that the PACKAGED FOOD shall be maintained at 5°C (41°F) or less and meet at least one of the following criteria: Pf

(a) Has an A_W of 0.91 or less, Pf

(b) Has a pH of 4.6 or less, Pf

(c) Is a MEAT or POULTRY product cured at a FOOD PROCESSING PLANT regulated by the USDA using substances specified in 9 CFR 424.21, Use of food ingredients and sources of radiation, and is received in an intact PACKAGE, Pf or

(d) Is a FOOD with a high level of competing organisms such as raw MEAT, raw POULTRY, or raw vegetables; Pf

(3) Describes how the PACKAGE shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to: Pf

(a) Maintain the FOOD at 5°C (41°F) or below, Pf and

(b) Discard the FOOD if within 14 calendar days of its PACKAGING it is not served for on-PREMISES consumption, or consumed if served or sold for off-PREMISES consumption; Pf

(4) Limits the refrigerated shelf life to no more than 14 calendar days from PACKAGING to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first; P

(5) Includes operational procedures that:

(a) Prohibit contacting READY-TO-EAT FOOD with bare hands as specified under ¶ 3-301.11(B), Pf

(b) Identify a designated work area and the method by which: Pf

(i) Physical barriers or methods of separation of raw FOODS and READY-TO-EAT FOODS minimize cross contamination, Pf and

(ii) Access to the processing EQUIPMENT is limited to responsible trained personnel familiar with the potential HAZARDS of the operation, Pf and

(c) Delineate cleaning and SANITIZATION procedures for FOOD-CONTACT SURFACES; Pf and

(6) Describes the training program that ensures that the individual responsible for the REDUCED OXYGEN PACKAGING operation understands the: Pf

(a) Concepts required for a safe operation, Pf

(b) EQUIPMENT and facilities, Pf and

(c) Procedures specified under Subparagraph (B)(5) of this section and ¶ 8-201.14(D). Pf

Fish

(C) *Except for FISH that is frozen before, during, and after PACKAGING*, a FOOD ESTABLISHMENT may not PACKAGE FISH using a REDUCED OXYGEN PACKAGING method. P

Cook-Chill or Sous Vide

(D) Except as specified under ¶ (C) of this section, a FOOD ESTABLISHMENT that PACKAGES FOOD using a cook-chill or sous vide process shall:

(1) Implement a HACCP PLAN that contains the information as specified under ¶ 8-201.14(D); Pf

(2) Ensure the FOOD is:

(a) Prepared and consumed on the PREMISES, or prepared and consumed off the PREMISES but within the same business entity with no distribution or sale of the PACKAGED product to another business entity or the CONSUMER, Pf

(b) Cooked to heat all parts of the FOOD to a temperature and for a time as specified under § 3-401.11, P

(c) Protected from contamination before and after cooking as specified under Parts 3-3 and 3-4, P

(d) Placed in a PACKAGE with an oxygen barrier and sealed before cooking, or placed in a PACKAGE and sealed immediately after cooking and before reaching a temperature below 57°C (135°F), P

(e) Cooled to 5°C (41°F) in the sealed PACKAGE or bag as specified under § 3-501.14 and subsequently: P

(i) *Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F) and held*

at that temperature until consumed or discarded within 30 days after the date of PACKAGING;[P]

(ii) *Cooled to 1°C (34°F) within 48 hours of reaching 5°C (41°F), removed from refrigeration equipment that maintains a 1°C (34°F) food temperature and then held at 5°C (41°F) or less for no more than 72 hours, at which time the* FOOD *must be consumed or discarded*; [P]

(iii) *Cooled to 3°C (38°F) or less within 24 hours of reaching 5°C (41°F) and held there for no more than 72 hours from* PACKAGING*, at which time the food must be consumed or discarded*; [P] or

(iv) Held frozen with no shelf life restriction while frozen until consumed or used. [P]

(f) Held in a refrigeration unit that is equipped with an electronic system that continuously monitors time and temperature and is visually examined for proper operation twice daily, [Pf]

(g) If transported off-site to a satellite location of the same business entity, equipped with verifiable electronic monitoring devices to ensure that times and temperatures are monitored during transportation, [Pf] and

(h) Labeled with the product name and the date PACKAGED;[Pf] and

(3) Maintain the records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP PLAN and:

(a) Make such records available to the REGULATORY AUTHORITY upon request, [Pf] and

(b) Hold such records for at least 6 months; [Pf] and

(4) Implement written operational procedures as specified under Subparagraph (B)(5) of this section and a training program as specified under Subparagraph (B)(6) of this section.[Pf]

(E) A FOOD ESTABLISHMENT that PACKAGES cheese using a REDUCED OXYGEN PACKAGING method shall:

Cheese

(1) Limit the cheeses PACKAGED to those that are commercially manufactured in a FOOD PROCESSING PLANT with no ingredients added in the FOOD ESTABLISHMENT and that meet the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR 133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses; [P]

(2) Have a HACCP PLAN that contains the information specified under ¶ 8-201.14(D) and as specified under ¶¶ (B)(1), (B)(3)(a), (B)(5) and (B)(6) of this section; [Pf]

(3) Labels the PACKAGE on the principal display panel with a "use by" date that does not exceed 30 days from its packaging or the original manufacturer's "sell by" or "use by" date, whichever occurs first; [Pf] and

(4) Discards the REDUCED OXYGEN PACKAGED cheese if it is not sold for off-PREMISES consumption or consumed within 30 calendar days of its PACKAGING. [Pf]

3-6 Food Identity, Presentation, and On-premises Labeling

Subparts

3-601 Accurate Representation

3-602 Labeling

3-603 Consumer Advisory

Accurate Representation

3-601.11 Standards of Identity.

PACKAGED FOOD shall comply with standard of identity requirements in 21 CFR 131-169 and 9 CFR 319 Definitions and standards of identity or composition, and the general requirements in 21 CFR 130 – Food Standards: General and 9 CFR 319 Subpart A – General.

3-601.12 Honestly Presented.

(A) FOOD shall be offered for human consumption in a way that does not mislead or misinform the CONSUMER.

(B) FOOD or COLOR ADDITIVES, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a FOOD.

Labeling

3-602.11 Food Labels.

(A) FOOD PACKAGED in a FOOD ESTABLISHMENT, shall be labeled as specified in LAW, including 21 CFR 101 - Food labeling, and 9 CFR 317 Labeling, marking devices, and containers.

(B) Label information shall include:

(1) The common name of the FOOD, or absent a common name, an adequately descriptive identity statement;

(2) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the FOOD;

(3) An accurate declaration of the quantity of contents;

(4) The name and place of business of the manufacturer, packer, or distributor; and

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient (Effective January 1, 2006). Pf

(6) Except as exempted in the Federal Food, Drug, and Cosmetic Act § 403(Q)(3) - (5), nutrition labeling as specified in 21 CFR 101 - Food Labeling and 9 CFR 317 Subpart B Nutrition Labeling.

(7) For any salmonid FISH containing canthaxanthin as a COLOR ADDITIVE, the labeling of the bulk FISH container, including a list of ingredients, displayed on the retail container or by other written means, such as a counter card, that discloses the use of canthaxanthin.

(C) Bulk FOOD that is available for CONSUMER self-dispensing shall be prominently labeled with the following information in plain view of the CONSUMER:

(1) The manufacturer's or processor's label that was provided with the FOOD; or

(2) A card, sign, or other method of notification that includes the information specified under Subparagraphs (B)(1), (2), and (5) of this section.

(D) *Bulk, unPACKAGED FOODS such as bakery products and unPACKAGED FOODS that are portioned to CONSUMER specification need not be labeled if:*

(1) *A health, nutrient content, or other claim is not made;*

(2) *There are no state or local LAWS requiring labeling; and*

(3) *The FOOD is manufactured or prepared on the PREMISES of the FOOD ESTABLISHMENT or at another FOOD ESTABLISHMENT or a FOOD PROCESSING PLANT that is owned by the same PERSON and is regulated by the FOOD regulatory agency that has jurisdiction.*

3-602.12 Other Forms of Information.

(A) If required by LAW, CONSUMER warnings shall be provided.

(B) FOOD ESTABLISHMENT or manufacturers' dating information on FOODS may not be concealed or altered.

Consumer Advisory

3-603.11 Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

(A) Except as specified in ¶ 3-401.11(C) and Subparagraph 3-401.11(D)(4) and under ¶ 3-801.11(C), if an animal FOOD such as beef, EGGS, FISH, lamb, milk, pork, POULTRY, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in READY-TO-EAT form or as an ingredient in another READY-TO-EAT FOOD, the PERMIT HOLDER shall inform CONSUMERS of the significantly increased RISK of consuming such FOODS by way of a DISCLOSURE and REMINDER, as specified in ¶¶ (B) and (C) of this section using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. Pf

(B) DISCLOSURE shall include:

(1) A description of the animal-derived FOODS, such as "oysters on the half shell (raw oysters)," "raw-EGG Caesar salad," and "hamburgers (can be cooked to order)"; Pf or

(2) Identification of the animal-derived FOODS by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients. Pf

(C) REMINDER shall include asterisking the animal-derived FOODS requiring DISCLOSURE to a footnote that states:

(1) Regarding the safety of these items, written information is available upon request; Pf

(2) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness; Pf or

(3) Consuming raw or undercooked MEATS, POULTRY, seafood, shellfish, or EGGS may increase your RISK of foodborne illness, especially if you have certain medical

conditions. [Pf]

3-7 Contaminated Food

Subparts

3-701 Disposition

Disposition

3-701.11 Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

(A) A FOOD that is unsafe, ADULTERATED, or not honestly presented as specified under § 3-101.11 shall be discarded or reconditioned according to an APPROVED procedure. [P]

(B) FOOD that is not from an APPROVED source as specified under §§ 3-201.11 - .17 shall be discarded. [P]

(C) READY-TO-EAT FOOD that may have been contaminated by an EMPLOYEE who has been RESTRICTED or EXCLUDED as specified under § 2-201.12 shall be discarded. [P]

(D) FOOD that is contaminated by FOOD EMPLOYEES, CONSUMERS, or other PERSONS through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded. [P]

3-8 Special Requirements For Highly Susceptible Populations

Subparts

3-801 Additional Safeguards

Additional Safeguards

3-801.11 Pasteurized Foods, Prohibited Re-Service, and Prohibited Food.

In a FOOD ESTABLISHMENT that serves a HIGHLY SUSCEPTIBLE POPULATION:

(A) The following criteria apply to JUICE:

(1) For the purposes of this paragraph only, children who are age 9 or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;

(2) PrePACKAGED JUICE or a prePACKAGED BEVERAGE containing JUICE, that bears a warning label as specified in 21 CFR, 101.17(g) Food labeling, warning, notice, and safe handling statements, Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens, or a PACKAGED JUICE or BEVERAGE containing JUICE, that bears a warning label as specified under ¶ 3-404.11(B) may not be served or offered for sale; [P] and

(3) UnPACKAGED JUICE that is prepared on the premises for service or sale in a READY-TO-EAT form shall be processed under a HACCP PLAN that contains the information specified under ¶¶ 8-201.14(B) - (E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls. [P]

(B) Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS in the preparation of: [P]

(1) FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, EGGnog, ice cream, and EGG-fortified BEVERAGES, [P] and

(2) Except as specified in ¶ (F) of this section, recipes in which more than one EGG is broken and the EGGS are combined; [P]

(C) The following FOODS may not be served or offered for sale in a READY-TO-EAT form: [P]

(1) Raw animal FOODS such as raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH, and steak tartare, [P]

(2) A partially cooked animal FOOD such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw EGGS, and meringue; [P] and

(3) Raw seed sprouts. [P]

(D) FOOD EMPLOYEES may not contact READY-TO-EAT FOOD as specified under ¶¶ 3-301.11(B) and (D). [P]

(E) Time only, as the public health control as specified under ¶ 3-501.19(D), may not be used for raw EGGS. [P]

(F) *Subparagraph (B)(2) of this section does not apply if:*

(1) *The raw EGGS are combined immediately before cooking for one CONSUMER'S serving*

at a single meal, cooked as specified under Subparagraph 3-401.11(A)(1), and served immediately, such as an omelet, soufflé, or scrambled EGGS*;*

(2) *The raw* EGGS *are combined as an ingredient immediately before baking and the* EGGS *are thoroughly cooked to a* READY-TO-EAT *form, such as a cake, muffin, or bread; or*

(3) *The preparation of the food is conducted under a HACCP* PLAN *that:*

(a) *Identifies the* FOOD *to be prepared,*

(b) *Prohibits contacting* READY-TO-EAT FOOD *with bare hands,*

(c) *Includes specifications and practices that ensure*:

(i) ***Salmonella* Enteritidis** *growth is controlled before and after cooking, and*

(ii) ***Salmonella* Enteritidis** *is destroyed by cooking the* EGGS *according to the temperature and time specified in Subparagraph 3-401.11(A)(2),*

(d) *Contains the information specified under ¶ 8-201.14(D) including procedures that:*

(i) *Control cross contamination of* READY-TO-EAT FOOD *with raw* EGGS*, and*

(ii) *Delineate cleaning and* SANITIZATION *procedures for* FOOD-CONTACT SURFACES, and

(e) *Describes the training program that ensures that the* FOOD EMPLOYEE *responsible for the preparation of the* FOOD *understands the procedures to be used*.

(G) Except as specified in paragraph (H) of this section, FOOD may be re-served as specified under Subparagraph 3-306.14(B)(1) and (2).

Re-service of Food

(H) *Food may not be re-served under the following conditions:*

Prohibited Re-service of Food

(1) *Any* FOOD *served to patients or clients who are under contact precautions in medical isolation or quarantine, or protective environment isolation may not be re-served to others outside*.

(2) *Packages of* FOOD *from any patients, clients, or other* CONSUMERS *should not be re-served to* PERSONS *in protective environment isolation*.

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