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Sequence Number: 01-03-18
Rule ID(s): 10670
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Effective Date: 04/04/18

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to Tenn. Code Ann. §§ 4-5-202, 4-5-207, and 4-5-229 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within ninety (90) days of the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by ten (10) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of ten (10) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Department of Health
Division:	General Environmental Health
Contact Person:	Mary Kennedy
Address:	710 James Robertson Parkway, 5th Floor, Nashville, TN
Zip:	37243
Phone:	(615) 253-4878
Email:	Mary.Kennedy@tn.gov

Revision Type (check all that apply):
X Amendment
___ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1200-23-01	Food Service Establishment
Rule Number	**Rule Title**
1200-23-01-.03	Food

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos-tn-gov-files.s3.amazonaws.com/forms/Rulemaking%20Guidelines_September2016.pdf.

Rule Chapter 1200-23-01
Food Service Establishment

Amendments

Rule 1200-23-01-.03 Food is amended by deleting subparts (4)(b)1(i) and (5)(a)6(i) in their entirety and substituting instead the following language, and is further amended by adding new part (4)(c)6, so that as amended, the new subparts and part shall read:

(4) (b) 1. (i) Except as specified in (ii) of this part, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish shall be:

(I) Frozen and stored at a temperature of -20°C (-4°F) or below for a minimum of 168 hours (7 days) in a freezer; (P)

(II) Frozen at -35°C (-31°F) or below until solid and stored at -35°C (-31°F) or below for a minimum of 15 hours; (P) or

(III) Frozen at -35°C (-31°F) or below until solid and stored at -20°C (-4°F) or below for a minimum of 24 hours. (P)

(4) (c) 6. A HACCP plan is not required when a food establishment uses a reduced oxygen packaging method to package time/temperature control for safety food that is always:

(i) Labeled with the production time and date,

(ii) Held at 5°C (41°F) or less during refrigerated storage, and

(iii) Removed from its package in the food establishment within 48 hours after packaging.

(5) (a) 6. (i) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 1200-23-01-.03(5)(a)9, and except as specified under (ii) and in (iii) of this part, time/temperature control for safety food shall be maintained:

(I) at 57°C (135°F) or above, except that roasts cooked to a temperature and for a time specified under 1200-23-01-.03(4)(a)1(ii) or reheated as specified in 1200-23-01-.03(4)(c)5 may be held at a temperature of 54°C (130°F) or above; (P) or

(II) at 5ºC (41ºF) or less (P).

Authority: T.C.A. §§ 68-14-701 through 68-14-726.

* If a roll-call vote was necessary, the vote by the Agency on these rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
N/A					

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the Department of Health, Division of General Health (*board/commission/other authority*) on 09/05/2017 (*date as mm/dd/yyyy*), and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of ninety (90) days of the filing of the proposed rule with the Secretary of State.

Date: Mary Kennedy

Signature: 12.07.17

Name of Officer: Mary Kennedy

Title of Officer: Deputy General Counsel, Department of Health

MARK INGRAM NOTARY PUBLIC STATE OF TENNESSEE DAVIDSON COUNTY

Subscribed and sworn to before me on: 12/7/17

Notary Public Signature:

My commission expires on: 5/6/19

Agency/Board/Commission: Department of Health, Division of General Health

Rule Chapter Number(s): 1200-23-01

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

12/28/2017

Date

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Effective on: 04/04/18

Tre Hargett

Tre Hargett
Secretary of State

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

(1) The extent to which the rule or rule may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

These rule do not overlap, duplicate, or conflict with other federal, state, or local governmental rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

These rules exhibit clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

These rules do not provide for additional compliance or reporting requirements for small businesses.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

These rules do not establish schedules or deadlines for compliance or reporting requirements for small businesses.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

These rules do not contain compliance or reporting requirements for small businesses.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

These rules do not establish performance standards, design for small businesses. They ease the burden of operational standards.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

The rules do not stifle entrepreneurial activity, curb innovation, or increase costs.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Tennessee Department of Health, Division of General Environmental Health

Rulemaking hearing date: N/A

1. **Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

   These rules will affect those businesses and governmental programs offering food services. These business and governmental entities will bear the cost of, and/or benefit from the proposed rule amendments.

2. **Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

   These rules amendments do not contain any new reporting, recordkeeping, or other administrative costs required for compliance with the proposed rule amendments.

3. **Statement of the probable effect on impacted small businesses and consumers:**

   Small business and consumers will benefit from the proposed rule amendments. Businesses will benefit from these rules as these amendments will make the rules clearer and give more guidance and options for compliance. Consumers should not be affected by these rule amendments.

4. **Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

   There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule amendments.

5. **Comparison of the proposed rule with any federal or state counterparts:**

   Federal: The FDA has adopted this language.

   State: Mississippi and South Carolina have adopted these rules.

6. **Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.**

   These rule amendments do not contain any exemptions for small businesses.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (http://publications.tnsosfiles.com/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly)

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The rule amendment to Rule 1200-23-01-.03(4)(b)1(i) corrects temperatures for parasite destruction. The amendment to Rule 1200-23-01-.03(4)(c)6 adds additional options for compliance. The amendment to Rule 1200-23-01-.03(5)(a)6(i) replaces language to include an additional temperature requirement.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

2013 Public Chapter 182.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These rules will affect those businesses and governmental programs offering food services.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

None.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

These rule amendments should not result in any increase or decrease in state or local government revenues or expenditures.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Mary Kennedy, Deputy General Counsel, Department of Health.

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Mary Kennedy, Deputy General Counsel, Department of Health.

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

710 James Robertson Parkway, 5th Floor – Andrew Johnson Building, Nashville, Tennessee 37243, (615) 532-7161, Mary.Kennedy@tn.gov.

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.

(Rule 1200-23-01-.02, continued)

1. Except as specified in part 2 of this subparagraph, an employee shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection cannot result.

2. A food employee may drink from a closed beverage container if the container is handled to prevent contamination of:

   (i) The employee's hands;

   (ii) The container; and

   (iii) Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(b) Discharges from the Eyes, Nose, and Mouth. Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

(c) Effectiveness.

1. Except as provided in part 2. of this subparagraph, food employees shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

2. This subparagraph does not apply to food employees such as counter staff who only serve beverages and wrapped or packaged foods, hostesses, and wait staff if they present a minimal risk of contaminating exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

(d) Handling Prohibition.

1. Except as specified in part 2. of this subparagraph, food employees may not care for or handle animals that may be present such as patrol dogs, service animals, or pets that are allowed as specified in subparts 1200-23-01-.06 (5) (o) 2(i) – (v). (Pf)

2 Food employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacean in display tanks if they wash their hands as specified under 1200-23-01-.02(3)(b) and 1200-23-01-.02(3)(c)3.

Authority: *T.C.A. §§ 68-14-701 through 68-14-726.* ***Administrative History:*** *Original rule filed March 26, 1987; effective May 9, 1987. Repeal and new rule filed August 24, 2000; effective November 7, 2000. Amendment filed October 22, 2004; effective January 5, 2005. Repeal and new rule filed April 17, 2015; effective July 16, 2015.*

1200-23-01-.03 FOOD.

(1) Condition - Safe, Unadulterated, and Honestly Presented. Food shall be safe, unadulterated, and, as specified under 1200-23-01-.03(6)(a)2, honestly presented. (P)

(2) Sources, Specifications and Original Containers and Records

(Rule 1200-23-01-.03, continued)

(a) Sources

1. Compliance with Food Law

(i) Food shall be obtained from sources that comply with law. (P)

(ii) Food from an Unlicensed Home Facility. Food from an unlicensed home facility shall not be served in a food establishment.

(iii) Packaged food shall be labeled as specified in law, including 21 CFR Part 101 Food Labeling, 9 CFR Part 317 Labeling, Marking Devices, and Containers, and 9 CFR Part 381 subpart N Labeling and Containers, and as specified under 1200-23-01-.03(2)(b)7 and 8. (Pf)

(iv) Fish, other than those specified in subpart 1200-23-01-.03(4)(a)1(iv), that are intended for consumption in raw or undercooked form and allowed as specified in 1200-23-01-.03(4)(a)1.(ii)-(iv), may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified under 1200-23-01-.03(4)(b); or if they are frozen on the premises as specified under 1200-23-01-.03(4)(b) and records are retained as specified under 1200-23-01-.03(4)(b)2.

(v) Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in 1200-23-01-.03(4)(a)1(iii) shall be:

(I) Obtained from a food processing plant that, upon request by the purchaser, packages the steaks and labels them, to indicate that the steaks meet the definition of whole-muscle, intact beef; .(Pf) or

(II) Deemed acceptable by the department based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef; (Pf) and

(III) If individually cut in a food establishment:

I. Cut from whole-muscle, intact beef that is labeled by a food processing plant as specified in item (v)(I) or identified as specified in item (v)(II).(Pf)

II. Prepared so they remain intact; (Pf) and

III. If packaged for undercooking in a food establishment, labeled as specified in item (v)(I) or identified as specified in item (v)(II) of this part. (Pf).

(vi) Meat and poultry that is not a ready-to-eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in law, including 9 CFR § 317.2(l) and 9 CFR § 381.125(b).

(vii) Eggs that have not been specifically treated to destroy all viable salmonellae shall be labeled to include safe handling instructions as specified in law, including 21 CFR § 101.17(h).

(Rule 1200-23-01-.03, continued)

2. Food in a Hermetically Sealed Container. Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant. (P)

3. Fluid Milk and Milk Products. Fluid milk and milk products shall be obtained from sources that comply with Grade A standards as specified in law. (P)

4. Fish

   (i) Fish that are received for sale or service shall be: (P)

      (I) Commercially and legally caught or harvested; (P) or

      (II) Approved for sale or service. (P)

   (ii) Molluscan shellfish that are recreationally caught may not be received for sale or service. (P)

5. Molluscan Shellfish.

   (i) Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. (P)

   (ii). Molluscan shellfish received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List. (P)

6. Wild Mushrooms.

   (i) Except as specified in subpart (ii) of this part, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert. (P)

   (ii) This section does not apply to:

      (I) Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or

      (II) Wild mushroom species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

7. Game Animals.

   (i) If game animals are received for sale or service they shall be:

      (I) Commercially raised for food (P) and:

         I. Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, (P) or

(Rule 1200-23-01-.03, continued)

II. Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, (P) and

III. Raised, slaughtered, and processed according to:

A. Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, (P) and

B. Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee; (P)

(II) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR Part 352 Exotic animals; voluntary inspection of rabbits that are "inspected and certified" in accordance with 9 CFR Part 354 Voluntary inspection of rabbits and edible products thereof; (P)

(III) As allowed by law, for wild game animals that are live-caught:

I. Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction, (P) and

II. Slaughtered and processed according to:

A. Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, (P) and

B. Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee; (P) or

(IV) As allowed by law, for field-dressed wild game animals under a routine inspection program that ensures the animals:

I. Receive a postmortem examination by an approved veterinarian or veterinarian's designee, (P) or

II. Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program, (P) and

III. Are processed according to laws governing meat and poultry as determined by the agency that has animal health

(Rule 1200-23-01-.03, continued)

jurisdiction and the agency that conducts the inspection program. (P)

(ii) A game animal may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR Part 17 Endangered and threatened wildlife and plants.

(b) Specifications for Receiving

1. Temperature.

(i) Except as specified in subpart 1.(ii) of this subparagraph, refrigerated, time/temperature control for safety food shall be at a temperature of 5°C (41°F) or below when received. (P)

(ii) If a temperature other than 5°C (41°F) for a time/temperature control for safety food is specified in law governing its distribution, such as laws governing milk and molluscan shellfish, the food may be received at the specified temperature.

(iii) Raw eggs shall be received in refrigerated equipment that maintains an ambient air temperature of 5°C (41°F) or less. (P)

(iv) Time/temperature control for safety food that is cooked to a temperature and for a time specified under 1200-23-01-.03(6)(a)1.- 3. and received hot shall be at a temperature of 57°C (135°F) or above. (P)

(v) A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen. (Pf)

(vi) Upon receipt, time/temperature control for safety food shall be free of evidence of previous temperature abuse.(Pf)

2. Additives. Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR Parts 170-180 relating to food additives, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR Parts 181-186, substances that exceed amounts specified in 9 CFR Subpart C § 424.21(b) Food ingredients and sources of radiation, or pesticide residues that exceed provisions specified in 40 CFR Part 180 Tolerances and exemptions for pesticide chemical residues in food. (P)

3. Eggs. Eggs shall be received clean and sound and may not exceed the restricted Egg tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.200 et seq., administered by the Agricultural Marketing Service of USDA. (P)

4. Eggs and Milk Products, Pasteurized.

(i) Egg Products shall be obtained pasteurized. (P)

(ii) Fluid and dry milk and milk products shall:

(I) Be obtained pasteurized;(P) and

(II) Comply with Grade A standards as specified in law. (P)

(Rule 1200-23-01-.03, continued)

(iii) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR Part 135 - Frozen desserts. (P)

(iv) Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR Part 133 - Cheeses and related cheese products, for curing certain cheese varieties. (P)

5. Package Integrity. Food packages shall be in good condition and protect the integrity of the contents so that the Food is not exposed to adulteration or potential contaminants. (Pf)

6. Ice. Ice for use as a food or a cooling medium shall be made from drinking water. (P)

7. Shucked Shellfish, Packaging and Identification.

(i) Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the: (Pf)

(I) Name, address, and certification number of the shucker, packer or re-packer of the molluscan shellfish; (Pf) and

(II) The "sell by" or "best if used by" date for packages with a capacity of less than 1.89 L (one-half gallon) or the date shucked for packages with a capacity of 1.89 L (one-half gallon) or more. (Pf)

(ii) A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified under subpart 7(i) of this subparagraph shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D § 1240.60(d) - Specific Administrative Decisions Regarding Interstate Shipments, Molluscan shellfish.

8. Shellstock Identification.

(i) Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list: (Pf)

(I) Except as specified under subitem III of this item, on the harvester's tag or label, the following information in the following order: (Pf)

I. The harvester's identification number that is assigned by the shellfish control authority, (Pf)

II. The date of harvesting, (Pf)

III. The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested, (Pf)

(Rule 1200-23-01-.03, continued)

IV. The type and quantity of shellfish, (Pf) and

V. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"; (Pf) and

(II) Except as specified in subpart (iv) of this part, on each dealer's tag or label, the following information in the following order: (Pf)

I. The dealer's name and address, and the certification numbers assigned by the shellfish control authority, (Pf)

II. The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested, (Pf)

III. The same information as specified for a harvester's tag under subitems (i)(I)II.-IV of this subpart, (Pf) and

IV. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days." (Pf)

(ii) A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under subpart (i) . of this part shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D § 1240.60(d) Specific Administrative Decisions Regarding Interstate Shipments.

(iii) If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first.

(iv) If the harvester's tag or label is designed to accommodate each dealer's identification as specified under items (i)(I) and (II) of this part, individual dealer tags or labels need not be provided.

9. Shellstock, Condition: When received by a food establishment, shellstock shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells shall be discarded.

10. Juice - Commercially Processed: Pre-packaged juice shall:

(i). Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120 Hazard Analysis and Critical Control (HACCP) Systems; (Pf) and

(ii). Be obtained pasteurized or otherwise treated to attain a 5 log reduction of the most resistant microorganism of public health significance as specified in 21 CFR § 120.24 Process Controls. (P)

(c) Original Containers and Records

1. Molluscan Shellfish, Original Container.

(Rule 1200-23-01-.03, continued)

(i) Except as specified in (ii) - (iv) of this part, molluscan shellfish may not be removed from the container in which they are received other than immediately before sale or preparation for service.

(ii) For display purposes, shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

(I) The source of the shellstock on display is identified as specified under 1200-23-01-.03(2)(b)8. and recorded as specified under 1200-23-01-.03(2)(c)1(v)(II) ; and

(II) The shellstock are protected from contamination.

(iii) Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

(I) The labeling information for the shellfish on display as specified under 1200-23-01-.03(2)(b)8. is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

(II) The shellfish are protected from contamination.

(iv) Shucked shellfish may be removed from the container in which they were received and repacked in consumer self-service containers where allowed by law if:

(I) The labeling information for the shellfish is on each consumer self-service container as specified under 1200-23-01-.03(2)(b)7. and 1200-23-01-.03(6)(b)1 and 2(i) – (v) ;

I. The labeling information as specified under 1200-23-01-.03(2)(b)7 is retained and correlated with the date when, or dates during which, the shellfish are sold or served;

II. The labeling information and dates specified under (v)(II) of this part are maintained for 90 days; and

III. The shellfish are protected from contamination.

(v) Shellstock, Maintaining Identification.

(I) Except as specified under subitem (III) II of this subpart, shellstock tags or labels shall remain attached to the container in which the shellstock are received until the container is empty. (Pf)

(II) The date when the last shellstock from the container is sold or served shall be recorded on the tag or label. (Pf)

(III) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date that is recorded on the tag or label, as specified under (II) of this subpart, by: (Pf)

(Rule 1200-23-01-.03, continued)

I. Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified under item (II) of this subpart; (Pf) and

II. If shellstock are removed from its tagged or labeled container:

A. Preserving source identification by using a record keeping system as specified under subpart 1.(ii) of this part, (Pf) and

B. Ensuring that shellstock from one tagged or labeled container are not commingled with shellstock from another container with different certification numbers; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the consumer. (Pf)

(3) Protection from Contamination after Receiving.

(a) Preventing Contamination by Employees

1. Preventing Contamination from Hands.

(i) Food employees shall wash their hands as specified under 1200-23-01-.02(3)(b).

(ii) Except when washing fruits and vegetables as specified under 1200-23-01-.03(3)(b)5 or as specified in (v) of this part, food employees may not contact exposed, ready-to-eat food with their bare hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment. (P)

(iii) Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form. (Pf)

(iv) Subpart (ii) of this subparagraph does not apply to a food employee who contacts exposed, ready-to-eat food with bare hands at the time the ready-to-eat food is being added as an ingredient to a food that is to be cooked in the food establishment to heat all parts of the food to a temperature of at least 74°C (165°F).

(v) Food employees not serving a highly susceptible population may contact exposed, ready-to-eat food with their bare hands if:

(I) The permit holder obtains prior approval from the department;

(II) Written procedures are maintained in the food establishment and made available to the department upon request that include:

I. For each bare hand contact procedure, a listing of the specific ready-to-eat foods that are touched by bare hands,

II. Diagrams and other information showing that handwashing facilities, installed, located, equipped, and maintained as specified under 1200-23-01-.05(2)(c)1, 1200-23-01-.05(2)(d)1,

(Rule 1200-23-01-.03, continued)

1200-23-01-.05(2)(e)1, 1200-23-01-.06(3)(a)1, 1200-23-01-.06(3)(a)3, and 1200-23-01-.06(3)(a)5, are in an easily accessible location and in close proximity to the work station where the bare hand contact procedure is conducted;

(III) A written employee health policy that details how the food establishment complies with 1200-23-01-.02(2)(a), (b), and (c) including:

I. Documentation that food employees and conditional employees acknowledge that they are informed to report information about their health and activities as they relate to gastrointestinal symptoms and diseases that are transmittable through food as specified under 1200-23-01-.02(2)(a)1.

II. Documentation that food employees and conditional employees acknowledge their responsibilities as specified under 1200-23-01-.02(2)(a)4 and 5; and

III. Documentation that the person in charge acknowledges the responsibilities as specified under 1200-23-01-.02(2)(a)2, 3, and 4, and 1200-23-01-.02(2)(b)and 1200-23-01-.02(2)(c);

(IV) Documentation that food employees acknowledge that they have received training in:

I. The risks of contacting the specific ready-to-eat foods with bare hands,

II. Proper handwashing as specified under 1200-23-01-.02(3)(b),

III. When to wash their hands as specified under 1200-23-01-.02(3)(c),

IV. Where to wash their hands as specified under 1200-23-01-.02(3)(d),

V. Proper fingernail maintenance as specified under 1200-23-01-.02(3)(f),

VI. Prohibition of jewelry as specified under 1200-23-01-.02(3)(g), and

VII. Good hygienic practices as specified under 1200-23-01-.02(4)(a) and 1200-23-01-.02(4)(b);

(V) Documentation that hands are washed before food preparation and as necessary to prevent cross contamination by food employees as specified under 1200-23-01-.02(3)(a), 1200-23-01-.02(3)(b), 1200-23-01-.02(3)(c), and 1200-23-01-.02(3)(d) during all hours of operation when the specific ready-to-eat foods are prepared;

(VI) Documentation that food employees contacting ready-to-eat food with bare hands use two or more of the following control measures to provide additional safeguards to hazards associated with bare hand contact:

I. Double handwashing,

II. Nail brushes,

III. A hand antiseptic after handwashing as specified under 1200-23-01-.02(3)(e),

IV. Incentive programs such as paid sick leave that assist or encourage food employees not to work when they are ill, or

V. Other control measures approved by the department; and

VI. Documentation that corrective action is taken when items (I) – (VI) of this subpart are not followed.

2. Preventing Contamination When Tasting. A food employee may not use a utensil more than once to taste food that is to be sold or served. (P)

(b) Preventing Food and Ingredient Contamination.

1. Packaged and Unpackaged Food – Separation, Packaging and Segregation

(i) Food shall be protected from cross contamination by:

(I) Except as specified in subitem III below, separating raw animal foods during storage, preparation, holding, and display from:

I. Raw ready-to-eat including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as fruits and vegetables, (P) and

II. Cooked ready-to-eat food; (P)

III. Frozen, commercially processed and packaged raw animal food may be stored or displayed with or above frozen, commercially processed and packaged, ready-to-eat food.

(II) Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:

I. Using separate equipment for each type, (P) or

II. Arranging each type of food in equipment so that cross contamination of one type with another is prevented, (P) and

III. Preparing each type of food at different times or in separate areas;

(III) Cleaning equipment and utensils as specified under 1200-23-01-.04(6)(b)1(i) and sanitizing as specified under 1200-23-01-.04(7)(c);

(Rule 1200-23-01-.03, continued)

(IV) Except as specified under 1200-23-01-.03(5)(a)5(ii)(II) and in part 2. of this subparagraph, storing the food in packages, covered containers, or wrappings;

(V) Cleaning hermetically sealed containers of food of visible soil before opening;

(VI) Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;

(VII) Storing damaged, spoiled, or recalled food being held in the food establishment as specified under 1200-23-01-.06(4)(d); and

(VIII) Separating fruits and vegetables, before they are washed, as specified under 1200-23-01-.03(5) from ready-to-eat foods.

(ii) Item (i)(IV) does not apply to:

(I) Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;

(II) Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;

(III) Whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;

(IV) Food being cooled as specified under 1200-23-01-.03(5)(a)5(ii)(II); or

(V) Shellstock.

2. Food Storage Containers, Identified with Common Name of Food. Except for containers holding food that can be readily and unmistakably recognized such as dry pasta, working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the food.

3. Pasteurized Eggs, Substitute for Raw Eggs for Certain Recipes: Pasteurized eggs or egg product shall be substituted for raw eggs in the preparation of foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-fortified beverages that are not:

(i) Cooked as specified under 1200-23-01-.03(4)(a)1(i)(I) or (II); (P) or

(ii) Included in 1200-23-01-.03(4)(a)1(iv). (P)

4. Protection from Unapproved Additives.

(i) Food shall be protected from contamination that may result from the addition of, as specified in 1200-23-01-.03(2)(b)2:

(I) Unsafe or unapproved food or color additives; (P) and

(II) Unsafe or unapproved levels of approved and color additives. (P)

(Rule 1200-23-01-.03, continued)

(ii) A food employee may not:

(I) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1; (P) or

(II) Except for grapes, serve or sell food specified under (i) of this part that is treated with sulfiting agents before receipt by the food establishment. (P)

5. Washing Fruits and Vegetables.

(i) Except as specified in subpart (ii) of this part and except for whole, raw fruits and vegetables that are intended for washing by the consumer before consumption, raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form.

(ii) Fruits and vegetables may be washed by using chemicals as specified under 1200-23-01-.07(2)(d)2.

(c) Preventing Contamination from Ice Used as Coolant

1. Ice Used as Exterior Coolant, Prohibited as Ingredient. After use as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice may not be used as food. (P)

2. Storage or Display of Food in Contact with Water or Ice.

(i) Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

(ii) Except as specified in subparts (iii) and (iv) of this part, unpackaged food may not be stored in direct contact with undrained ice.

(iii) Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.

(iv) Raw poultry and raw fish that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.

(d) Preventing Contamination from Equipment, Utensils and Linens

1. Food Contact with Equipment and Utensils – Food shall only contact:.

(i) Equipment and utensils that are cleaned as specified under 1200-23-01-.04(6) of this Chapter and sanitized as specified under 1200-23-01-.04(7) of this Chapter; (P) or

(ii) Single-service and single-use articles. (P)

(Rule 1200-23-01-.03, continued)

(iii) Linens, such as cloth napkins, as specified under 1200-23-01-.03(3)(d)3. that are laundered as specified under 1200-23-01-.04(8)(b) of this Chapter.

2. In-Use Utensils, Between-Use Storage. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

(i) Except as specified under subpart (ii) of this part, in the food with their handles above the top of the food and the container;

(ii) In food that is not time/temperature control for safety food with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;

(iii) On a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the food-contact surface of the food preparation table or cooking equipment are cleaned and sanitized at a frequency specified under 1200-23-01-.04(6)(b) and 1200-23-01-.04(7)(b);

(iv) In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;

(v) In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not time/temperature control for safety food; or

(vi) In a container of water if the water is maintained at a temperature of at least 57°C (135°F) and the container is cleaned at a frequency specified under 1200-23-01-.04(6)(b)1(iv)(VII).

3. Linens and Cloth Napkins, Use Limitation. Linens and cloth napkins may not be used in contact with food unless they are used to line a container for the service of foods and the linens and napkins are replaced each time the container is refilled for a new consumer.

4. Wiping Cloths, Use Limitation.

(i) Cloths in-use for wiping food spills from tableware and carry-out containers that occur as food is being served shall be:

(I) Maintained dry; and

(II) Used for no other purpose.

(ii) Cloths in-use for wiping counters and other equipment surfaces shall be:

(I) Held between uses in a chemical sanitizer solution at a concentration specified under 1200-23-01-.04(5)(a)14; and

(II) Laundered daily as specified under 1200-23-01-.04(8)(b)4.

(iii) Cloths in-use for wiping surfaces in contact with raw animal foods shall be kept separate from cloths used for other purposes.

(iv) Dry wiping cloths and the chemical sanitizing solutions specified in item (ii)(I) of this part in which wet wiping cloths are held between uses shall be free of food debris and visible soil.

(Rule 1200-23-01-.03, continued)

(v) Containers of chemical sanitizing solutions specified in item (ii)(I) of this part in which wet wiping cloths are held between uses shall be stored off the floor and used in a manner that prevents contamination of food, equipment, utensils, linens, single-service, or single-use articles.

(vi) Single-use disposable sanitizer wipes shall be used in accordance with EPA-approved manufacturer's label use instructions.

5. Gloves - Use Limitation.

(i) If used, single-use gloves shall be used for only one task such as working with ready-to-eat or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation. (P)

(ii) Except as specified in subpart (iii) of this part, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under 1200-23-01-.03(4)(a)-(b) such as frozen food or a primal cut of meat.

(iii) Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a single-use glove.

(iv) Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required under 1200-23-01-.03(4)(a)-(b) such as frozen food or a primal cut of meat.

6. Using Clean Tableware for Second Portions and Refills.

(i) Except for refilling a consumer's drinking cup or container without contact between the pouring utensil and the lip-contact area of the drinking cup or container, food employees may not use tableware, including single-service articles, soiled by the consumer, to provide second portions or refills.

(ii) Except as specified in (iii) of this part, self-service consumers may not be allowed to use soiled tableware, including single-service articles, to obtain additional food from the display and serving equipment.

(iii) Drinking cups and containers may be reused by self-service consumers if refilling is a contamination-free process as specified under 1200-23-01-.04(2)(d)3(i),(ii) and (iv).

7. Refilling Returnables.

(i) A take-home food container returned to a food establishment may not be refilled at a food establishment with a time/temperature control for safety food.

(ii) Except as specified in subpart (iii) of this subpart, a take-home food container refilled with food that is not time/temperature control for safety food shall be cleaned as specified under 1200-23-01-.04(6)(c)7(ii).

(Rule 1200-23-01-.03, continued)

(iii) Personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under 1200-23-01-.04(2)(d)3(i), (ii) and (iv).

(e) Preventing Contamination from the Premises

1. Food Storage.

(i) Except as specified in subparts (ii) and (iii) of this part, food shall be protected from contamination by storing the food:

(I) In a clean, dry location;

(II) Where it is not exposed to splash, dust, or other contamination; and

(III) At least 15 cm (6 inches) above the floor.

(ii) Food in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling equipment as specified under 1200-23-01-.04(9)(c)1(iv).

(iii) Pressurized beverage containers, cased food in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture.

2. Food Storage, Prohibited Areas. Food may not be stored:

(i) In locker rooms;

(ii) In toilet rooms;

(iii) In dressing rooms;

(iv) In garbage rooms;

(v) In mechanical rooms;

(vi) Under sewer lines that are not shielded to intercept potential drips;

(vii) Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;

(viii) Under open stairwells; or

(ix) Under other sources of contamination.

3. Food Preparation. During preparation, unpackaged food shall be protected from environmental sources of contamination.

(f) Preventing Contamination by Consumers

1. Food Display. Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of

(Rule 1200-23-01-.03, continued)

packaging; counter, service line, or salad bar food guards; display cases; or other effective means. (P)

2. Condiments, Protection. Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.

3. Consumer Self-Service Operations.

(i) Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish may not be offered for consumer self-service. This paragraph does not apply to:

(I) Consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish;

(II) Ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue; or

(III) Raw, frozen, shell-on shrimp, or lobster.

(ii) Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination. (Pf)

(iii) Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures. (Pf)

4. Returned Food and Re-Service of Food.

(i) Except as specified in subpart (ii) of this part, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption. (P)

(ii) Except as specified under 1200-23-01-.03(8)(g), a container of food that is not time/temperature control for safety food may be re-served from one consumer to another if:

(I) The food is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

(II) The food, such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition.

5. Preventing Contamination from Other Sources - Miscellaneous Sources of Contamination: Food shall be protected from contamination that may result from a factor or source not specified under 1200-23-01-.03(3)(a)-(f).

(4) Destruction of Organisms of Public Health Concern

(a) Cooking

1. Raw Animal Foods.

(Rule 1200-23-01-.03, continued)

(i) Except as specified under subparts (ii),(iii) and (iv) of this part, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:

(I) 63˚C (145˚F) or above for 15 seconds for: (P)

I. Raw eggs that are broken and prepared in response to a consumer's order and for immediate service, (P) and

II. Except as specified under items (i)(II) and (i)(III) and subparts (ii), and (iii) of this part, fish and meat including game animals commercially raised for food as specified under 1200-23-01-.03(2)(a)7(i) and game animals under a voluntary inspection program as specified under 1200-23-01-.03(2)(a)7(ii); (P)

(II) 68˚C (155˚F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites, mechanically tenderized, and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under 1200-23-01-.03(2)(a)7(i), and game animals under a voluntary inspection program as specified under 1200-23-01-.03(2)(a)7(i)(II) and raw eggs that are not prepared as specified under 1(i)(I)I of this subparagraph: (P) or

Minimum	
Temperature °C (°F)	**Time**
63 (145)	3 minutes
66 (150)	1 minute
70 (158)	< 1 second (instantaneous)

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 4.5 kg (10lbs)	4.5 kg (10 lbs) or More
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity[1]	121°C (250°F) or less	121°C (250°F) or less
[1]Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.		

(III) 74°C (165°F) or above for 15 seconds for poultry, baluts, wild game animals as specified under 1200-23-01-.03(2) (a) 7 (iii) and (iv), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry, or ratites. (P)

(ii) Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:

(I) In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature: (P); and

(II) As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature: (P)

(Rule 1200-23-01-.03, continued)

Temperature °C (°F)	Time[1] in Minutes	Temperature °C (°F)	Time[1] in Seconds
54.4 (130)	112	63.9 (147)	134
55.0 (131)	89	65.0 (149)	85
56.1 (133)	56	66.1 (151)	54
57.2 (135)	36	67.2 (153)	34
57.8 (136)	28	68.3 (155)	22
58.9 (138)	18	69.4 (157)	14
60.0 (140)	12	70.0 (158)	0
61.1 (142)	8		
62.2 (144)	5		
62.8 (145)	4		
[1]Holding time may include postoven heat rise.			

(iii) A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:

(I) The food establishment serves a population that is not a highly susceptible population,

(II) The steak is labeled to indicate that it meets the definition of "whole-muscle, intact beef" as specified under 1200-23-01-.03(2)(a)1(v), and

(III) The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.

(iv) A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in (iii) of this part, may be served or offered for sale upon consumer request or selection in a ready-to-eat form if:

(I) As specified under 1200-23-01-.03(8)(c)1 and 2, the food establishment serves a population that is not a highly susceptible population;

(II) The food, if served or offered for service by consumer selection from a children's menu, does not contain comminuted; (Pf) and

(III) The consumer is informed as specified under 1200-23-01-.03(6)(c) that to ensure its safety, the food should be cooked as specified under subparts (i) or (ii) of this part; or

(IV) The department grants a variance from (i) or (ii) of this part as specified in 1200-23-01-.08(1)(d)1 based on a HACCP plan that:

I. Is submitted by the permit holder and approved as specified under 1200-23-01-.08(1)(d)2,

II. Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food, and

III. Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions of the variance.

2. Microwave Cooking. Raw animal foods cooked in a microwave oven shall be:

(i) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(ii) Covered to retain surface moisture;

(iii) Heated to a temperature of at least 74˚C (165˚F) in all parts of the food; and

(iv) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

3. Plant Food Cooking for Hot Holding. Fruits and vegetables cooked for hot holding shall be cooked to a temperature of 57˚C (135˚F). (Pf)

4. Non-Continuous Cooking of Raw Animal Foods. Raw animal foods cooked using a non-continuous cooking process shall be:

(i) Subject to an initial heating process that is no longer than sixty minutes in duration; (P)

(ii) Immediately after initial heating, cooled according to the time and temperature parameters specified for cooked time /temperature control for safety food under 1200-23-01-.03(5)(a)4; (P)

(iii) After cooling, held frozen or cold, as specified for time/temperature control for safety food under 1200-23-01-.03(5)(a)6(i); (P)

(iv) Prior to sale or service, cooked using a process that heats all parts of the food to a temperature of at least 74°C (165°F) for 15 seconds; (P)

(v) Cooled according to the time and temperature parameters specified for cooked time /temperature control for safety food under 1200-23-01-.03(5)(a)4 if not either hot held as specified under 1200-23-01-.03(5)(a)6, served immediately, or held using time as a public health control as specified under 1200-23-01-.03(5)(a)9 after complete cooking; (P) and

(vi) Prepared and stored according to written procedures that:

(I) Have obtained prior approval from the department; (Pf)

(II) Are maintained in the food establishment and are available to the department upon request; (Pf)

(Rule 1200-23-01-.03, continued)

(III) Describe how the requirements specified under (i)-(v) of this part are to be monitored and documented by the permit holder and the corrective actions to be taken if the requirements are not met; (Pf)

(IV) Describe how the foods, after initial heating, but prior to complete cooking, are to be marked or otherwise identified as foods that must be cooked as specified under subpart (iv) of this part prior to being offered for sale or service; (Pf) and

(V) Describe how the foods, after initial heating but prior to cooking as specified under subpart (iv) of this part, are to be separated from ready-to-eat foods as specified under 1200-23-01-.03(5)(c). (Pf)

(b) Freezing

1. Parasite Destruction.

~~(i) Except as specified in (ii) of this part, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish shall be:~~

~~(I) Frozen and stored at a temperature of 20°C (4°F) or below for a minimum of 168 hours (7 days) in a freezer; (P)~~

~~(II) Frozen at 35°C (31°F) or below until solid and stored at 35°C (31°F) or below for a minimum of 15 hours; (P) or~~

~~(III) Frozen at 35°C (31°F) or below until solid and stored at 20°C (4°F) or below for a minimum of 24 hours. (P)~~

(i) Except as specified in (ii) of this part, before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish shall be:

(I) Frozen and stored at a temperature of -20°C (-4°F) or below for a minimum of 168 hours (7 days) in a freezer; (P)

(II) Frozen at -35°C (-31°F) or below until solid and stored at -35°C (-31°F) or below for a minimum of 15 hours; (P) or

(III) Frozen at -35°C (-31°F) or below until solid and stored at -20°C (-4°F) or below for a minimum of 24 hours. (P)

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(ii) Subpart (i) of this part does not apply to:

(I) Molluscan shellfish;

(II) Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), Scallops consisting only of the shucked abductor muscle, or Thunnus thynnus (Bluefin tuna, Northern); or

(III) Aquacultured fish, such as salmon, that:

I. If raised in open water, are raised in net-pens, or

II. Are raised in land-based operations such as ponds or tanks, and

III. Are fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish.

(IV) Fish eggs that have been removed from the skein and rinsed.

2. Records, Creation and Retention.

(i) Except as specified in 1200-23-01-.03(4)(b)1(ii) and (ii) of this part, if raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person-in-charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish. (Pf)

(ii) If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 1200-23-01-.03(4)(b)1 may substitute for the records specified under subpart (i) of this part.

(iii) If raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, and the fish are raised and fed as specified in 1200-23-01-.03(4)(b)1(ii)(III), a written agreement or statement from the supplier or aquaculturist stipulating that the fish were raised and fed as specified in 1200-23-01-.03(4)(b)1(ii)(III) shall be obtained by the person in charge and retained in the records of the food establishment for 90 calendar days beyond the time of service or sale of the fish. (Pf)

3. Preparation for Immediate Service. Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

(c) Reheating for Hot Holding.

1. Except as specified under parts 2, 3 and 5 of this subparagraph, time/temperature control for safety food) that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74˚C (165˚F) for 15 seconds. (P)

2. Except as specified under part 3 of this subparagraph, time/temperature control for safety food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74˚C (165˚F) and the food is rotated or stirred, covered, and allowed to stand covered for 2 minutes after reheating. (P)

3. Ready-to-eat taken from a commercially processed, heremetically-sealed container, or from an intact package from a food processing plant that is inspected by the food department that has jurisdiction over the plant, shall be heated to a temperature of at least 57˚C (135˚F) for hot holding. (P)

4. Reheating for hot holding as specified under parts 1. through 3. of this subparagraph shall be completed within 2 hours and the time the food is

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between 5ºC (41°F) or 7°C (45°F) and the temperatures specified under 1 through 3 of this subparagraph may not exceed 2 hours. (P)

5. Remaining unsliced portions of meat roasts that are cooked as specified under 1200-23-01-.03(4)(a)1(ii) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 1200-23-01-.03(4)(a)1(ii).

6. A HACCP plan is not required when a food establishment uses a reduced oxygen packaging method to package time/temperature control for safety food that is always:

(i) Labeled with the production time and date,

(ii) Held at 5°C (41°F) or less during refrigerated storage, and

(iii) Removed from its package in the food establishment within 48 hours after packaging.

(d) Treating Juice. Juice packaged in a food establishment shall be:

1. Treated under a HACCP PLAN as specified in 1200-23-01-.08(2)(d) to attain a 5-log reduction, which is equal to a 99.999% reduction, of the most resistant microorganism of public health significance; (P) or

2. Labeled, if not treated to yield a 5-log reduction of the most resistant microorganism of public health significance: (Pf)

(i) As specified under 1200-23-01-.03(6)(b), (Pf) and

(ii) 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 with the following, "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." (Pf)

(5) Limitation of Growth of Organisms of Public Health Concern.

(a) Temperature and Time Control.

1. Frozen Food. Stored frozen foods shall be maintained frozen.

2. Time/Temperature Control for Safety Food, Slacking. Frozen time/temperature control for safety food that is slacked to moderate the temperature shall be held:

(i) Under refrigeration that maintains the food temperature at 5ºC (41ºF) or less.

(ii) At any temperature if the food remains frozen.

3. Thawing. Except as specified in subpart (iv) of this part, time/temperature control for safety food shall be thawed:

(i) Under refrigeration that maintains the food temperature at 5ºC (41ºF) or less°.

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(Rule 1200-23-01-.03, continued)

(ii) Completely submerged under running water:

(I) At a water temperature of 21°C (70°F) or below,

(II) With sufficient water velocity to agitate and float off loose particles in an overflow,

(III) Such that for ready-to-eat food, the temperature of thawed portions do not rise above 5°C (41°F), and

(IV) Such that for raw animal food requiring cooking as specified under 1200-23-01-.03(4)(a)1(i) or (ii), thawed portions are not above 5°C (41°F) , for more than 4 hours including:

I. The time the food is exposed to the running water and the time needed for preparation for cooking, or

II. The time it takes under refrigeration to lower the food temperature to 5°C (41°F);

(iii) As part of a cooking process if the food that is frozen is:

(I) Cooked as specified under 1200-23-01-.03(4)(a)1(i) or (ii) or under 1200-23-01-.03(4)(a)2(i), or

(II) Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or

(iv) Using any procedure if a portion of frozen ready-eat-food is thawed and prepared for immediate service in response to an individual consumer's order.

4. Cooling.

(i) Cooked time/temperature control for safety food shall be cooled:

1. Within 2 hours from 57ºC (135ºF) to 21ºC (70ºF); (P) and

2. Within a total of 6 hours from 57°C (135°F) to 5°C (41ºF) or less. (P)

(ii) Time/temperature control for safety food shall be cooled within 4 hours to 5°C (41°F) or less, if prepared from ingredients at ambient temperature such as reconstituted foods and canned tuna. (P)

(iii) Except as specified under subpart (iv) of this part, a time/temperature control for safety food received in compliance with laws allowing a temperature above 5°C (41°F) during shipment from the supplier as specified under 1200-23-01-.03(2)(b)1(ii), shall be cooled within 4 hours to 5°C (41°F) or less. (P)

(iv) Raw eggs shall be received as specified under under 1200-23-01-.03(2)(b)3 and immediately placed in refrigerated equipment that maintains an ambient air temperature of 5°C (41°F) or less. (P)

(Rule 1200-23-01-.03, continued)

5. Cooling Methods.

(i) Cooling shall be accomplished in accordance with the time and temperature criteria specified under 1200-23-01-.03(5)(a)4 by using one or more of the following methods based on the type of food being cooled:

(I) Placing the food in shallow pans; (Pf)

(II) Separating the food into smaller or thinner portions; (Pf)

(III) Using rapid cooling equipment; (Pf)

(IV) Stirring the food in a container placed in an ice water bath; (Pf)

(V) Using containers that facilitate heat transfer; (Pf)

(VI) Adding ice as an ingredient; (Pf) or

(VII) Other effective methods. (Pf)

(ii) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:

(I) Arranged in the equipment to provide maximum heat transfer through the container walls; and

(II) Loosely covered, or uncovered if protected from overhead contamination as specified under 1200-23-01.03(3)(e)1(i)(I), during the cooling period to facilitate heat transfer from the surface of the food.

6. Time/Temperature Control for Safety Food, Hot and Cold Holding.

~~(i) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 1200-23-01-.03(5)(a)9, and except as specified under (ii) and in (iii) of this part, time/temperature control for safety food shall be maintained at 57°C (135°F) or above, except that roasts cooked to a temperature and for a time specified under 1200-23-01-.03(4)(a)1(ii) or reheated as specified in 1200-23-01-.03(4)(c)5 may be held at a temperature of 54°C (130°F) or above. (P)~~

(i) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 1200-23-01-.03(5)(a)9, and except as specified under (ii) and in (iii) of this part, time/temperature control for safety food shall be maintained:

(I) at 57°C (135°F) or above, except that roasts cooked to a temperature and for a time specified under 1200-23-01-.03(4)(a)1(ii) or reheated as specified in 1200-23-01-.03(4)(c)5 may be held at a temperature of 54°C (130°F) or above; (P) or

(II) at 5ºC (41ºF) or less. (P).

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(Rule 1200-23-01-.03, continued)

(ii) Eggs that have not been treated to destroy all viable Salmonellae shall be stored in refrigerated equipment that maintains an ambient air temperature of 5°C (41°F) or less. (P)

(iii) Time/temperature control for safety food in a homogenous liquid form may be maintained outside of the temperature control requirements, as specified under (i) of this part, while contained within specially designed equipment that complies with the design and construction requirements as specified under 1200-23-01-.04(2)(d)3(v).

7. Ready-to-Eat, Time/Temperature Control for Safety Food Date Marking

(i) Except when packaging food using a reduced oxygen packing method as specified under 1200-23-01-.03(5)(c), and except as specified in subpart (v) of this part, refrigerated, ready-to-eat, time/temperature control for safety food prepared and held in a food establishment for more than 24 hours shall be marked to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combination of 5°C (41°F) or less for a maximum of 7 days. The day of preparation shall be counted as day 1. (Pf)

(ii) Except as specified in (v) - (vi) of this part, refrigerated, ready-to-eat, time/temperature control for safety food prepared and packaged by a food processing plant shall be clearly marked, at the time the original container is opened in a food establishment and if the food is held for more than 24 hours, to indicate the date or day by which the food shall be consumed on the premises, sold, or discarded, based on the temperature and time combinations specified in (i) of this part and: (Pf)

(I) The day the original container is opened in the food establishment shall be counted as day 1; (Pf) and

(II) The day or date marked by the food establishment may not exceed a manufacturer's use-by date if the manufacturer determined the use-by date based on food safety. (Pf)

(iii) A refrigerated, ready-to-eat, time/temperature control for safety food ingredient or a portion of a refrigerated, ready-to-eat, time/temperature control for safety food that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest-prepared or first-prepared ingredient. (Pf)

(iv) A date marking system that meets the criteria stated in subparts (i) and (ii) of this part may include:

(I) Using a method approved by the department for refrigerated, ready-to-eat time/temperature control for safety food that is frequently rewrapped, such as lunchmeat or a roast, or for which date marking is impractical, such as soft serve mix or milk in a dispensing machine;

(II) Marking the date or day of preparation, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under subpart (i) of this part;

(Rule 1200-23-01-.03, continued)

(III) Marking the date or day the original container is opened in a food establishment, with a procedure to discard the food on or before the last date or day by which the food must be consumed on the premises, sold, or discarded as specified under subpart (ii) of this part; or

(IV) Using calendar dates, days of the week, color-coded marks, or other effective marking methods, provided that the marking system is disclosed to the department upon request.

(v) Subparts (i) and (ii) of this part do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.

(vi) Subpart (ii) of this part does not apply to the following foods prepared and packaged by a food processing plant inspected by a department:

(I) Deli salads, such as ham salad, seafood salad, chicken salad, egg salad, pasta salad, potato salad, and macaroni salad, manufactured in accordance with 21 CFR Part 110 Current good manufacturing practice in manufacturing, packing, or holding human food;

(II) Hard cheeses containing not more than 39% moisture as defined in 21 CFR Part 133 Cheeses and related cheese products, such as cheddar, gruyere, parmesan and reggiano, and romano;

(III) Semi-soft cheeses containing more than 39% moisture, but not more than 50% moisture, as defined in 21 CFR Part 133 Cheeses and related cheese products, such as blue, edam, gorgonzola, gouda, and monterey jack;

(IV) Cultured dairy products as defined in 21 CFR Part 131 Milk and cream, such as yogurt, sour cream, and buttermilk;

(V) Preserved fish products, such as pickled herring and dried or salted cod, and other acidified fish products as defined in 21 CFR Part 114 Acidified foods;

(VI) Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices, and containers, and which retain the original casing on the product; and

(VII) Shelf stable salt-cured products such as prosciutto and Parma (ham) that are not labeled "Keep Refrigerated" as specified in 9 CFR Part 317 Labeling, marking devices, and containers.

8. Ready-to-Eat, time/temperature control for safety food, Disposition.

(i) A food specified in 1200-23-01-.03(5)(a)7(i) or (ii) shall be discarded if it:

(I) Exceeds the temperature and time combination specified in 1200-23-01-.03(5)(a)7(i), except time that the product is frozen; (P)

(II) Is in a container or package that does not bear a date or day; (P) or

(Rule 1200-23-01-.03, continued)

(III) Is appropriately marked with a date or day that exceeds a temperature and time combination as specified in 1200-23-01-.03(5)(a)7(i). (P)

(ii) Refrigerated, ready-to-eat, potentially hazardous foods time/temperature control for safety food prepared in a food establishment and dispensed through a vending machine with an automatic shutoff control shall be discarded if it exceeds a temperature and time combination as specified in 1200-23-01-.03(5)(a)7(i).

9. Time as a Public Health Control.

(i) Except as specified under subpart (iv) of this part, if time without temperature control is used as the public health control for a working supply of time/temperature control for safety food before cooking, or for ready-to-eat time/temperature control for safety food that is displayed or held for sale or service:

(I) Written procedures shall be prepared in advance, maintained in the food establishment and made available to the department upon request that specify: (Pf)

I. Methods of compliance with items (ii)(I)-(IV) or (iii)(I)-(V) of this part; (Pf) and

II. Methods of compliance with 1200-23-01-.03(5)(a)4 for food that is prepared, cooked, and refrigerated before time is used as a public health control. (Pf)

(ii) If time without temperature control is used as the public health control up to a maximum of 4 hours:

(I) The food shall have an initial temperature of 5°C (41°F) or less when removed from cold holding temperature control, or 57°C (135°F) or greater when removed from hot holding temperature control; (P)

(II) The food shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the food is removed from temperature control; (Pf)

(III) The food shall be cooked and served, served at any temperature if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control; (P) and

(IV) The food in unmarked containers or packages, or marked to exceed a 4-hour limit shall be discarded. (P)

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

(I) The food shall have an initial temperature of 5°C (41°F) or less when removed from temperature control and the food temperature may not exceed 21°C (70°F) within a maximum time period of 6 hours; (P)

(II) The food shall be monitored to ensure the warmest portion of the food does not exceed 21°C (70°F) during the 6 hour period, unless

(Rule 1200-23-01-.03, continued)

an ambient air temperature is maintained that ensures the food does not exceed 21°C (70°F) during the 6-hour holding period; (Pf)

(III) The food shall be marked or otherwise identified to indicate: (Pf)

I. The time when the food is removed from 5°C (41°F) or less cold holding temperature control, (Pf) and

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

(IV) The food shall be:

I. Discarded if the temperature of the food exceeds 21°C (70°F), (P) or

II. 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 5°C (41°F) or less cold holding temperature control; (P) and

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

(iv) A food establishment that serves a highly susceptible population may not use time as specified under subparts (i), (ii) or (iii) of this part as the public health control for raw eggs.

(b) Specialized Processing Methods: Variance Requirement. A food establishment shall obtain a variance from the department as specified in 1200-23-01-.08(1)(d)1 and under 1200-23-01-.08(1)(d)2 before: (Pf)

1. Smoking food as a method of food preservation rather than as a method of flavor enhancement; (Pf)

2. Curing food; (Pf)

3. Using food additives or adding components such as vinegar: (Pf)

(i) As a method of food preservation rather than as a method of flavor enhancement, (Pf) or

(ii) To render a food so that it is not time/temperature control of safety food; (Pf)

4. Packaging food using a reduced oxygen packing method except where the growth of and toxin formation by Clostridium botulinum and the growth of Listeria monocytogenes are controlled as specified under 1200-23-01-.03(5)(c); (Pf)

5. Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption; (Pf)

6. Custom processing animals that are for personal use as food and not for sale or service in a food establishment; (Pf)

(Rule 1200-23-01-.03, continued)

7. Preparing food by another method that is determined by the department to require a variance; (Pf)or

8. Sprouting seeds or beans. (Pf)

(c) Clostridium botulinum and Listeria moncytogenes Controls. - Reduced Oxygen Packaging Without a Variance, Criteria.

1. Except for a food establishment that obtains a variance as specified under 1200-23-01-.03(5)(b)4, a food establishment that packages 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)

2. A food establishment that packages time/temperature control for safety food using a reduced oxygen method shall have a HACCP plan that contains the information specified under 1200-23-01-.08(2)(d)4 and that: (Pf)

(i) Identifies the food to be packaged; (Pf)

(ii) Except as specified under parts 3. – 5. of this subparagraph, 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)

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

(II) Has a Ph of 4.6 or less, (Pf)

(III) 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

(IV) Is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables; (Pf)

(iii) 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)

(I) Maintain the food at 5˚C (41˚F) or below, (Pf) and

(II) Discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption; (Pf)

(iv) Limits the refrigerated shelf life to no more than 14 calendar days from packing 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)

(v) Includes operational procedures that:

(i) Prohibit contacting ready-to-eat food with bare hands as specified under 1200-23-01-.03(3)(a)1(ii), (Pf)

(Rule 1200-23-01-.03, continued)

(II) 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

III. Delineate cleaning and sanitation procedures for food-contact surfaces; (Pf) and

(vi) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the: (Pf)

(I) Concepts required for a safe operation, (Pf)

(II) Equipment and facilities, (Pf) and

(III) Procedures specified under subpart 2(v) of this part and 1200-23-01-.08(2)(d)4. (Pf)

3. 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)

4. Except as specified under part 3 of this subparagraph, a food establishment that packages food using a cook-chill or sous vide process shall:

(i) Implement a HACCP plan that contains the information as specified under 1200-23-01-.08(2)(d)4; (Pf)

(ii) Ensure the food is:

(I) 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)

(II) Cooked to heat all parts of the food to a temperature and for a time as specified under 1200-23-01-.03(4)(a)1, (Pf)

(III) Protected from contamination before and after cooking as specified under 1200-23-01-.03(3)-(5), (P)

(IV) 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)

(V) Cooled to 5°C (41°F) in the sealed package or bag as specified under 1200-23-01-.03(5)(a)4 and subsequently; (P)

(VI) 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)

(Rule 1200-23-01-.03, continued)

(VII) 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)

(VIII) 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

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

(X) 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)

(XI) 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

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

(I) Make such records available to the department upon request (Pf); and

(II) Hold such records for at least 6 months; (Pf) and

(iv) Implement written operational procedures as specified under subpart 2(v) of this subparagraph and a training program as specified under subpart 2(vi) of this subparagraph.

5. A food establishment that packages cheese using a reduced oxygen packaging method shall:

(i) 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)

(ii) Have a HACCP plan that contains the information specified under 1200-23-01-.08(2)(d)4 and as specified under subparts 2(i), 2(v) and 2(vi) and item (2)(iii)(I) of this subparagraph; (Pf)

(iii) 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

(iv) 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)

(Rule 1200-23-01-.03, continued)

(6) Food Identity, Presentation, and On-Premises Labeling

(a) Accurate Representation.

1. Standards of Identity. Packaged food shall comply with standard of identity requirements in 21 CFR Parts 131-169 and 9 CFR Part 319 Definitions and standards of identity or composition, and the general requirements in 21 CFR Part 130 – Food Standards: General and 9 CFR Part 319 Subpart A – General Provisions.

2. Honestly Presented.

(i) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

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

(b) Labeling.

1. Food packaged in a food establishment, shall be labeled as specified in law, including 21 CFR Part 101 - Food labeling, and 9 CFR Part 317 Labeling, marking devices, and containers.

2. Label information shall include:

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

(ii) 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;

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

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

(v) 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)

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

(vii) 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.

3. Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:

(i) The manufacturer's or processor's label that was provided with the food; or

(Rule 1200-23-01-.03, continued)

(ii) A card, sign, or other method of notification that includes the information specified under subparts 2(i), (ii), and (v) of this part.

4. Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:

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

(ii) There are no state or local laws requiring labeling; and

(iii) 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.

5. Other Forms of Information.

(i) If required by law, consumer warnings shall be provided.

(ii) Food establishment or manufacturers' dating information on foods may not be concealed or altered.

(c) Consumer Advisory - Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens.

1. Except as specified in 1200-23-01-.03(4)(a)1(iii) and 1200-23-01-.03(4)(a)1(iv)(IV) and under 1200-23-01-.03(8)(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 parts and 3 of this subparagraph using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means. (Pf)

2. Disclosure shall include:

(i) 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

(ii) 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)

3. Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:

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

(ii) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness; (Pf) or

(Rule 1200-23-01-.03, continued)

(iii) 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)

(7) Contaminated Food - Disposition. Discarding or Reconditioning Unsafe, Adulterated, or Contaminated Food.

(a) A food that is unsafe, adulterated, or not honestly presented as specified under 1200-23-01-.03(1) shall be discarded or reconditioned according to an approved procedure. (P)

(b) Food that is not from an approved source as specified under 1200-23-01-.03(2)(a) – (c) 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 1200-23-01-.02(2)(b) 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)

(8) Special Requirements for Highly Susceptible Populations - 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 1200-23-01-.03(4)(d)2 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 1200-23-01-.08(2)(d) 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 paragraph, 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)

(Rule 1200-23-01-.03, continued)

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 1200-23-01-.03(3)(a)1.(ii) and (iv). (P)

(e) Time only, as the public health control as specified under 1200-23-01-.03(5)(a)9(iv), may not be used for raw eggs.

(f) Subparagraph (b)2 of this paragraph 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 1200-23-01-.03(4)(a)1(i)(I), and served immediately, such as an omelet, soufflé, or scrambled eggs; (P)

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:

(i) Identifies the food to be prepared,

(ii) Prohibits contacting ready-to-eat food with bare hands,

(iii) 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 1200-23-01-.03(4)(a)1(i)(II),

(iv) Contains the information specified under 1200-23-01-.08(2)(d)4 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

(v) 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 subparagraph (h) of this paragraph, food may be re-served as specified under 1200-23-01-.03(3)(f)4(ii)(I) and (II).

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

(Rule 1200-23-01-.03, continued)

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.

Authority: *T.C.A. §§ 68-14-701 through 68-14-726.* ***Administrative History:*** *Original rule filed March 26, 1987; effective May 9, 1987. Amendment filed January 4, 1995; effective March 20, 1995. Withdrawal of 1200-23-.03(3)(d) filed November 3, 2000. Repeal and new rule filed August 24, 2000; effective November 7, 2000. Amendment filed October 22, 2004; effective January 5, 2005. Repeal and new rule filed April 17, 2015; effective July 16, 2015.*

1200-23-01-.04 EQUIPMENT, UTENSILS, AND LINENS.

(1) Materials for Construction and Repair

(a) Multiuse

1. Characteristics

(i) Materials that are used in the construction of utensils and food-contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be: (P)

(I) Safe; (P)

(II) Durable, corrosion-resistant, and nonabsorbent;

(III) Sufficient in weight and thickness to withstand repeated warewashing;

(IV) Finished to have a smooth, easily cleanable surface; and

(V) Resistant to pitting, chipping, crazing, scratching, scoring, distortion and decomposition.

(ii) Cast Iron, Use Limitation.

(I) Except as specified in items (II) and (III) of this subpart, cast iron may not be used for utensils or food-contact surfaces of equipment.

(II) Cast iron may be used as a surface for cooking.

(III) Cast iron may be used in utensils for serving food if the utensils are used only as part of an uninterrupted process from cooking through service.

(iii) Lead, Use Limitation.

(I) Ceramic, china, and crystal utensils, and decorative utensils such as hand painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories (P)