



COLORADO
Department of Public
Health & Environment

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To: Members of the State Board of Health

From: Troy Huffman, Retail Food Program Coordinator, Division of Environmental Health and Sustainability
Cary E. Ruble, Regulation Development and Enforcement Coordinator, Division of Environmental Health and Sustainability

Through: Jeff Lawrence, Director
Division of Environmental Health and Sustainability (jL)

Date: September 20, 2017

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1010-2, *Colorado Retail Food Establishment Rules and Regulations*, with a request for a November 2017 rulemaking hearing

The Division of Environmental Health and Sustainability (“division”) is proposing revisions throughout 6 CCR 1010-2, *Colorado Retail Food Establishment Rules and Regulations*, and is requesting that the Board of Health schedule a rulemaking hearing to consider adoption of the proposed amendments at the November 15, 2017, Board of Health meeting.

In compliance with Executive Order D 2012-002 and the State Administrative Procedure Act, §24-4-103.3, C.R.S., the department has conducted a mandatory review of 6 CCR 1010-2, *Colorado Retail Food Establishment Rules and Regulations*. Based on this review, the department is recommending amendments to align Colorado with the U.S. Food and Drug Administration’s 2013 model Food Code and the 2015 Supplement to the Food Code. The proposed changes will maintain or increase public health protections while: allowing the department and local public health agencies that perform this work increased access to federal resources, including multi-language materials, federal training and grant opportunities; minimizing variance requests and the workload for retail food establishments, local public health agencies and the department associated with these requests; improved data within the state and the opportunity to draw upon national data to inform decision-making; increasing efficiency in the rulemaking process; and, allowing the department and local public health agencies to target their limited resources to the greatest opportunities to protect our public health.

The division appreciates the Board’s consideration.

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY**

for Amendments to

6 CCR 1010-2, *Colorado Retail Food Establishment Rules and Regulations*

Basis and Purpose.

Rationale:

State statute directs CDPHE to establish regulations and ensure uniform statewide administration, implementation and enforcement for the retail food program. The purpose of the *Colorado Retail Food Establishment Rules and Regulations*, 6 CCR 1010-2, is to protect the health of the citizens and visitors to Colorado by ensuring food consumed in and from Colorado retail food establishments is safe, unadulterated, and honestly presented. The Centers for Disease Control and Prevention (CDC) estimates that each year roughly 48 million Americans (one in six) get sick, 128,000 are hospitalized, and 3,000 die of foodborne illnesses. Moreover, foodborne illnesses cost over \$50 billion each year. Reducing foodborne illness by just 10 percent would prevent 5 million Americans from getting sick each year. Preventing a single fatal case of *E. coli* O157 infection would save an estimated \$7 million dollars.

In compliance with Executive Order D 2012-002 and the State Administrative Procedure Act (§24-4-103.3, C.R.S.), the department has conducted a mandatory review of 6 CCR 1010-2, *Colorado Retail Food Establishment Rules and Regulations*. The purpose of the review is to determine if:

- the regulation achieves the statutory intent with the minimum regulatory requirements;
- the regulation is implemented in an efficient and effective manner; and
- there is a more efficient and effective manner of accomplishing the purpose of the regulation.

As written, the rule draws upon the U.S. Food and Drug Administration's model Food Code and supplements to the Food Code (the Food Code). The Food Code is a model code and reference document available for adoption by state, city, county and tribal agencies that regulate operations that include restaurants, grocery stores, food vendors, special/temporary events, and food service operations in institutions such as schools, hospitals, assisted living, nursing homes, and child care centers. An updated edition of the Food Code is published on a four-year cycle and is based on recommendations that are proposed every two years at the Conference for Food Protection (CFP).

The structure of the CFP provides a representative and equitable partnership among regulators, industry, academia, professional organizations and consumers to identify problems, formulate recommendations, and develop and implement practices and assist with code development to ensure safe food. The CFP provides the framework and forum for a national stakeholder process for the development of the Food Code, which in turn functions as the national standard for food safety. Adoption of the Food Code is favored by industry (particularly by national chain restaurants and grocery stores), and will assist Colorado in meeting the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS); a measure of an effective regulatory retail food program.

Large portions of the current rule mirror the Food Code. Some provisions were modified and tailored to Colorado as a Colorado-specific standard. The department has studied each of the deviations from the federal standard to determine if the deviation meets a need unique to Colorado consumers or if the deviation increases the public health protections to Coloradans and those visiting Colorado.

Throughout its review, the department did not find that the deviations from the federal standard improved our public health outcomes. Conversely, the department found that the deviations increased the administrative burden to the retail food establishments, local public health agencies and the department. By deviating from the national standard, Colorado was unable to utilize federal education and outreach material that supports safe practices and prevents disease. Similarly, deviating from the federal standard increased the number of variance requests that shifts resources from education, outreach and enforcement to processing requests to be excused from a Colorado-specific regulatory requirement. In studying the variance requests, the department concluded that portions of the rule do not reflect the minimum standard to protect public health, and thus, retail food establishments were excused from the requirement. This creates a patchwork of inconsistency across the state. Due to the Colorado-specific standards and the deviations, Colorado lost the opportunity to use national and other-state data to inform best practices. The result of the rule review was that the rule could be improved.

Following the review, the division spoke with industry, Local Public Health Agencies (LPHAs) and the State Board of Health (January 2017) to assess the viability of amending the regulation to incorporate the Food Code by reference rather than adopting a modified version of the national standard. Industry and the State Board of Health were supportive of the concept. LPHAs had varying levels of support or concerns. Based upon this feedback, a stakeholder process was initiated. Stakeholders included representatives from LPHAs, the Colorado Restaurant Association, retail food establishments, Indian Health Services, Colorado State University, various food industry associations, CDPHE's Disease Control and Environmental Epidemiology Division and Prevention Services Division, other state departments that rely upon the Retail Food Code, the U.S. Food and Drug Administration, and the U.S. Department of Agriculture. The result is this rule, which moves from a hybrid of national and state-specific standards to incorporating large portions of the U.S. Food Code without modification. The stakeholder process assessed the costs and benefits of the change, and then focused on removing or reducing barriers to the transition.

The proposed incorporation by reference of the Food Code will keep Colorado retail food establishments consistent with current health and sanitation requirements and nationally recognized science and evidence-based recommendations. The food safety principles do not change. By adopting the Food Code, Colorado will:

- promote uniform national standards for retail food safety by reducing complexity and better compliance;
- conform to uniform national standards using the most current science-based recommendations;
- have access to extensive resource-sharing with FDA and other participating states;
- reduce state and local agency work load associated with development of interpretations by using FDA interpretations of the Food Code;

- promote a common understanding of risk, risk control/management and food safety between industry and regulators, thereby, reducing the risk of foodborne illness; and
- reduce cost and complexity associated with future updates to the inspection data systems as the model Food Code is provided by data system vendors.

Overview of the proposed rule:

➤ **Adopting the Food Code establishes two new requirements.**

○ ***Certified Food Protection Manager***

Section 2-102.20 of the model Food Code requires that at least one employee with the authority to direct and control food preparation and service be a food protection manager who has been certified by an accredited program. As defined in the Food Code, only ANSI- accredited Food Protection Manager courses meet the requirements.

Having educated food managers is an effective way to protect the public and retail food employees. Properly trained food handlers improves food safety and reduces risks and behaviors commonly associated with foodborne illness and outbreaks. Some retail food establishments have Certified Food Protection Managers and some have employees serving in a similar capacity that would benefit from additional training. For some retail food establishments, this will be a new or increased requirement. The delayed implementation date discussed below allows the retail food establishments time to obtain the necessary training. The new requirement for a Certified Food Protection Manager at retail food establishments was evaluated during the stakeholder process and resulted in consensus to incorporate this portion of the Food Code into Colorado regulation.

○ ***Date Marking***

Section 3-501.17 of the model Food Code requires industry to implement procedures for identifying the date or day by which the food must be consumed, sold, or discarded (date marking). Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as *Listeria monocytogenes* (“LM”), is significantly slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase the risk to public health in ready-to-eat foods. Based on a predictive growth curve for LM, ready-to-eat, potentially hazardous food may be kept at 5°C (41°F) a total of 7 days. Food, which is prepared and held or prepared, frozen, and thawed, must be controlled to ensure its safety based on the total amount of time it was held at refrigeration temperature, and to limit the time for LM, to multiply.

Date marking is the mechanism by which the Food Code requires the control of the temperature and time combinations for the cold holding of potentially hazardous food. Date marking requirements apply to containers of commercially manufactured foods which are potentially hazardous that have been opened and to potentially hazardous food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is under the control of the food

establishment. This requirement is an expansion of the previous requirement for retail food operators serving highly susceptible populations. The requirement was evaluated during the stakeholder process, resulting in consensus to incorporate this portion of the Food Code into Colorado regulation.

➤ ***Updating definitions in the Food Code to align with state statute***

In select instances there is terminology used and defined in both the FDA Food Code and Colorado statute. Under these circumstances, the term, as used in the Food Code, shall have the meaning contained in the Colorado Food Protection Act, part 16, article 4, title 25, C.R.S.

➤ ***Portions of the Food Code are not incorporated***

The following four sections of the Food Code were not incorporated by reference due to conflicts with state law or resource limitations:

- 8-203.10 - Preoperational Inspections: Section 25-4-1606(2), C.R.S. specifies that the department or an LPHA under delegation agreement with the department may conduct a pre-opening inspection before licensing a retail food establishment. Section 8-203.10 of the Food Code requires that a preopening inspection be conducted. This conflicts with the intent of the statute, which takes into consideration local staffing resources and compliance circumstance that might or might not require a pre-opening inspection;
- 8-3 - Permit to Operate: The powers and duties of the department to grant or refuse licenses or certificates of licenses are specified in section 25-4-1604, C.R.S. The delegation of these powers and duties to LPHAs are also specified in the statute. Therefore, the incorporation of this section of the Food Code is not necessary;
- 8-401.10 - Establishing Inspection Interval: Colorado's retail food program has used a risk-based inspectional frequency methodology since 2004. This methodology considers factors such as food risk, operational risk, and compliance history. Based on these risk factors, the methodology establishes an inspection frequency of once every two years, once per year, twice per year, or three time per year. This methodology allows the department and delegated LPHAs to direct resources to the highest risk facilities, resulting in a more manageable workload obligation. The Food Code requires inspections every six months, which contradicts this established methodology and increases workload; and
- 8-401.20 - Performance-and Risk-Based (Inspections): See above.

➤ ***Implementation and the proposed effective date of the revised regulation***

The department is proposing a January 1, 2019 effective date. This gives the community time to prepare for the transition to the Federal Code. While the substantive requirements are largely unchanged, moving to the Food Code is a shift in practice for the department and LPHAs that regulate retail food establishments. Rule numbers and citations for those inspecting facilities will change. This requires new forms and data

entry. It also requires inspectors to be familiar with the new format and material.

The department and stakeholders formed five workgroups (Communications, Training, Guidance, Plan Review and Data Standardization) to ensure a seamless transition. The data standardization workgroup is comprised of department and LPHA representatives. The communications, training, guidance and plan review workgroups also include representatives from industry and the FDA. These workgroups will meet regularly during the coming year to further define and resolve specific implementation issues identified during the stakeholder process.

➤ **Formatting and technical edits to improve readability**

These proposed changes align this incorporation by reference with other incorporations used by the division. The format aligns with the Secretary of State's requirements.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes:

- §25-1-108(1)(c)(I), C.R.S. [The Board of Health has the following specific powers and duties... to issue from time to time such orders, to adopt such rules and regulations, and to establish such standards as the board may deem necessary or proper to carry out the provisions and purposes of this part 1 and to administer and enforce the public health laws of this state.]
- §25-4-1603, C.R.S. [Food Protection Act: The department is hereby designated the state licensing, certification, and food protection agency for the purpose of protecting the public health and ensuring a safe food supply in this state. In addition to such designation, the department is hereby authorized to regulate and control retail food establishments, promulgate rules governing the operation of such establishments, and uniformly enforce and administer this part 16.]
- §25-4-1604(1)(b)(I), C.R.S., [Food Protection Act: To promulgate rules for adoption by the state board of health pursuant to article 4 of title 24, C.R.S., for the uniform statewide administration, implementation, interpretation, and enforcement of this part 16 and, as necessary, to ensure a safe food supply in retail food establishments. Such rules may include provisions for the initial and periodic medical examination by the department or other competent medical authority of all employees of retail food establishments and shall include provisions specifying and regulating the places and conditions under which food shall be prepared for consumption, a uniform code of sanitary rules, and such other rules as the department deems necessary. Such rules may be modified and changed from time to time.]

and,

- §25-5-420, C.R.S. [Pure Food and Drug Law: (1) The authority to promulgate regulations for the efficient enforcement of this part 4 is vested in the department. The department is authorized to make the regulations promulgated under this part 4

conform, insofar as practicable, with those promulgated under the federal act, the federal "Fair Packaging and Labeling Act" (15 U.S.C. secs. 1451-1461), and the federal "Meat Inspection Act of March 4, 1907", as amended (21 U.S.C. secs. 71-91). All regulations promulgated under this part 4 shall be promulgated in accordance with the provisions of article 4 of title 24, C.R.S.]

Additional Statutory Background:

While this rule implements numerous portions of the Colorado Revised Statutes, this portion of the Food Protection Act is included to provide additional background about the context, scope and enforcement of the Retail Food Code.

25-4-1604. Powers and duties of department - rules

(1) The department shall have the following powers and duties:

(a) To grant or refuse licenses and certificates of license pursuant to section 25-4-1606, or to suspend or revoke licenses and certificates of license pursuant to section 25-4-1609;

(b) (I) To promulgate rules for adoption by the state board of health pursuant to article 4 of title 24, C.R.S., for the uniform statewide administration, implementation, interpretation, and enforcement of this part 16 and, as necessary, to ensure a safe food supply in retail food establishments. Such rules may include provisions for the initial and periodic medical examination by the department or other competent medical authority of all employees of retail food establishments and shall include provisions specifying and regulating the places and conditions under which food shall be prepared for consumption, a uniform code of sanitary rules, and such other rules as the department deems necessary. Such rules may be modified and changed from time to time.

(II) For purposes of this paragraph (b), a uniform code of sanitary rules means rules for the preparation, sale, and serving of food, including but not be limited to general overall retail food establishment and equipment design and construction; sanitary maintenance of equipment, utensils, and facilities for food preparation, service, and storage; wholesomeness of food and drink; source and protection of food and water; disposal of liquid and solid wastes; and other rules for the effective administration and enforcement of this part 16.

(c) To hear and determine all complaints against licensees or grantees of certificates of license and to administer oaths and issue subpoenas to require the presence of any person necessary to the determination of any such hearing;

(d) To uniformly enforce this part 16 and the rules promulgated pursuant to this section;

(e) To enter retail food establishments during business hours and at other times during which activity is evident to conduct inspections and other interventions related to food safety and the protection of public health;

(f) To develop and enforce uniform statewide standards of program conduct and performance to be followed and adhered to by employees of the department and county or district boards of health;

(g) To provide technical assistance, equipment and product review, training and standardization, program evaluation, and other services necessary to assure the uniform statewide administration, implementation, interpretation, and enforcement of this part 16 and rules promulgated under this part 16;

(h) To review and approve HACCP plans submitted for evaluation to verify and ensure that food handling risks are reduced to prevent food-borne illness outbreaks;

(i) To delegate to any county or district board of health the powers and duties described in paragraphs (a), (c), (d), (e), and (h) of this subsection (1) at the request of such county or district board of health.

(2) Subsection (1) of this section shall not apply to the city and county of Denver, which, by ordinance, may provide for the licensure of retail food establishments.

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____; rules are ___ authorized ___ required.
 X No

Is this rulemaking due to a federal statutory or regulatory change?

_____ Yes
 X No

Does this rule incorporate materials by reference?

 X Yes
_____ No

Does this rule create or modify fines or fees?

_____ Yes
 X No

REGULATORY ANALYSIS

for Amendments to

6 CCR 1010-2, *Colorado Retail Food Establishment Rules and Regulations*

1. **A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.**

There are over 20,000 department-regulated retail food establishments throughout the state. Retail food establishments include restaurants, grocery stores, mobile food carts, food vendors at temporary events/special events and farmers markets (farmers markets that offer more than uncut fresh fruit and vegetables for sale), and food service operations in institutions such as schools, hospitals, correctional facilities.

The department and local public health agencies (LPHAs) are affected by the proposed rule. Both the department and LPHAs:

- regulate retail food establishments;
- oversee disease control activities and in association therewith investigate foodborne illness in Colorado communities; and
- work with retail food establishments to promote and expand healthy food offerings in their communities to prevent chronic disease.

The different touchpoints for the department and LPHAs were considered in developing the proposed rules.

The department, LPHAs and the regulated community are all affected and will benefit from the proposed incorporation by reference of the Food Code. Costs are largely born by the department to ensure infrastructure supports to state operations and to any LPHA that regulates retail food.

Wholesale food processors and manufactures will not be affected.

The public will benefit from the revisions, which are scientifically based to prevent the occurrence of foodborne illness.

2. **To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.**

The incorporation by reference of the Food Code maintains uniformity and allows retail food establishments to more effectively and efficiently comply with regulation. Therefore, enabling industry to not only be required to meet food safety standards which are recognized nationally and operate under one set of uniform regulations that will not vary from county to county and for national and regional chains from state to state.

Adoption of the Food Code establishes two new requirements; manager certification and date marking. Section 2-102.20 of the model Food Code requires that at least one employee with the authority to direct and control food preparation and service be a food protection manager who has been certified by an accredited program. Section 3-501.17 of

the model Food Code require industry to implement a system of identifying the date or day by which the food must be consumed, sold, or discarded (date marking). This requirement is an expansion of the previous requirement for retail food establishment operators. Both of these new requirements provides better public health protection within the retail food industry in Colorado. Though there is a cost to industry, it varies by particular retail food establishment and whether the retail food establishment already had date marking and a food protection manager. The cost in the short-term is offset by the benefit of improved food safety practices. The two new requirement support continuity in business operations; these practices help the business avoid closure for unsafe practices, closure due to an outbreak investigation or loss of business due to an outbreak. Similarly, these food safety practices benefit retail food establishments as employers as employees and customers are both adversely effected by foodborne illness.

While the substantive requirements are largely unchanged, moving to the Food Code is a shift in practice for the department and LPHAs that regulate retail food establishments. Rule numbers and citations for those inspecting facilities will change. This requires new forms and data entry. It also requires inspectors to be familiar with the new format and material. While the vast majority of the Food Code content is not new and inspectors are familiar with it, removing the Colorado-specific language will require inspectors to locate the applicable provision in the Food Code. In addition, under the current rule, Colorado-specific language sometimes prescribed a specific course. With moving to the Food Code, there will be circumstances where a new and possibly multiple pathways for achieving compliance are available. Though the content is largely the same, the conversation for those out in the field may be quite different. There will be opportunities for problem-solving. Local businesses and food safety regulators will benefit from this engagement. The delayed effective date allows everyone time to prepare for the process changes.

The shift to the Food Code maximizes the current allocation of resources by improving administrative efficiency. Along with efficiency in the rulemaking process, moving to the Food Code allows the department, LPHAs and the regulated community access to federal guidance and resources that will support compliance and evidence-based practices. Additionally, this approach, by directly aligning our regulation with the FDA Food Code provides for increased eligibility to the department and LPHAs for federal funding. Finally, moving to the Food Code standardizes our data and allows Colorado to compare its work with other states and national data sets. Data is an invaluable resource that allows the regulators and regulated community to make informed decisions and allocate efforts to areas of increased risk or increased opportunity to improve food safety. Improved data will also increase Colorado's compatibility with intra- and multi-state outbreak response protocols.

LPHAs have the opportunity to increase administrative efficiency but the extent to which efficiency is increased is dependent upon the local jurisdiction's implementation of the contract and delegation. For example, a LPHA that relies upon the state data system will have less cost than an agency that opts to procure or build a county-specific system. Though there is efficiency and increased effectiveness when the state's data system is used, the department has not required local government to use the state system. Statute permits the department to delegate Food Protection Act responsibilities to a county or district board of health, §25-4-1604(1)(i), C.R.S. and a LPHA may implement practices and administrative efficiencies so long as the practices do not conflict with these rules or department policies.

While LPHAs are not required to regulate retail food, many have opted to do so. Currently, thirty-four (34) local public health agencies have delegated authority to implement the regulations in 58 of the 64 counties in the State; whereas the division currently implements the regulations in the remaining 6 counties. LPHAs are involved to the extent they agree to serve as the department's designee for the purpose of retail food establishment inspections. Many local public health agencies contribute local dollars to implement additional desired program elements, these costs would remain as desired by the local decision makers. LPHAs are a partner in this work; however, the proposed regulation does not contain a local government mandate as defined by statute.

This regulation does not apply to establishments in the City and County of Denver, who are exempt by statute, 25-4-1604(2), from using the proposed regulations. The City and County of Denver was represented in the stakeholder process, and is a current and historical partner with the department and other local health jurisdictions in assuring their requirements are substantially equivalent to these regulations.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

Minimal costs will be incurred by retail food establishments attaining compliance with new requirements regarding manager certification. Those minor costs are outweighed by the increased public health benefit this new requirement provides. While the adoption of the FDA Model Food Code is not mandated, it is strongly favored by industry, particularly by national and regional chain restaurants and grocery stores. Adoption of the Food Code will allow Colorado to meet a number of the Voluntary National Retail Food Regulatory Program Standards, a measure of an effective retail food program.

Required costs to the department and LPHAs are minimal and associated with staff training and data system updates. While this change does necessitate modifications to existing data systems, the migration of data and use of the State's data system is available LPHA partners at no cost. Currently 23 out of the 34 delegated counties utilize this system. For those that do not opt to use the state data system, costs associated with procuring another database, building a database or customizing a database would vary. No LPHA is required to incur these costs. Staff training costs are also anticipated to be minimal and incurred in the short-term. Stakeholders have developed a work plan to ensure regulators and the regulated community are prepared to apply the Food Code by the delayed effective date of January 1, 2019. After implementation, costs will reduce or be avoided for the reasons discussed above. For example, due to extensive resource-sharing with FDA, costs associated with the development of Colorado-specific guidance documents will be reduced and result in a more uniform application of Food Code requirements. Long-term LPHA cost-savings may result; however, this is dependent upon how the local jurisdiction implements the delegation.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

The current rule was adopted by the Board of Health on November 21, 2012. Since adoption, the department has studied the implementation. The department assessed its data, processes, administrative burdens, the feedback of regulated entities and local public health agencies and the public health outcomes achieved under the rule. Upon full review of the system, the department determined that moving to the Food Code maximizes the resources available to achieve the public health outcomes. The food safety administration costs exceed the resources available; this rule is an effort to close the gap between the costs and the resources by making our regulatory processes as efficient as possible. Adoption of the Food Code benefits industry and therefore benefits consumers. Uniformly enforced, nationally recognized science- and evidence-based food safety standards ensures the effective and efficient utilization of the fees paid by the industry to the department and local public health agencies.

Inaction results in continued enforcement of the current regulation. Portions of the regulation are prescriptive and thus, regulated entities must seek approval to deviate from the requirements. While variances are merited in limited circumstances, a pattern of variances indicates a rule is poorly written or does not clearly communicate the minimum standard. While Colorado could continue the development and maintenance of Colorado-specific guidance, doing so requires the department to allocate resources to administrative processing. It will not increase our opportunity to allocate resources to high-need areas as documented by the data. It does not allow the department to work with industry proactively to maintain healthy businesses, a healthy workforce or consumers free from acute foodborne illness. As time passes, the current standards will continue to drift further away from national evidence-based standards. The rules will become increasingly antiquated and Colorado's food safety performance will decline. As time passes, the costs to modernize our practice and our infrastructure supports of those practices will increase. Similarly, inaction limits the department and our local partners' ability to leverage other sources of revenue to support this work; participating in the Voluntary National Retail Food Regulatory Program Standards increases federal funding opportunities.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Every effort was made when developing the proposed regulations to take into consideration the probable impacts. The proposed rule is the most effective and efficient approach to achieving a safe food supply in Colorado. Adoption of the food safety requirements contained within the Food Code is necessary to provide the regulated community and the general public at large with a regulation that is consistent with current health and sanitation requirements and nationally recognized science- and evidence-based requirements to protect public health. By utilizing the incorporation by reference method, significant costs savings to both the regulated community and regulating agencies are realized by streamlining the process. The short-term costs are out-weighed by the operational efficiencies and health benefits. The department will update the incorporation by reference as need to remain current.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

The alternative to the proposed rulemaking was to amend and update the existing Colorado Retail Food Establishment Rules and Regulations. This alternative was rejected because the current regulations, as identified during the 2012 rulemaking, already closely mirror the FDA model Food Code. Adoption by reference is a more efficient use of time and resources for the department and local public health agencies, as it captures current advances in food safety through a concise incorporation. Adopting the FDA model Food Code keeps Colorado retail food establishments consistent with the most current nationally recognized science- and evidence-based health and sanitation requirements, and also immediately avails Colorado to the training, guidance, and multi-lingual resources from the FDA and other jurisdictions using the model Food Code. Implementation of the Food Code will ensure long-term consistency in the application of food safety requirements and will significantly improve the division's ability to track compliance data and increase Colorado's compatibility with intra- and multi-state outbreak response protocol.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

Analysis of the consequences associated with the incorporation by reference of the Food Code included review of Center for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) publications, Code of Federal Regulations (CFR), guidance documents, studies, variance requests submitted between 2013 and 2016, lean processes, quality improvement projects, interviews with database vendors and data specialists, feedback from LPHAs, feedback from industry, and budget documentation.

Additionally, the department reviewed references to the current retail food regulation in Code of Colorado Regulations. This regulation is referenced, cited, or incorporated by reference into the following regulations:

- Department of Public Health and Environment
 - Rules and Regulations Governing Schools (6 CCR 1010-6),
 - Rules And Regulations Governing The Health and Sanitation Of Child Care Facilities (6 CCR 1010-7),
 - Wholesale Food (6 CCR 1010-21),
 - Sanitary Standards For Penal Institutions (6 CCR 1010-13),
 - Nursing Care Facilities (6 CCR 1011-1, Chapter 05),
 - Standards For Hospitals and Health Facilities: Chapter VII - Assisted Living Residences (6 CCR 1011-1, Chapter 07), and
 - State Board Of Health, Core Public Health Services, (6 CCR 1014-7)
- Department of Revenue
 - Medical Marijuana Rules (1 CCR 212-1), and
 - Retail Marijuana Rules (1 CCR 212-2);

- Department Of Labor and Employment, Division of Vocational Rehabilitation, (7 CCR 1105-1)
- Department Of Health Care Policy And Financing Medical Services Board, Medical Assistance - (Section 8.500, 10 CCR 2505-10)
- Department Of Human Services
 - Services For The Aging Older Americans Act (Oaa) Programs (Rule Manual Volume 10) (12 CCR 2510-1), and
 - Division of Rehabilitation, Rehabilitation Services (Staff Manual Volume 9) (12 CCR 2513-1).

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1010-2, Colorado Retail Food Establishment Rules and Regulations

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:

The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

The retail food stakeholder group included representatives from local public health agencies (LPHAs), the Colorado Restaurant Association, retail food establishments, Indian Health Services, Colorado State University, various food industry associations, other Colorado Department of Public Health and Environment (CDPHE) divisions, other state departments, the U.S. Food and Drug Administration, and the U.S. Department of Agriculture.

Retail Food Rulemaking Stakeholders

- Adamson, Deb, Weld County Public Health
- Aguilar, Nicole, Larimer County Health Department
- Alvarez, Kelly, Kit Carson County Public Health
- Atkinson, Richard, USDA
- Austin, Jim, Montrose County Health and Human Services
- Babcock, Kelly, CSU
- Bailey, Grier, Colorado Wyoming Petroleum Marketers
- Bare, Gina, Boulder County Public Health
- Bernido, Alyssa, Indian Health Services
- Blehm, Jerry, Larimer County Public Health
- Braun, Elizabeth, Consumer
- Brookhill, Le Peep, Le Peep
- Bunning, Marisa, CSU Extension Service
- Burk, Kim, Broomfield Health and Human Services
- Bustos, Mel, Northeast County Health Department
- Carlton, Vicki, Pueblo County
- Carlstrom, Andrea, Chaffee County Public Health
- Chapman, MaryLou, Rocky Mountain Food Industry Association
- Chevalier, Steven, Tri-County Health Department
- Coin, Heather, Northeast County Health Department
- Collins, Daniel E., Broomfield Health and Human Services
- Cowman, Scott, Routt County Dept. of Environment
- Cross, Sheila, Park County Public Health
- Dahl, Kurt, Pitkin County
- Darden, Sid, Fremont County Env. Health Services
- Daugherty, Brian, Pitkin County
- Davidson, Abby, City and County of Denver
- Devore, Jim, Larimer County Public Health
- Drager, Lane, Boulder County Public Health
- Dugdale, Sherri, San Juan Basin Public Health
- Eisenman, Tom, Park County Public Health
- Fawcett, Laura, Eagle County Env. Health
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Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

- Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.
- Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The division has been tracking opportunities to improve and modernize this regulation since its last amendment in November 2012. Over the last 18 months, the division began having informal discussions with stakeholders to discuss the approach of incorporation by reference of the Food Code. Based on these discussions and positive feedback, formal regulation revision stakeholder meetings were scheduled and held on March 1, May 25, June 22, and August 8, 2017. Since the current *Colorado Retail Food Establishment Rules and Regulations* are recognized and understood by the involved and effected stakeholders and closely align with the model Food Code there were few significant factual or policy issues encountered.

The new requirement for a Certified Food Protection Manager at retail food establishments was evaluated during the stakeholder process and resulted in consensus. The date marking requirement is an expansion of a previous requirement for retail food establishment operators serving highly susceptible populations and was evaluated during the stakeholder process and also resulted in consensus.

Local public health agency (LPHA) response has been varied. Many appreciate the efficiency identified with the proposed rule. The concern and thus, the focus of the stakeholder engagement has been: ensuring the database is available, providing staff time and training to transition to the revised rule, and studying how the rule integrates with local government efforts authorized under statute. The stakeholder group has developed a work plan to implement the process improvements.

Division representatives met internally with representatives of CDPHE's Disease Control and Environmental Epidemiology Division (DCEED) and the Prevention Services Division (PSD) to confirm that the incorporation by reference of the Food Code supports or does not interfere with each division's respective missions, strategic priorities, and regulations. No significant factual or policy issues for these divisions or their partners were encountered.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

The incorporation by reference of the Food Code will continue to safeguard public health and ensure that food served in Colorado is unadulterated and honestly presented when offered to the consumer, regardless of race, color, national origin, or income. The revised and proposed regulation will continue to assure uniformity and effectiveness in the implementation of food safety standards and promote the full health potential of all Coloradans. The federal resources are available in multiple languages and the department anticipates that these resources will help inform stakeholders and individuals interested in learning more about food safety. The revised rule may enable regulators and regulated industry to be proactive and prevent disease; this influences the determinants of health for the retail food establishment owners and workforce by providing economic stability through maintained employment and resources for those that may be Limited English Proficient.

1 COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2
3 Division of Environmental Health and Sustainability

4
5 COLORADO RETAIL FOOD ESTABLISHMENT REGULATIONS

6
7 6 CCR 1010-2

8
9 Adopted by the Board of Health on _____; effective, January 1, 2019

10
11 2.1 Authority

12
13 This regulation is adopted pursuant to sections 25-1-108(1)(c)(I), 25-4-1603, 25-4-
14 1604(1)(b)(I), and 25-5-420, Colorado Revised Statute (C.R.S.) and is consistent with the
15 requirements of the State Administrative Procedure Act, section 24-4-101, et seq., C.R.S.

16
17 2.2 Scope and Purpose

- 18
19 A. This regulation shall be applied for the protection of public health by providing food to
20 consumers that is safe, unadulterated, and honestly presented.
- 21
22 B. This regulation establishes definitions; sets standards for management and personnel,
23 food operations, equipment and facilities; and provides for food establishment
24 inspection, employee restriction, and permit suspension.
- 25
26 C. This regulation does not apply to facilities or conditions listed in section 25-4-
27 1602(14)(a) - (m), C.R.S.
- 28
29 D. Section 2.6 of this regulation incorporates by reference:
- 30
31 1. Food Code, 2013 Recommendations of the United States Public Health
32 Service/Food and Drug Administration as published by the U.S. Department of
33 Health and Human Services, Public Health Service, Food and Drug
34 Administration (the Code), as published on November 15, 2017.
- 35
36 2. Supplement to the 2013 Food Code (2015), U.S. Department of Health and
37 Human Services, Public Health Service, Food and Drug Administration, (the
38 Supplement), as published on November 15, 2017.

39
40 2.3 Applicability

- 41
42 A. Pursuant to the provisions of sections 25-4-1602(14), 25-4-1603, and 25-4-
43 1604(1)(b)(I), C.R.S., this regulation:
- 44
45 1. Shall apply to a retail establishment that stores, prepares, or packages food for
46 human consumption or serves or otherwise provides food for human
47 consumption to consumers directly or indirectly through a delivery service,
48 whether such food is consumed on or off the premises or whether there is a
49 charge for such food.

- 50
51 B. In accordance with section 25-4-1604(b)(II), C.R.S., this regulation shall include but
52 not be limited to general overall retail food establishment and equipment design and
53 construction; sanitary maintenance of equipment, utensils, and facilities for food
54 preparation, service, and storage; wholesomeness of food and drink; source and
55 protection of food and water; disposal of liquid and solid wastes; and other rules for
56 the effective administration and enforcement of the Colorado Food Protection Act,
57 part 16, article 4, title 25, C.R.S.
58
59 C. The department shall utilize *the Code, the Supplement*, or other department
60 approved methods as authorized by statute and as appropriate to assure that retail
61 food establishments comply with the Colorado Food Protection Act, part 16, article 4,
62 title 25, C.R.S.
63

64 2.4 Definitions

- 65
66 A. For the purpose of these rules and regulations:
67
68 1. Food establishment (as used in *the Code and Supplement*) means, for the
69 purposes of this regulation, Retail Food Establishment as defined in section 25-
70 4-1602(14) C.R.S.
71
72 2. Inspection (as used in *the Code and Supplement*) means, for the purposes of
73 this regulation, Inspection as defined in section 25-4-1602(7) C.R.S.
74
75 3. Permit (as used in *the Code and Supplement*) means, for the purposes of this
76 regulation, License as defined in section 25-4-1602(8) C.R.S.
77
78 4. Permit holder (as used in *the Code and Supplement*) means, for the purposes of
79 this regulation, Licensee as defined in section 25-4-1602(9) C.R.S.
80
81 5. Regulatory authority (as used in *the Code and Supplement*) means, for the
82 purposes of this regulation, Department as defined in section 25-4-1602(3),
83 C.R.S. and any county or district board of health with powers and duties
84 delegated by the department in accordance with section 25-4-1604(1)(i), C.R.S.
85

86 2.5 License Requirements

87
88 Retail food establishments in Colorado must be licensed in accordance with the Colorado Food
89 Protection Act, part 16, article 4, title 25, C.R.S.
90

91 2.6 Incorporation by Reference

- 92
93 A. Throughout these regulations, standards and requirements of outside organizations
94 have been adopted and incorporated by reference. The material incorporated by
95 reference cited herein includes only those versions that were in effect on November
96 15, 2017, and no later amendments to the incorporated materials. These regulations
97 incorporate by reference:
98
99 1. *Food Code, 2013 Recommendations of the United States Public Health*
100 *Service/Food and Drug Administration* as published by the U.S. Department of

- 101 Health and Human Services, Public Health Service, Food and Drug
102 Administration (*the Code*); and
103
104 2. *Supplement to the 2013 Food Code (2015)*, U.S. Department of Health and
105 Human Services, Public Health Service, Food and Drug Administration, (*the*
106 *Supplement*).
107
108 B. These regulations do not incorporate by reference:
109
110 1. *Subpart 8-203.10 (Preoperational Inspections) of the Code;*
111
112 2. *Section 8-3 (Permit to Operate) of the Code;*
113
114 3. *Subpart 8-401.10 (Establishing Inspection Interval) of the Code; and*
115
116 4. *Subpart 8-401.20 (Performance- and Risk-Based) of the Code.*
117
118 C. The Division of Environmental Health and Sustainability shall maintain certified copies
119 of the complete text of the incorporated materials, which shall be available for public
120 inspection during regular business hours, and shall provide certified copies of the
121 materials at cost upon request. For information regarding how the incorporated
122 materials may be obtained or examined, contact:
123
124 Division Director
125 Division of Environmental Health and Sustainability
126 Colorado Department of Public Health and Environment
127 4300 Cherry Creek Drive South
128 Denver, Colorado 80246-1530
129
130 D. The incorporated materials are available at:
131
132 www.colorado.gov/pacific/cdphe/food-regulations/food-code

133

134

135

136

**~~COLORADO RETAIL FOOD
ESTABLISHMENT RULES AND
REGULATIONS~~**

137

~~6 CCR 1010-2~~

138

~~Adopted by the State Board of Health~~

139

140

~~Most recently amended November 21, 2012, effective March 1, 2013 with the
exception of section 3-801 which becomes effective July 1, 2013~~

141

142

143

144

145

146

147



148

Colorado Department
of Public Health
and Environment

149

Authority
**Sections 25-4-1604(1)(b)(I), 25-5-420, 25-1.5-104(1)(g)
and 25-1-108(1)(c)(I), Colorado Revised Statute**

150

~~COLORADO DEPARTMENT OF PUBLIC HEALTH
AND ENVIRONMENT~~

151

152

~~DIVISION OF ENVIRONMENTAL HEALTH AND SUSTAINABILITY~~

153

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154

~~DENVER, CO 80246-1530~~

155

156

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157

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455

CHAPTER 1

456

PURPOSE AND DEFINITIONS

1-101—Purpose

458

~~The following rules and regulations shall be applied for the protection of public health.~~

459

~~The purpose of this Regulation is to safeguard public health and provide to consumers food that is safe and unadulterated. This Regulation establishes definitions; sets standards for management and personnel, food operations and equipment and facilities; and provides for food establishment plan review, license issuance, inspections, employee restriction and enforcement. This Regulation is intended to be the standard for the Department and its authorized agents and employees, to be applied uniformly by all parties.~~

460

461

462

463

464

1-202—Definitions

466

~~A. The following terms are defined for the purposes of the rules and regulations.~~

467

~~1. “Accredited Program” means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to the national standards for organizations that certify individuals. Accredited Program does not refer to training functions or educational programs.~~

468

469

470

471

~~2. “Adulterated” means as stated in the Colorado Pure Food and Drug Act, section 25-5-4, C.R.S.~~

472

473

~~3. “Allergens” — See major food allergens definition 1-202(66).~~

474

~~4. “Approved” means acceptable to the Department, based on determination of conformity with principles, practices, and generally recognized standards that protect public health.~~

475

476

~~5. “Asterisk (*)” means any section or portion thereof denoted with an * indicates it is a critical item.~~

477

478

~~6. “Asymptomatic”:~~

479

~~a. Means without obvious symptoms; not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice.~~

480

481

482

~~b. Includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.~~

483

484

485

~~7. “ a_w ” means water activity which is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w .~~

486

487

488

~~8. “Balut” means an embryo inside a fertile egg that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.~~

489

490

491

~~9. “Bulk Foods” means foods as defined in section 25-4-1302, C.R.S.~~

492

~~10. “Catering Operation” means a retail food establishment that provides a contracted, prearranged number of meals and/or food products that are prepared at a licensed retail food~~

493

- 494 establishment for service and consumed at the same or another prearranged offsite location
495 and not available for individual purchase.
- 496 11. ~~“Certified Food Protection Manager” means a person in charge that is certified by an~~
497 ~~accredited program for food protection.~~
- 498 12. ~~“CFR” means Code of Federal Regulations. Citations in this Code to the CFR refer~~
499 ~~sequentially to the Title, Part, and Section numbers, such as 40 CFR 180.194 refers to Title~~
500 ~~40, Part 180, Section 194.~~
- 501 13. ~~“Clean In Place (CIP)” means cleaned in place by the circulation or flowing by mechanical~~
502 ~~means through a piping system of a detergent solution, water rinse, and sanitizing solution~~
503 ~~onto or over equipment surfaces that require cleaning, such as the method used, in part, to~~
504 ~~clean and sanitize a frozen dessert machine.~~
- 505 ~~— CIP does not include the cleaning and sanitization of equipment such as band saws, cutting~~
506 ~~boards, slicers or mixers that are subjected to in place manual cleaning without the use of an~~
507 ~~automated CIP system.~~
- 508 14. ~~“Commercial Design” means equipment that is certified or classified by an American~~
509 ~~National Standards Institute (ANSI) accreditation certification program, such as the National~~
510 ~~Sanitation Foundation (NSF), Underwriters Laboratories (UL) sanitation standards,~~
511 ~~Environmental Testing Laboratories, Inc. (ETL) sanitation standards, Baking Industry~~
512 ~~Sanitation Standards Committee (BISSC), or other comparable design criteria as approved~~
513 ~~by the Department during a standardized equipment review.~~
- 514 15. ~~“Commingle” means:~~
- 515 a. ~~To combine shellstock harvested on different days or from different growing areas~~
516 ~~as identified on the tag or label, or~~
- 517 b. ~~To combine shucked shellfish from containers with different container codes or~~
518 ~~different shucking dates.~~
- 519 16. ~~“Comminuted” means reduced in size by methods including chopping, flaking, grinding, or~~
520 ~~mincing. This includes fish or meat products that are reduced in size and restructured or~~
521 ~~reformulated such as gefilte fish, formed roast beef, gyros, ground beef, and sausage; and a~~
522 ~~mixture of two or more types of meat which have been reduced in size and combined, such~~
523 ~~as sausages made from two or more meats.~~
- 524 17. ~~“Commissary” means a facility that is approved by the Department as a base of operation~~
525 ~~for a temporary retail food establishment, pushcart, or mobile food establishment where~~
526 ~~food, containers, or supplies are kept, handled, prepared, packaged or stored and is~~
527 ~~constructed and operated in compliance with the Rules and Regulations.~~
- 528 18. ~~“Conditional Employee” means a potential food employee to whom a job offer is made,~~
529 ~~conditional on responses to subsequent medical questions or examinations designed to~~
530 ~~identify potential food employees who may be suffering from a disease that can be~~
531 ~~transmitted through food and done in compliance with Title 1 of the Americans with~~
532 ~~Disabilities Act of 1990.~~
- 533 19. ~~“Contamination” means exposure to or contact with a contaminant. Actions that may~~
534 ~~contaminate or cause contamination include: unsanitary food contact surfaces, coughing,~~
535 ~~sneezing, spitting, unnecessary handling, flooding, draining, leakage from overhead pipes,~~
536 ~~and condensation. “Contaminant” means a substance, organism, or entity that might cause~~
537 ~~disease or threaten public health, and includes soil, dust, insects, rodents, other pests, and~~
538 ~~poisonous or toxic materials.~~

- 539 20. ~~“Confirmed Disease Outbreak” means a foodborne disease outbreak in which laboratory~~
540 ~~analysis of appropriate specimens identifies a causative agent and epidemiological analysis~~
541 ~~implicates the food as the source of the illness.~~
- 542 21. ~~“Corrosion Resistant Materials” means a material that maintains acceptable surface~~
543 ~~cleanability characteristics under prolonged influence of the food to be contacted, the normal~~
544 ~~use of cleaning compounds and sanitizing solutions, and other conditions of the use~~
545 ~~environment.~~
- 546 22. ~~“Critical Control Point” means any point in a food preparation process at which loss of~~
547 ~~control might result in an unacceptable consumer health risk.~~
- 548 23. ~~“Critical item” means a provision of these rules and regulations that, if in noncompliance, is~~
549 ~~more likely than other violations to contribute to food contamination, illness, or an~~
550 ~~environmental health hazard. These are items denoted in these rules and regulations with an~~
551 ~~asterisk*.~~
- 552 24. ~~“Critical Limit” means the maximum or minimum value to which a physical, biological, or~~
553 ~~chemical parameter must be controlled at a critical control point to minimize the risk that the~~
554 ~~identified food safety hazard may occur.~~
- 555 25. ~~“Cross Connection” means any connection or arrangement, physical or otherwise, between~~
556 ~~a potable water supply system and any plumbing fixture or any tank, receptor, equipment or~~
557 ~~device, to which it may be possible for non-potable, used, unclean, polluted or contaminated~~
558 ~~water, or other substances, to enter any part in such potable water system under any~~
559 ~~condition.~~
- 560 26. ~~“Cross contamination” means the transfer of harmful bacteria to food from other foods,~~
561 ~~such as raw or undercooked animal products, to cutting boards, utensils, etc. if they are not~~
562 ~~handled properly.~~
- 563 27. ~~“Cut Leafy Greens” means fresh leafy greens whose leaves have been cut, shredded, sliced,~~
564 ~~chopped, or torn. The term “leafy greens” includes iceberg lettuce, romaine lettuce, leaf~~
565 ~~lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole,~~
566 ~~endive, spring mix, spinach, cabbage, kale, arugula and chard. The term “leafy greens” does~~
567 ~~not include herbs such as cilantro or parsley.~~
- 568 28. ~~“Department” means the Colorado Department of Public Health and Environment, and its~~
569 ~~authorized employees as well as any county or district board of health who have been~~
570 ~~delegated the powers and duties described in Sections 25-4-1604(1)(a), (c), (d) and (h)~~
571 ~~C.R.S.~~
- 572 29. ~~“Drinking Water”~~
- 573 a. ~~“Drinking Water” means water that meets criteria as specified in section 25-1.5-2,~~
574 ~~C.R.S., *Colorado Primary Drinking Water Regulations*~~
- 575 b. ~~“Drinking Water” is traditionally known as “potable water.”~~
- 576 c. ~~“Drinking Water” includes the term “water” except where the term used connotes~~
577 ~~that the water is not potable, such as “boiler water,” “mop water,” “rainwater,”~~
578 ~~“wastewater,” and “nondrinking” water.~~
- 579 30. ~~“Dry Storage Area” means a room or area designated for the storage of packaged or~~
580 ~~containerized bulk food that is not potentially hazardous (time and temperature control for~~
581 ~~food safety) and dry goods such as single-service items.~~

- 582 31. ~~“Easily Cleanable” means surfaces are readily accessible and fabricated of such materials~~
583 ~~and finishes that residue can be effectively removed by normal cleaning methods.~~
- 584 32. ~~“Egg” means the shell egg of avian species such as chicken, duck, goose, guinea, quail,~~
585 ~~ratites or turkey.~~
- 586 ~~“Egg” does not include:~~
- 587 a. ~~A balut;~~
- 588 b. ~~The egg of reptile species such as alligator; or~~
- 589 c. ~~An egg product.~~
- 590 33. ~~“Egg Product”~~
- 591 a. ~~“Egg Product” means all, or a portion of, the contents found inside eggs separated~~
592 ~~from the shell and pasteurized in a food processing plant, with or without added~~
593 ~~ingredients, intended for human consumption, such as dried, frozen or liquid eggs~~
- 594 b. ~~“Egg Product” does not include food which contains eggs only in a relatively small~~
595 ~~proportion such as cake mixes.~~
- 596 34. ~~“Employee” means the licensee, person in charge, food employee, person having~~
597 ~~supervisory or management duties, person on the payroll, family member, volunteer, person~~
598 ~~performing work under contractual agreement, and any person working in a food~~
599 ~~establishment.~~
- 600 35. ~~“Enterohemorrhagic Escherichia coli” means E. coli which cause hemorrhagic colitis,~~
601 ~~meaning bleeding enterically or bleeding from the intestine. The term is typically used in~~
602 ~~association with E. coli that have the capacity to produce Shiga toxins and to cause attaching~~
603 ~~and effacing lesions in the intestine. EHEC is a subset of Shiga toxin producing E. coli~~
604 ~~(STEC), whose members produce additional virulence factors. Infections with EHEC may~~
605 ~~be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis)~~
606 ~~and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP).~~
607 ~~Examples of serotypes of EHEC include: E. coli O157:H7; E. coli O157:NM; E. coli~~
608 ~~O26:H11; E. coli O145:NM; E. coli O103:H2; or E. coli O111:NM. Also see Shiga toxin-~~
609 ~~producing E. coli.~~
- 610 36. ~~“EPA” means the U.S. Environmental Protection Agency~~
- 611 37. ~~“Equipment” means an article used in the operation of a food establishment, such as, but~~
612 ~~not limited to a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach in~~
613 ~~refrigerator, range, scale, sink, slicer, stove, table, temperature measuring device, or~~
614 ~~warewashing machine.~~
- 615 ~~Equipment does not include items used for handling or storing large quantities of packaged~~
616 ~~foods received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts,~~
617 ~~dollies, pallets, racks, and skids.~~
- 618 38. ~~“Exclude” means to prevent a person from working as an employee in a food establishment~~
619 ~~or entering a food establishment as an employee.~~
- 620 39. ~~“Extensively Remodeled” means any major alteration of an existing configuration in a food~~
621 ~~establishment which might affect the food operation that results in one or more of the~~
622 ~~following conditions:~~

- 623 a. ~~Seating capacity, including service provided anywhere on the premises, is increased~~
 624 ~~by a minimum of 15 seats or 20 percent whichever is greater in either a single~~
 625 ~~construction project or an incremental series of construction activities;~~
- 626 b. ~~Alterations or revisions involving retail food establishments or related equipment~~
 627 ~~that require a building or construction permit by local building authorities. Routine~~
 628 ~~maintenance, repairs or cosmetic changes shall not be defined as extensive~~
 629 ~~remodeling;~~
- 630 c. ~~Changes or alterations made in the nonpublic areas that result in a reduction or~~
 631 ~~increase of total space by 25 percent or more; or~~
- 632 d. ~~The facility's capabilities to handle food, equipment, and utensils in a sanitary~~
 633 ~~manner have been diminished due to a food process or significant menu change that~~
 634 ~~introduces new risks for foodborne illness.~~
- 635 40. ~~“Fish”~~
- 636 a. ~~“Fish” means fresh or saltwater finfish, crustaceans and other forms of aquatic life~~
 637 ~~(including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and~~
 638 ~~the roe of such animals) other than birds or mammals, and all mollusks, if such~~
 639 ~~animal life is intended for human consumption.~~
- 640 b. ~~“Fish” includes an edible human food product derived in whole or in part from fish,~~
 641 ~~including fish that have been processed in any manner.~~
- 642 41. ~~“Food” means a raw, cooked, or processed edible substance, ice, beverage, or ingredient~~
 643 ~~used or intended for use or for sale in whole or in part for human consumption.~~
- 644 42. ~~“Foodborne Disease Outbreak” means an incident in which:~~
- 645 a. ~~Two or more otherwise unrelated persons experience a similar illness after ingestion~~
 646 ~~of a common food; and~~
- 647 b. ~~Epidemiological analysis implicates the food as the source of the illness.~~
- 648 43. ~~“Foodborne Illness Risk Factor” means the five most significant contributing factors,~~
 649 ~~behaviors and practices, which have been determined to contribute directly to foodborne~~
 650 ~~illness within retail food establishments by the Centers for Disease Control and Prevention.~~
 651 ~~The five categories are:~~
- 652 a. ~~Food from unsafe sources~~
- 653 b. ~~Inadequate cooking~~
- 654 c. ~~Improper holding temperatures~~
- 655 d. ~~Contaminated equipment~~
- 656 e. ~~Poor personal hygiene~~
- 657 44. ~~“Food Contact Surfaces” means those surfaces of equipment and utensils with which food~~
 658 ~~normally comes in contact, and those surfaces from which food may drain, drip, or splash~~
 659 ~~back onto surfaces in contact with food. This excludes ventilation hoods.~~
- 660 45. ~~“Food Employee” means an individual who works directly with unpackaged food, food~~
 661 ~~equipment or utensils, or food contact surfaces. A food employee does not include~~
 662 ~~employees who are hostesses, servers and/or others who do not directly handle food or clean~~
 663 ~~equipment and utensils.~~

- 664 46. ~~“Food Preparation” means packaging, processing, assembling, portioning, or any operation~~
665 ~~that changes the form, flavor, or consistency of food, but does not include trimming of~~
666 ~~produce for display prior to sale.~~
- 667 47. ~~“Food Processing Establishment” means an establishment in which food is processed,~~
668 ~~prepared, packaged, and distributed for human consumption and approved by the~~
669 ~~Department.~~
- 670 48. ~~“Game Animal”~~
- 671 a. ~~“Game Animal” means an animal, the products of which are food, that is not~~
672 ~~classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR~~
673 ~~301.2 Definitions, or as poultry, or fish.~~
- 674 b. ~~“Game Animal” includes mammals such as reindeer, elk, deer, antelope, water~~
675 ~~buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic~~
676 ~~reptiles such as land snakes.~~
- 677 c. ~~“Game Animal” does not include ratites such as emu, ostrich and rhea~~
- 678 49. ~~“Ground Beef” means meat that is derived from the voluntary striated muscle of beef, with~~
679 ~~a maximum of thirty percent total fat by weight, with no water, phosphates, extenders, or~~
680 ~~binders added.~~
- 681 50. ~~“HACCP Plan” means a written document that delineates the formal procedures for~~
682 ~~following the Hazard Analysis Critical Control Point principles.~~
- 683 51. ~~“Handwashing Sink” means a lavatory, a basin or vessel for washing, a wash basin, or a~~
684 ~~plumbing fixture especially placed for use in personal hygiene and designed for the washing~~
685 ~~of the hands.~~
- 686 52. ~~“Hazard” means a biological, chemical, or physical property that might cause an~~
687 ~~unacceptable consumer health risk.~~
- 688 53. ~~“Health Practitioner” means a physician licensed to practice medicine, or if allowed by~~
689 ~~law, a nurse practitioner, physician assistant, or similar medical professional.~~
- 690 54. ~~“Hermetically Sealed Container” means a container designed and intended to be secure~~
691 ~~against the entry of microorganisms and to maintain the commercial sterility of its content~~
692 ~~after processing.~~
- 693 55. ~~“Highly Susceptible Population” means persons who are more likely than other people in~~
694 ~~the general population to experience foodborne disease because they are~~
695 ~~immunocompromised, preschool age children, or older adults; and they obtain food at a~~
696 ~~facility that provides services such as custodial care, health care, or assisted living, such as a~~
697 ~~child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional~~
698 ~~or socialization services such as a senior center.~~
- 699 56. ~~“Hygroscopic” means readily taking up and retaining moisture.~~
- 700 57. ~~“Imminent Health Hazard” means a significant threat or danger to health that is considered~~
701 ~~to exist when there is evidence sufficient to show that a product, practice, circumstance, or~~
702 ~~event creates a situation that requires immediate correction or cessation of operation to~~
703 ~~prevent injury or illness based on:~~
- 704 a. ~~The number of potential injuries or illnesses, and~~
- 705 b. ~~The nature, severity, and duration of the anticipated injury or illness.~~

- 706 58. ~~“**Injected**” means manipulating meat to which a solution has been introduced into its interior~~
707 ~~by processes that are referred to as “injecting,” “pump marinating,” or “stitch pumping”.~~
- 708 59. ~~“**Inspection**” means an inspection of a retail food establishment conducted by the~~
709 ~~department or a county or district board of health to ensure compliance by such~~
710 ~~establishment with these rules.~~
- 711 60. ~~“**Juice**”~~
- 712 a. ~~“**Juice**” means the aqueous liquid expressed or extracted from one or more fruits or~~
713 ~~vegetables, purées of the edible portions of one or more fruits or vegetables, or any~~
714 ~~concentrates of such liquid or purée.~~
- 715 b. ~~“**Juice**” does not include, for purposes of HACCP, liquids, purées, or concentrates~~
716 ~~that are not used as beverages or ingredients of beverages.~~
- 717 61. ~~“**Kitchenware**” means all multi-use utensils other than tableware, used in the storage,~~
718 ~~preparation, transportation or serving of food.~~
- 719 62. ~~“**Law**” means applicable local, state, and federal statutes, regulations, and ordinances.~~
- 720 63. ~~“**License**” means a grant to a license to operate a retail food establishment.~~
- 721 64. ~~“**Licensee**” means a person that is licensed or who holds a certificate of license and is~~
722 ~~responsible for the lawful operation of a retail food establishment.~~
- 723 65. ~~“**Linens**” means fabric items such as cloth hampers, cloth napkins, tablecloths, wiping~~
724 ~~cloths, and work garments including cloth gloves.~~
- 725 66. ~~“**Major Food Allergen**”~~
- 726 a. ~~“**Major Food Allergen**” means: Milk, egg, fish (such as bass, flounder, cod, and~~
727 ~~including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as~~
728 ~~almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or a food ingredient~~
729 ~~that contains protein derived from a food, as specified in this paragraph.~~
- 730 b. ~~“**Major Food Allergen**” does not include: Any highly refined oil derived from a~~
731 ~~food specified in paragraph (a) of this definition and any ingredient derived from~~
732 ~~such highly refined oil; or any ingredient that is exempt under the petition or~~
733 ~~notification process specified in the Food Allergen Labeling and Consumer~~
734 ~~Protection Act of 2004 (Public Law 108-282).~~
- 735 67. ~~“**Meat**” means the flesh of animals used as food including the dressed flesh of cattle, swine,~~
736 ~~sheep, or goats and other edible animals, except fish, poultry, and wild game animals.~~
- 737 68. ~~“**Mechanically Tenderized**”~~
- 738 a. ~~“**Mechanically Tenderized**” means manipulating meat with deep penetration by~~
739 ~~processes which may be referred to as “blade tenderizing,” “jaccarding,” “pinning,”~~
740 ~~“needling,” or using blades, pins, needles or any mechanical device.~~
- 741 b. ~~“**Mechanically Tenderized**” does not include processes by which solutions are~~
742 ~~injected into meat.~~
- 743 69. ~~“**mg/L**” means milligrams per liter, which is the metric equivalent of parts per million~~
744 ~~(ppm).~~
- 745 70. ~~“**Mobile Retail Food Establishment**” means a retail food establishment that is a wheeled~~
746 ~~vehicle or trailer that is readily moveable and designed for the service of food from the~~

- 747 interior of the unit that is intended to physically report to and operate from a commissary for
748 servicing, restocking, and maintenance each operating day.
- 749 71. — **“Molluscan Shellfish”** means any edible species of fresh or frozen oysters, clams, mussels,
750 and scallops or edible portions thereof, except when the scallop product consists only of the
751 shucked adductor muscle.
- 752 72. — **“New Retail Food Establishment”** means a facility that makes its initial application as a
753 retail food establishment, a facility that changes its physical location, a newly constructed or
754 extensively remodeled establishment, or when there is a change in the Department of
755 Revenue Sales Tax ID Number.
- 756 73. — **“Nonfood Contact Surfaces”** means all surfaces other than food contact surfaces.
- 757 74. — **“Non-Continuous Cooking”**:
- 758 a. — Means the cooking of food in a food establishment using a process in which the
759 initial heating of the food is intentionally halted so that it may be cooled and held for
760 complete cooking at a later time prior to sale or service such as, but not limited to,
761 the par cooking of bacon.
- 762 b. — Does not include cooking procedures that only involve temporarily interrupting or
763 slowing an otherwise continuous cooking process.
- 764 75. — **“Non-Critical item”**:
- 765 a. — Means a provision in this Code that is not designated as a critical item.
- 766 b. — Does not include cooking procedures that only involve temporarily interrupting or
767 slowing an otherwise continuous cooking process.
- 768 76. — **“Packaged”**
- 769 a. — Means bottled, canned, cartoned, securely bagged, or securely wrapped, whether
770 packaged in a food establishment or a food processing plant.
- 771 b. — **“Packaged”** does not include a wrapper, carry out box, or other nondurable
772 container used to containerize food with the purpose of facilitating food protection
773 during service and receipt of the food by the consumer.
- 774 77. — **“Person”** means an association, a corporation, individual, partnership, other legal entity,
775 government, or governmental subdivision or agency.
- 776 78. — **“Person In Charge”** means the individual present at a retail food establishment who is
777 responsible for the operation at the time of inspection. If no individual is responsible, then
778 any employed person present is the person in charge.
- 779 79. — **“Personal Care Items”** means items or substances that may be poisonous, toxic, or a source
780 of contamination which are used to maintain or enhance a person's health, hygiene, or
781 appearance, such as medicines, first aid supplies, cosmetics, toiletries such as lotion,
782 toothpaste and mouthwash.
- 783 80. — **“pH”** means the measure of the degree of acidity or alkalinity of a solution. pH between 0
784 and 7 indicate acidity and pH between 7 and 14 indicate alkalinity. The value for pure
785 distilled water is 7, which is considered neutral.
- 786

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 788 81. ~~“Physical Facilities” means the structure and interior surfaces of a retail food establishment~~
 789 ~~including floors, walls, ceilings, lighting, and premises, including, but not limited to~~
 790 ~~accessories such as soap and towel dispensers and attachments such as light fixtures and~~
 791 ~~heating or air conditioning system vents.~~
- 792 82. ~~“Poisonous or Toxic Materials” means substances not intended for ingestion and are~~
 793 ~~included in four categories:~~
- 794 a. ~~Cleaners and sanitizers, which include cleaning and sanitizing agents and agents~~
 795 ~~such as caustics, acids, drying agents, polishes, and other chemicals;~~
- 796 b. ~~Pesticides, which include substances such as insecticides and rodenticides;~~
- 797 c. ~~Substances necessary for the operation and maintenance of the establishment such as~~
 798 ~~nonfood grade lubricants and personal care items that may be deleterious to health;~~
 799 ~~and~~
- 800 d. ~~Substances that are not necessary for the operation and maintenance of the~~
 801 ~~establishment and are on the premises for retail sale, such as petroleum products and~~
 802 ~~paints.~~
- 803 83. ~~“Potentially Hazardous Food (Time/Temperature Control for Safety Food)”~~
- 804 a. ~~“Potentially Hazardous Food (time/temperature control for safety food)” means a~~
 805 ~~food that requires time/temperature control for safety (TCS) to limit pathogenic~~
 806 ~~microorganism growth or toxin formation.~~
- 807 b. ~~“Potentially Hazardous Food (time/temperature control for safety food)” includes:~~
- 808 (1) ~~A food of animal origin that is raw or heat treated; a food of plant origin~~
 809 ~~that is heat treated or consists of raw seed sprouts, cut melons, cut leafy~~
 810 ~~greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a~~
 811 ~~way so that they are unable to support pathogenic microorganism growth or~~
 812 ~~toxin formation, or garlic in oil mixtures that are not modified in a way so~~
 813 ~~that they are unable to support pathogenic microorganism growth or toxin~~
 814 ~~formation; and~~
- 815 (2) ~~Except as specified in Subparagraph (c)(4) of this definition, a food that~~
 816 ~~because of the interaction of its a_w and pH values is designated as Product~~
 817 ~~Assessment Required (PA) in Table A or B of this definition.~~

Table A. Interaction of pH and aw for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged

aw values	pH values		
	4.6 or less	>4.6–5.6	>5.6
≤0.92	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food
>0.92–.95	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
>0.95	non-PHF/non-TCS food	PA	PA

* PHF means Potentially Hazardous Food
 ** TCS food means Time/Temperature Control for Safety food
 *** PA means Product Assessment required

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged				
a_w values	pH values			
	<4.2	4.2–4.6	>4.6–5.0	≥5.0
<0.88	non-PHF*/ non-TCS food**	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food
0.88–0.90	non-PHF/ non-TCS food	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA***
>0.90–0.92	non-PHF/ non-TCS food	non-PHF/ non-TCS food	PA	PA
>0.92	non-PHF/ non-TCS food	PA	PA	PA

* PHF means Potentially Hazardous Food
 ** TCS food means Time/Temperature Control for Safety food
 *** PA means Product Assessment required

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820

e. ~~"Potentially Hazardous Food (time/temperature control for safety food)" does not include:~~

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(1) ~~An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae; and~~

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(2) ~~A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution.~~

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(3) ~~A food that because of its pH or a_w value, or interaction of a_w and pH values, is designated as a non-PHF/non-TCS food in Table A or B of this definition;~~

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833

(4) ~~A food that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:~~

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(a) ~~Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;~~

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(b) ~~Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, of~~

841

(c) ~~a combination of intrinsic and extrinsic factors; or~~

842

843

(5) ~~A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subparagraphs (c)(1)–(4) of~~

- 844 ~~this definition even though the food may contain a pathogenic~~
 845 ~~microorganism or chemical or physical contaminant at a level sufficient to~~
 846 ~~cause illness or injury.~~
- 847 84. ~~“Poultry” means any domesticated bird such as chickens, turkeys, ducks, geese, or guineas~~
 848 ~~or squabs and any migratory waterfowl, game bird, such as pheasant, partridge, quail,~~
 849 ~~grouse, or pigeon.~~
- 850 85. ~~“Premises” means the physical facility, its contents, and the contiguous land or property and~~
 851 ~~its facilities and contents that may impact retail food establishment personnel, facilities, or~~
 852 ~~operations.~~
- 853 86. ~~“Primal Meat Cuts” means a basic major cut into which carcasses and sides of meat are~~
 854 ~~separated, such as a beef round, pork loin, lamb flank, or veal breast.~~
- 855 87. ~~“Private Boarding Houses” means a house at which meals, or meals and lodging, may be~~
 856 ~~obtained for payment.”~~
- 857 ~~“Private Boarding Houses” does not include:~~
- 858 a. ~~Hotels~~
- 859 b. ~~Motels~~
- 860 c. ~~Homeless shelters~~
- 861 d. ~~Youth hostel~~
- 862 e. ~~Other commercial facilities providing lodging and/or meals for the indigent~~
 863 ~~population whether or not there is a charge for such food and/or lodging.~~
- 864 88. ~~“Pushcart” means a retail food establishment that is a non-motorized, unit designed so~~
 865 ~~foods are served from the exterior of the unit, and which is intended to physically report~~
 866 ~~to and operate from a commissary for servicing, restocking and maintenance each~~
 867 ~~operating day.~~
- 868 89. ~~“Ratite” means a flightless bird such as an emu, ostrich, or rhea.~~
- 869 90. ~~“Ready-to-Eat Food” means food that is edible without further washing, cooking, or~~
 870 ~~additional preparation and that is reasonably expected to be consumed in that form.~~
 871 ~~Ready-to-eat food does not include whole, raw fruits and vegetables that are intended for~~
 872 ~~washing by the consumer before consumption~~
- 873 91. ~~“Reconstituted” means dehydrated food products recombined with water or other~~
 874 ~~liquids.~~
- 875 92. ~~“Reduced Oxygen Packaging”~~
- 876 a. ~~“Reduced Oxygen Packaging” means:~~
- 877 (1) ~~The reduction of the amount of oxygen in a package by removing~~
 878 ~~oxygen; displacing oxygen and replacing it with another gas or~~
 879 ~~combination of gases; or otherwise controlling the oxygen content to a~~
 880 ~~level below that normally found in the atmosphere (approximately 21%~~
 881 ~~at sea level); and~~
- 882 (2) ~~A process as specified in section (a)(1) of this definition that involves a~~
 883 ~~food for which the hazards Clostridium botulinum or Listeria~~
 884 ~~monocytogenes require control in the final packaged form.~~
- 885 b. ~~“Reduced Oxygen Packaging” includes:~~

- 886 (1) ~~Vacuum packaging, in which air is removed from a package of food and~~
 887 ~~the package is hermetically sealed so that a vacuum remains inside the~~
 888 ~~package;~~
- 889 (2) ~~Modified atmosphere packaging, in which the atmosphere of a package~~
 890 ~~of food is modified so that its composition is different from air but the~~
 891 ~~atmosphere may change over time due to the permeability of the~~
 892 ~~packaging material or the respiration of the food. Modified atmosphere~~
 893 ~~packaging includes reduction in the proportion of oxygen, total~~
 894 ~~replacement of oxygen, or an increase in the proportion of other gases~~
 895 ~~such as carbon dioxide or nitrogen;~~
- 896 (3) ~~Controlled atmosphere packaging, in which the atmosphere of a package~~
 897 ~~of food is modified so that until the package is opened, its composition is~~
 898 ~~different from air, and continuous control of that atmosphere is~~
 899 ~~maintained, such as by using oxygen scavengers or a combination of~~
 900 ~~total replacement of oxygen, nonrespiring food, and impermeable~~
 901 ~~packaging material;~~
- 902 (4) ~~Except as specified in section (c), Cook chill packaging, in which cooked~~
 903 ~~food is hot filled into impermeable bags which have the air expelled and~~
 904 ~~are then sealed or crimped closed, the bagged food is rapidly chilled and~~
 905 ~~refrigerated at temperatures that inhibit the growth of psychrotrophic~~
 906 ~~pathogens; or~~
- 907 (5) ~~Sous vide packaging, in which raw or partially cooked food is vacuum~~
 908 ~~packaged in an impermeable bag, cooked, rapidly chilled, and~~
 909 ~~refrigerated at temperatures that inhibit the growth of psychrotrophic~~
 910 ~~pathogens.~~
- 911 e. ~~"Reduced Oxygen Packaging" does not include:~~
- 912 (1) ~~Placing product in a bag and sealing it immediately prior to or after,~~
 913 ~~cooking, cooling or reheating the product as long as the product is:~~
- 914 (a) ~~Labeled with the time and date the product is placed in the bag;~~
 915 ~~and~~
- 916 (b) ~~Removed from the bag within 48 hours of the time the product is~~
 917 ~~placed in the bag.~~
- 918 93. ~~"Refuse" means solid waste not carried by water through the sewage system.~~
- 919 94. ~~"Re-service" means the transfer of food that is unused and returned by a consumer after~~
 920 ~~being served or sold and in the possession of the consumer, to another person.~~
- 921 95. ~~"Restrict" means to limit the activities of a food employee so that there is no risk of~~
 922 ~~transmitting a disease that is transmissible through food and the food employee does not~~
 923 ~~work with exposed food, clean equipment, utensils, linens, or unwrapped single service~~
 924 ~~or single-use articles.~~
- 925 96. ~~"Retail Food Establishment" means a retail operation that stores, prepares, or packages~~
 926 ~~food for human consumption or serves or otherwise provides food for human~~
 927 ~~consumption to consumers directly or indirectly through a delivery service, whether such~~
 928 ~~food is consumed on or off the premises or whether there is a charge for such food.~~
- 929 ~~"Retail Food Establishment" does not include:~~

- 930 a. ~~Any private home;~~
- 931 b. ~~Private boarding houses;~~
- 932 c. ~~Hospital and health facility patient feeding operations licensed by the Department;~~
- 933 d. ~~Child care centers and other child care facilities licensed by the Department of~~
- 934 ~~Human services;~~
- 935 e. ~~Hunting camps and other outdoor recreation locations where food is prepared in the~~
- 936 ~~field rather than at a fixed base of operation;~~
- 937 f. ~~Food or beverage wholesale manufacturing, processing, or packaging plants, or~~
- 938 ~~portions thereof, that are subject to regulatory controls under state or federal laws or~~
- 939 ~~regulations;~~
- 940 g. ~~Motor vehicles used only for the transport of food;~~
- 941 h. ~~Establishments preparing and serving only hot coffee, hot tea, instant hot beverages,~~
- 942 ~~and nonpotentially hazardous doughnuts or pastries obtained from sources~~
- 943 ~~complying with all laws related to food and food labeling;~~
- 944 i. ~~Establishments that handle only nonpotentially hazardous prepackaged food and~~
- 945 ~~operations serving only commercially prepared, prepackaged foods requiring no~~
- 946 ~~preparation other than the heating of food within its original container or package;~~
- 947 j. ~~Farmers markets and roadside markets that offer only uncut fresh fruit and~~
- 948 ~~vegetables for sale;~~
- 949 k. ~~Automated food merchandising enterprises that supply only prepackaged~~
- 950 ~~nonpotentially hazardous food or drink or food or drink in bottles, cans, or cartons~~
- 951 ~~only, and operations that dispense only chewing gum or salted nuts in their natural~~
- 952 ~~protective covering;~~
- 953 l. ~~The donation, preparation, sale, or service of food by a nonprofit or charitable~~
- 954 ~~organization in conjunction with an event or celebration if such donation,~~
- 955 ~~preparation, sale, or service of food;~~
- 956 (1) ~~Does not exceed the duration of the event or celebration or a maximum of~~
- 957 ~~fifty two days within a calendar year; and~~
- 958 (2) ~~Takes place in the county in which such nonprofit or charitable organization~~
- 959 ~~resides or is principally located.~~
- 960 97. ~~“Risk” means the likelihood that an adverse health effect will occur within a population as a~~
- 961 ~~result of a hazard in a food.~~
- 962

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964 98. —“**Safe Materials**” means articles manufactured from or composed of materials that may not
965 reasonably be expected to result, directly or indirectly, in their becoming a component or
966 otherwise affecting the characteristic of any food. If materials are food additives or color
967 additives as defined in section 25-5-402(3) or (12), C.R.S., of the “Colorado Pure Food and
968 Drug Law”, as used, they are “safe” only if they are used in conformity with all applicable
969 regulations of the U.S. Food and Drug Administration.
- 970 99. —“**Sanitization**” means the application of cumulative heat or chemicals on cleaned food-
971 contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs,
972 which is equal to a 99.999% reduction, of representative disease microorganisms of public
973 health importance.
- 974 100. —“**Sealed**” means free of cracks or other openings that allow the entry or passage of
975 moisture or debris.
- 976 101. —“**Self Contained Mobile Retail Food Establishment**” means a licensed mobile retail food
977 establishment that is approved to operate without a commissary, and is not connected to
978 fixed utilities such as water, sewer and electricity, and is required to report to an approved
979 servicing location for sewage disposal and water.
- 980 102. —“**Service Animal**” means any dog or miniature horse that is individually trained to do work
981 or perform tasks for the benefit of an individual with a disability, including a physical,
982 sensory, psychiatric, intellectual, or other mental disability. Other species of animals,
983 whether wild or domestic, trained or untrained, are not service animals for the purposes of
984 this definition. The work or tasks performed by a service animal must be directly related to
985 the handler's disability. Examples of work or tasks include, but are not limited to, assisting
986 individuals who are blind or have low vision with navigation and other tasks, alerting
987 individuals who are deaf or hard of hearing to the presence of people or sounds, providing
988 non-violent protection or rescue work, pulling a wheelchair, assisting an individual during a
989 seizure, alerting individuals to the presence of allergens, retrieving items such as medicine or
990 the telephone, providing physical support and assistance with balance and stability to
991 individuals with mobility disabilities, and helping persons with psychiatric and neurological
992 disabilities by preventing or interrupting impulsive or destructive behaviors. The crime
993 deterrent effects of an animal's presence and the provision of emotional support, well-being,
994 comfort, or companionship do not constitute work or tasks for the purposes of this definition.
- 995 103. —“**Sewage**” means liquid waste containing animal or plant matter in suspension or solution
996 and may include liquids containing chemicals in solution.
- 997 104. —“**Shellstock**” means raw, in-shell, molluscan shellfish.
- 998 105. —“**Shiga Toxin-Producing *Escherichia coli*” (STEC)** means any *E. coli* capable of
999 producing Shiga toxins (also called verocytotoxins or “Shiga-like” toxins). Examples of
1000 serotypes of STEC include both O157 and non-O157 *E. coli*. *Also see* Enterohemorrhagic
1001 *Escherichia coli*.
- 1002 106. —“**Shucked Shellfish**” means molluscan shellfish that have one or both shells removed.
- 1003 107. —“**Single Service Articles**” means cups, containers, lids, closures, plates, knives, forks,
1004 spoons, stirrers, paddles, straws, napkins, place mats, doilies, wrapping materials, toothpicks
1005 and similar articles intended for one-time, one-consumer use and then discarded after use.
- 1006

- 1007
1008 108. — ~~“Single-Use Articles”~~
- 1009 a. — ~~“Single-Use Articles” means utensils and bulk food containers designed and~~
1010 ~~constructed to be used once and discarded;~~
- 1011 b. — ~~“Single-Use Articles” includes items such as wax paper, butcher paper, plastic~~
1012 ~~wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread~~
1013 ~~wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the~~
1014 ~~materials, durability, strength, and cleanability specifications under 4-101, and 4-~~
1015 ~~201 for multiuse utensils.~~
- 1016 109. — ~~“Slacking” means the process of moderating the temperature of a food such as allowing a~~
1017 ~~food to gradually increase from a temperature of 23°C (-10°F) to 4°C (25°F) in preparation~~
1018 ~~for deep-fat frying or to facilitate even heat penetration during the cooking of previously~~
1019 ~~block-frozen food such as shrimp.~~
- 1020 110. — ~~“Smooth” means:~~
- 1021 a. — ~~A food-contact surface having a surface free of pits and inclusions with a~~
1022 ~~cleanability equal to or exceeding that of (100-grit) number 3 stainless steel;~~
- 1023 b. — ~~A nonfood-contact surface of equipment having a surface equal to that of~~
1024 ~~commercial-grade hot-rolled steel free of visible scale; and~~
- 1025 c. — ~~A floor, wall, or ceiling having an even or level surface with no roughness,~~
1026 ~~projections, perforations, pits, or inclusions that render it difficult to clean.~~
- 1027 111. — ~~“Tableware” means eating, drinking, and serving utensils for table use, such as forks,~~
1028 ~~knives, and spoons; including bowls, cups, serving dishes, tumblers and plates.~~
- 1029 112. — ~~“Temperature Measuring Device” means a thermometer, thermocouple, thermistor, or~~
1030 ~~other device that indicates the temperature of food, air, or water.~~
- 1031 113. — ~~“Temporary Event” means a single community event or celebration that operates for a~~
1032 ~~period of time of not more than the fourteen (14) consecutive days and may include town~~
1033 ~~celebrations, fairs, and festivals.~~
- 1034 — ~~Temporary events do not include:~~
- 1035 a. — ~~Regularly scheduled series of events at venues such as sporting arenas, concert halls,~~
1036 ~~flea markets, or farmers’ markets;~~
- 1037 b. — ~~Events serviced by licensed caterers are not considered temporary events.~~
- 1038 c. — ~~Sporadic promotional events such as grand openings are not considered temporary~~
1039 ~~events.~~
- 1040 114. — ~~“Temporary Retail Food Establishment” means a food establishment that is limited to~~
1041 ~~operating at temporary events only.~~
- 1042 115. — ~~“USDA” means the U.S. Department of Agriculture.~~
- 1043 116. — ~~“Utensil” means a food-contact implement or container used in the storage, preparation,~~
1044 ~~transportation, dispensing, sale or service of food, such as kitchenware or tableware that is~~
1045 ~~multiuse, single-service, or single-use.~~
- 1046 117. — ~~“Variance” means a written document issued by the Colorado Department of Public Health~~
1047 ~~and Environment (CDPHE) that authorizes a modification or waiver of one or more~~

- 1048 requirements of this Code if, in the opinion of CDPHE, a health hazard or nuisance will not
1049 result from the modification or waiver.
- 1050 118. ~~“Warewashing” means the cleaning and sanitizing of utensils and food contact surfaces of~~
1051 ~~equipment.~~
- 1052 119. ~~“Water Activity” see a_w definition in section 1-201(7).~~
- 1053 120. ~~“Whole Muscle, Intact Beef” means whole muscle beef that is not injected, mechanically~~
1054 ~~tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.~~
- 1055

- 1056 **CHAPTER 2**
- 1057 **MANAGEMENT AND PERSONNEL**
- 1058 **~~2-1~~ SUPERVISION**
- 1059 **~~2-101~~ Responsibilities**
- 1060 The operator shall be the person in charge or shall designate a person in charge and shall ensure that a
1061 person in charge is present at the retail food establishment during all hours of operation.
- 1062 **~~*2-102~~ Demonstration**
- 1063 Based on the risks of foodborne illness inherent to the food operation, during inspections and upon
1064 request the person in charge shall demonstrate to the Department knowledge of foodborne disease
1065 prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements
1066 of these rules and regulations. The person in charge shall demonstrate this knowledge by:
- 1067 A. ~~Complying with these rules and regulations by having no violations of critical items during~~
1068 ~~the current inspection; or~~
- 1069 B. ~~Being a certified food protection manager who has shown proficiency of required~~
1070 ~~information through passing a test that is part of an accredited program; or~~
- 1071 C. ~~Responding correctly to the inspector's questions as they relate to the specific food~~
1072 ~~operation. The areas of knowledge include:~~
- 1073 1. ~~Describing the relationship between the prevention of foodborne disease and the~~
1074 ~~personal hygiene of a food employee;~~
- 1075 2. ~~Explaining the responsibility of the person in charge for preventing the transmission of~~
1076 ~~foodborne disease by a food employee who has a disease or medical condition that~~
1077 ~~may cause foodborne disease;~~
- 1078 3. ~~Describing the symptoms associated with the diseases that are transmissible through~~
1079 ~~food;~~
- 1080 4. ~~Explaining the hazards involved in the consumption of raw or undercooked meat,~~
1081 ~~poultry, eggs and fish;~~
- 1082 5. ~~Stating the required temperatures and times for the safe cooking, refrigerated storage,~~
1083 ~~hot holding, cooling, and reheating of potentially hazardous food (time/temperature~~
1084 ~~control for safety food);~~
- 1085 6. ~~Describing the relationship between the prevention of foodborne illness and the~~
1086 ~~management and control of the following:~~
- 1087 a. ~~Cross contamination,~~
- 1088 b. ~~Hand contact with ready-to-eat foods,~~
- 1089 c. ~~Handwashing, and~~
- 1090 d. ~~Maintaining the food establishment in a clean condition and in good repair;~~
- 1091

- 1092
1093 7. — Explaining the relationship between food safety and providing equipment that is:
1094 a. — Sufficient in number and capacity, and
1095 b. — Properly designed, constructed, located, installed, operated, maintained, and
1096 cleaned;
- 1097 8. — Explaining correct procedures for cleaning and sanitizing utensils and food contact
1098 surfaces of equipment;
- 1099 9. — Identifying the source of water used and measures taken to ensure that it remains
1100 protected from contamination such as providing protection from backflow and
1101 precluding the creation of cross connections;
- 1102 10. Identifying poisonous or toxic materials in the food establishment and the procedures
1103 necessary to ensure that they are safely stored, dispensed, used, and disposed of
1104 according to law;
- 1105 11. Explaining the relationship between maintaining the time and temperature of
1106 potentially hazardous food (time/temperature control for safety food);
- 1107 12. Identifying critical control points in the operation from purchasing through sale or
1108 service that when not controlled may contribute to the transmission of foodborne
1109 illness and explaining steps taken to ensure that the points are controlled in
1110 accordance with the requirements of these rules and regulations.
- 1111 13. Explaining the details of how the establishment, person in charge and food employees
1112 complies with conditions of any approved variance or any Department approved
1113 time as a public health control plan for potentially hazardous food (time/temperature
1114 control for safety food) and with any HACCP plan required by the Department.
- 1115 14. Explaining the responsibilities, rights, and authorities assigned by these rules and
1116 regulations to the:
- 1117 a. — Food employee
1118 b. — Conditional employee
1119 c. — Person in charge, and
1120 d. — Department
- 1121 15. Explaining how the person in charge, food employees, and conditional employees
1122 comply with reporting responsibilities and exclusion or restriction of food
1123 employees.
- 1124 16. Describing foods identified as major food allergens and the symptoms that a major food
1125 allergen could cause in a sensitive individual who has an allergic reaction.

1126 ***2-103 — Person in charge**

- 1127 The person in charge shall educate and monitor employees to ensure that:
- 1128 A. — Employees are effectively cleaning their hands, by routinely monitoring the employees'
1129 handwashing;
- 1130 B. — Employees are visibly observing foods as they are received to determine that they are from
1131 approved sources, delivered at the required temperatures, protected from contamination,

- 1132 unadulterated, and accurately presented, by routinely monitoring the employees'
1133 observations and periodically evaluating foods upon their receipt;
- 1134 C.— Employees are properly cooking potentially hazardous food (time/temperature control for
1135 safety food), being particularly careful in cooking those foods known to cause severe
1136 foodborne illness and death, such as eggs and comminuted meats, through daily oversight
1137 of the employees' routine monitoring of the cooking temperatures using appropriate
1138 temperature measuring devices properly sealed and calibrated as specified in section 4-
1139 401 of these rules and regulations;
- 1140 D.— Employees are using proper methods to rapidly cool potentially hazardous foods
1141 (time/temperature control for safety foods) that are not held hot or are not for
1142 consumption within 4 hours, through daily oversight of the employees' routine
1143 monitoring of food temperatures during cooling;
- 1144 E.— Employees are properly sanitizing cleaned multiuse equipment and utensils before they are
1145 reused, through routine monitoring of solution temperature and exposure time for hot
1146 water sanitizing, and chemical concentration, pH, temperature, and exposure time for
1147 chemical sanitizing;
- 1148 F.— Consumers are notified that clean tableware is to be used when they return to self-service
1149 areas such as salad bars and buffets as specified in section 3-411(A);
- 1150 G.— Employees prevent bare hand contact with ready-to-eat food by properly using suitable
1151 utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment;
- 1152 H.— Employees are properly trained in food safety as it relates to their assigned duties;
- 1153 I.— Food employees and conditional employees are informed of their responsibilities to report
1154 their illnesses and infections transmissible through food to the person in charge, so that
1155 the person in charge may exclude or restrict any employees who are ill, have a boil or
1156 wound, and when to notify the department of illnesses;
- 1157 J.— Employees and other persons such as delivery and maintenance persons and pesticide
1158 applicators entering the food preparation food storage, and warewashing areas comply
1159 with this code; and
- 1160 K.— Consumers who order raw or partially cooked ready-to-eat foods of animal origin are
1161 informed as specified in section 3-801 of these rules and regulations that the food is not
1162 cooked sufficiently to ensure its safety.

1163 ~~2-2~~ — EMPLOYEE HEALTH

1164 ~~*2-201~~ — Responsibility of Licensee, Person in charge, and Employees

- 1165 A.— The licensee shall require food employees and conditional employees to report to the person
1166 in charge information about their health and activities as they relate to diseases that are
1167 transmissible through food. A food employee or conditional employee shall report pertinent
1168 information in a manner that allows the person in charge to reduce the risk of foodborne
1169 disease transmission, if the food employee or conditional employee:
- 1170 1.— Has any of the following symptoms:
- 1171 a.— Vomiting;
- 1172 b.— Diarrhea;

- 1173 e. — Jaundice;
- 1174 d. — Sore throat with fever; or
- 1175 e. — A lesion containing pus such as a boil or infected wound that is open and/or
- 1176 draining and is:
- 1177 (1) — On the hands or wrists, unless an impermeable cover such as a finger
- 1178 cot or stall protects the lesion and a single use glove is worn over
- 1179 the impermeable cover;
- 1180 (2) — On exposed portions of the arms, unless the lesion is protected by an
- 1181 impermeable cover; or
- 1182 (3) — On other parts of the body, unless the lesion is covered by a dry,
- 1183 durable, tight fitting bandage.
- 1184 2. — Has an illness diagnosed by a health practitioner due to:
- 1185 a. — Norovirus;
- 1186 b. — Hepatitis A virus;
- 1187 c. — Shigella spp.;
- 1188 d. — Enterohemorrhagic or Shiga Toxin Producing Escherichia coli;
- 1189 e. — Salmonella Typhi; or
- 1190 f. — Other enteric bacterial pathogen such as Salmonella or Campylobacter.
- 1191 3. — Had a previous illness, diagnosed by a health practitioner, within the past three (3)
- 1192 months due to Salmonella Typhi, as determined by a health practitioner.
- 1193 B. — The person in charge shall notify the Department when a food employee is:
- 1194 1. — Jaundiced; or
- 1195 2. — Diagnosed with an illness due to a pathogen as specified in Subparagraphs (A)(2) and
- 1196 (A)(3) of this section.
- 1197 C. — The person in charge shall ensure that a conditional employee who exhibits or reports a
- 1198 symptom, or who reports a diagnosed illness as specified in Subparagraphs (A)(1) (3) of this
- 1199 section, is prohibited from becoming a food employee until the conditional employee meets
- 1200 the criteria for the specific symptoms or diagnosed illness as specified section 2-203.
- 1201 D. — The person in charge shall ensure that a food employee who exhibits or reports a symptom,
- 1202 or who reports a diagnosed illness as specified in subparagraphs (A)(1) (3) of this section is:
- 1203 1. — Excluded as specified in 2-202 (A) (D)(1), (E)(1), (F), (G)(1), and in compliance with
- 1204 the provisions specified under 2-203(A) (F); or
- 1205 2. — Restricted as specified in subparagraphs 2-202 (D)(2), (E)(2), (F), (G)(2), (H), and in
- 1206 compliance with the provisions specified under 2-203 (A) (F).
- 1207 E. — A food employee or conditional employee shall report to the person in charge the
- 1208 information as specified in (A) of this section.
- 1209 F. — A food employee shall:
- 1210 1. — Comply with an exclusion as specified in 2-202 (A) (D)(1), (E)(1), (F), (G)(1); or

1211 2. ~~Comply with a restriction as specified in subparagraphs 2-202 (D)(2), (E)(2), (F),~~
 1212 ~~(G)(2), (H), and in compliance with the provisions specified under 2-203 (A) (F).~~

1213 **~~*2-202 Exclusions and Restrictions~~**

1214 ~~The person in charge shall exclude or restrict a food employee from a food establishment in~~
 1215 ~~accordance with the following:~~

1216 A. ~~Except when the symptom is from a noninfectious condition, exclude a food employee if the~~
 1217 ~~food employee is:~~

1218 1. ~~Symptomatic with vomiting or diarrhea; or~~

1219 2. ~~Symptomatic with vomiting or diarrhea and diagnosed with an infection from~~
 1220 ~~Norovirus, Shigella spp., or Enterohemorrhagic or Shiga toxin producing E. coli.~~

1221 B. ~~Exclude a food employee who is:~~

1222 1. ~~Jaundiced and the onset of jaundice occurred within the last seven (7) calendar days,~~
 1223 ~~unless the food employee provides to the person in charge written medical~~
 1224 ~~documentation from a health practitioner specifying that the jaundice is not caused~~
 1225 ~~by hepatitis A virus or other fecal-orally transmitted infection;~~

1226 2. ~~Diagnosed with an infection from hepatitis A virus within fourteen (14) calendar days~~
 1227 ~~from the onset of any illness symptoms, or within seven (7) calendar days of the~~
 1228 ~~onset of jaundice; or~~

1229 3. ~~Diagnosed with an infection from hepatitis A virus without developing symptoms.~~

1230 C. ~~Exclude a food employee who is diagnosed with an infection from Salmonella Typhi, or~~
 1231 ~~reports a previous infection with Salmonella Typhi within the past three (3) months as~~
 1232 ~~specified under Subparagraph 2-201(A)(3).~~

1233 D. ~~If a food employee is diagnosed with an infection from Shigella spp. and is asymptomatic:~~

1234 1. ~~Exclude the food employee who works in a food establishment serving a highly~~
 1235 ~~susceptible population; or~~

1236 2. ~~Restrict the food employee who works in a food establishment not serving a highly~~
 1237 ~~susceptible population.~~

1238 E. ~~If a food employee is diagnosed with an infection from Enterohemorrhagic or Shiga toxin-~~
 1239 ~~producing E. coli, and is asymptomatic:~~

1240 1. ~~Exclude the food employee who works in a food establishment serving a highly~~
 1241 ~~susceptible population; or~~

1242 2. ~~Restrict the food employee who works in a food establishment not serving a highly~~
 1243 ~~susceptible population.~~

1244 F. ~~If a food employee is diagnosed with another bacterial enteric pathogen and is asymptomatic~~
 1245 ~~consult with the Department to determine the need for exclusion or restriction.~~

1246 G. ~~If a food employee is ill with symptoms of acute onset of sore throat with fever:~~

1247 1. ~~Exclude the food employee who works in a food establishment serving a highly~~
 1248 ~~susceptible population; or~~

1249 2. ~~Restrict the food employee who works in a food establishment not serving a highly~~
 1250 ~~susceptible population.~~

1251 H. ~~If a food employee is infected with a skin lesion containing pus such as a boil or infected~~
 1252 ~~wound that is open or draining and not properly covered as specified in section 2-~~
 1253 ~~201(A)(1)(e), restrict the food employee.~~

1254 ~~*2-203~~ **Removal, Adjustment, or Retention of Exclusions and Restrictions**

1255 The person in charge shall adhere to the following conditions when removing, adjusting, or retaining
 1256 the exclusion or restriction of a food employee:

1257 A. ~~Reinstate a food employee who was excluded as specified in section 2-202(A)(1) if the~~
 1258 ~~employee:~~

1259 1. ~~Is asymptomatic for at least 24 hours; or~~

1260 2. ~~Provides to the person in charge written medical documentation from a health~~
 1261 ~~practitioner that states the symptom is from a noninfectious condition.~~

1262 3. ~~If a food employee was diagnosed with an infection from Norovirus and excluded as~~
 1263 ~~specified in section 2-202(A)(2), the food employee should not be reinstated until~~
 1264 ~~the employee has been asymptomatic for at least 48 hours and the person in charge~~
 1265 ~~obtains approval from the Department.~~

1266 4. ~~If a food employee was diagnosed with an infection from Shigella spp. and excluded as~~
 1267 ~~specified in section 2-202(A)(2), the food employee should not be reinstated until~~
 1268 ~~the employee has met parameters listed in the Colorado Communicable Disease~~
 1269 ~~Manual and the person in charge obtains approval from the Department.~~

1270 5. ~~If a food employee was diagnosed with an infection from Enterohemorrhagic or Shiga~~
 1271 ~~toxin-producing Escherichia coli and excluded as specified in section 2-202(A)(2),~~
 1272 ~~the food employee should not be reinstated until the employee has met parameters~~
 1273 ~~listed in the Colorado Communicable Disease Manual and the person in charge~~
 1274 ~~obtains approval from the Department.~~

1275 B. ~~Reinstate a food employee who was excluded as specified under Subparagraphs 2-202(B) if~~
 1276 ~~the employee has met parameters listed in the Colorado Communicable Disease Manual and~~
 1277 ~~the person in charge obtains approval from the Department.~~

1278 C. ~~Reinstate a food employee who was excluded as specified in 2-202(C). If the employee has~~
 1279 ~~met parameters listed in the Colorado Communicable Disease Manual and the person in~~
 1280 ~~charge obtains approval from the Department.~~

1281 D. ~~Reinstate a food employee who was restricted as specified in 2-202(H) if the skin, infected~~
 1282 ~~wound, cut, or pustular boil is properly covered with one of the following:~~

1283 1. ~~An impermeable cover such as a finger cot or stall and a single use glove over the~~
 1284 ~~impermeable cover if the infected wound or pustular boil is on the hand, finger, or~~
 1285 ~~wrist;~~

1286 2. ~~An impermeable cover on the arm if the infected wound or pustular boil is on the arm;~~
 1287 ~~or~~

1288 3. ~~A dry, durable, tight fitting bandage if the infected wound or pustular boil is on another~~
 1289 ~~part of the body.~~

1290 E. ~~Reinstate a food employee who was excluded as specified under subparagraphs 2-202(D)(1)~~
 1291 ~~or who was restricted under Subparagraph 2-202(D)(2). The food employee should not be~~
 1292 ~~reinstated until the employee has been asymptomatic for at least 48 hours and the person in~~
 1293 ~~charge obtains approval from the Department.~~

- 1294 ~~F. Reinstatement of a food employee who was excluded or restricted as specified in Subparagraphs 2-~~
 1295 ~~202(H)(1) or (2) if the food employee provides to the person in charge written medical~~
 1296 ~~documentation from a health practitioner stating that the food employee meets one of the~~
 1297 ~~following conditions:~~
- 1298 ~~1. Has received antibiotic therapy for Streptococcus pyogenes infection for more than 24~~
 1299 ~~hours;~~
 - 1300 ~~2. Has at least one negative throat specimen culture for Streptococcus pyogenes infection;~~
 1301 ~~or~~
 - 1302 ~~3. Is otherwise determined by a health practitioner to be free of a Streptococcus pyogenes~~
 1303 ~~infection.~~

1304 ~~2-204 Discharges from the Eyes, Nose and Mouth~~

1305 ~~Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges~~
 1306 ~~from the eyes, nose or mouth may not work with exposed food, clean equipment, utensils, and linens,~~
 1307 ~~or unwrapped single service or single use articles.~~

1308 ~~2-3 AUTHORIZED PERSONNEL~~

1309 ~~Only persons necessary to the operation and maintenance of the retail food establishment shall be~~
 1310 ~~allowed in food preparation, food storage, food equipment storage, and warewashing areas.~~

1311 ~~2-4 PERSONAL CLEANLINESS~~

1312 ~~*2-401 Food employees shall keep their hands and exposed portions of their arms clean.~~

1313 ~~*2-402 Cleaning Procedure~~

- 1314 ~~A. Food employees shall clean their hands and exposed portions of their arms including~~
 1315 ~~surrogate prosthetic devices for hands or arms with soap and water for at least 20 seconds~~
 1316 ~~and shall use the following cleaning procedure:~~
- 1317 ~~1. Vigorous friction on the surfaces of the lathered fingers, finger tips, areas~~
 1318 ~~between the fingers, hands and arms for at least 15 seconds, followed by;~~
 - 1319 ~~2. Thorough rinsing under clean, running warm water; and~~
 - 1320 ~~3. Immediately follow the cleaning procedure with thorough drying of cleaned~~
 1321 ~~hands and arms with disposable or single use towels or a mechanical hand drying~~
 1322 ~~device.~~
- 1323 ~~B. Food employees shall pay particular attention to removing soil underneath the~~
 1324 ~~finger nails during the cleaning procedure.~~
- 1325 ~~C. If approved and capable of removing the types of soils encountered in the food operations~~
 1326 ~~involved, an automatic handwashing facility installed and operated as per section 5-~~
 1327 ~~208(I) may be used by food employees to clean their hands.~~

1328 ~~*2-403—When to Wash~~

1329 ~~Food employees shall clean their hands and exposed portions of their arms immediately before~~
1330 ~~engaging in food preparation including working with exposed food, clean equipment and utensils,~~
1331 ~~and unwrapped single service and single use articles and:~~

1332 ~~A. Before leaving the restroom, and after returning to food and beverage preparation, food~~
1333 ~~storage, equipment storage and warewashing areas from using the restroom;~~

1334 ~~B. After coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or~~
1335 ~~drinking;~~

1336 ~~C. When switching between working with raw foods of animal origin and working with ready-~~
1337 ~~to eat foods;~~

1338 ~~D. After touching bare human body parts other than clean hands and clean, exposed portions of~~
1339 ~~arms;~~

1340 ~~E. During food preparation, as often as necessary to remove soil and contamination and to~~
1341 ~~prevent cross contamination when changing tasks;~~

1342 ~~F. Before handling or putting on single use gloves for working with food, and between~~
1343 ~~removing soiled gloves and putting on clean gloves;~~

1344 ~~G. After handling soiled equipment or utensils;~~

1345 ~~H. After caring for or handling any animals;~~

1346 ~~I. After engaging in any activities that contaminate the hands; and~~

1347 ~~J. After handling fish in aquariums, shellfish, or crustacea in display tanks.~~

1348 ~~*2-404—Hand Antiseptics~~

1349 ~~Hand antiseptics may be used in addition to but not in place of proper handwashing.~~

1350 ~~*2-405—Where to Wash~~

1351 ~~Food employees shall clean their hands in a handsink or approved automatic handwashing facility~~
1352 ~~and may not clean their hands in a sink used for food preparation or warewashing, in a dump sink, or~~
1353 ~~in a utility sink or a curbed cleaning facility used for the disposal of mop water and similar liquid~~
1354 ~~waste.~~

1355 ~~*2-406—Fingernail Care~~

1356 ~~A. Food employees shall keep their fingernails clean, trimmed, filed and maintained so the~~
1357 ~~edges and surfaces are cleanable and not rough.~~

1358 ~~B. Unless wearing intact gloves in good repair, a food employee may not wear fingernail~~
1359 ~~polish or artificial fingernails when working with exposed food.~~

1360 ~~2-407—Clothing~~

1361 ~~Employees shall wear clean outer clothing to prevent cross contamination.~~

1362 ~~2-408—Jewelry~~

1363 ~~Except for a plain ring such as a wedding band, while preparing food, food employees may not wear~~
 1364 ~~jewelry, watches, or medical information bracelets on their wrists and hands or any other area of the~~
 1365 ~~arm that may interfere with proper handwashing or result in contamination of food.~~

1366 ~~2-5—HYGIENIC PRACTICES~~1367 ~~*2-501—General~~

1368 ~~Employees shall maintain a high degree of personal cleanliness and shall conform to good hygienic~~
 1369 ~~practices during all working periods. Proper hygienic practices must be followed by retail food~~
 1370 ~~employees in performing assigned duties to ensure the safety of the food, prevent the introduction of~~
 1371 ~~foreign objects into the food, and minimize the possibility of transmitting disease through food.~~

1372 ~~*2-502—Eating, Drinking, or Using Tobacco~~

1373 ~~A. — Except as specified in paragraph B, employees shall consume food, drink or use tobacco only~~
 1374 ~~in designated areas. Such designated areas must be located so that eating or tobacco use by~~
 1375 ~~an employee does not result in contamination of food, equipment, utensils, or other items~~
 1376 ~~needing protection.~~

1377 ~~B. — An employee may drink from a closed beverage container such as pop top sport bottles when~~
 1378 ~~teeth or mouth are used to open the top, cups with a lid and a straw, and cups with snap on~~
 1379 ~~lids with a hole in the top if:~~

1380 ~~1. — The container is clean;~~

1381 ~~2. — It does not contaminate the employee's hands; and~~

1382 ~~3. — It is stored to prevent the contamination of exposed food, clean equipment, utensils,~~
 1383 ~~linens, unwrapped single service and single use articles.~~

1384 ~~2-503—Hair Restraints~~

1385 ~~A. — Except as provided under paragraph B of this section, food employees engaged in food~~
 1386 ~~preparation shall wear hair restraints, such as hats, hair coverings, hair or beard nets, or other~~
 1387 ~~effective means, to effectively keep hair from contacting exposed food, clean equipment,~~
 1388 ~~utensils, and linens, and unwrapped single service or single use articles.~~

1389 ~~B. — This section does not apply to employees such as counter staff who serve only beverages and~~
 1390 ~~wrapped or packaged foods, or hosts, bartenders, and wait staff who present a minimal risk~~
 1391 ~~of contaminating exposed foods, clean equipment, utensils, and linens, and unwrapped~~
 1392 ~~single service and single use articles.~~

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CHAPTER 3

FOOD

~~3-1~~ CHARACTERISTICS

~~*3-101~~ General

~~Food shall be safe and unadulterated. Food shall be in sound condition, free from spoilage or contamination and shall be safe for human consumption. Food shall not contain unsafe or unapproved food or color additives per 21 CFR 170-186. Food shall be obtained from approved sources that comply with the applicable laws relating to food and food labeling. Food prepared or stored in a private home shall not be used, distributed, or offered for sale.~~

~~3-2~~ SOURCES AND SPECIFICATIONS

~~3-201~~ Shellfish and Fish

~~*A.~~ Molluscan Shellfish

~~———— 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.~~

~~B.~~ Maintaining Shellstock Identification

~~*1. ——— Fresh and frozen shucked molluscan shellfish (oysters, clams, mussels or scallops) shall be received and/or repacked in non-returnable packages identified with the name and address of the original shellstock processor, shucker packer, or repacker, and the state shellstock certification number issued according to law. Shucked molluscan shellfish shall be kept in the container in which they were received until used or sold.~~

~~———— Each original container of unshucked molluscan shellfish shall be identified by an attached tag, to be retained for a period of 90 days after the container is emptied. The tag shall be marked with the empty date and, the name and address of the original shellfish processor, the kind and quantity of shellfish, and the certification number issued by the State or foreign shellfish control agency, where applicable. Tags shall be stored in chronological order from the empty date.~~

~~———— Shellstock from one tagged or labeled container shall not be commingled with shellstock from another container before being ordered by the consumer.~~

~~*2. ——— When received by a food establishment, unshucked 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.~~

~~*C. ——— Molluscan shellfish that are recreationally caught may not be received for sale or service.~~

~~*D. ——— Fish that are received for sale or service shall be:~~

~~1. ——— Commercially and legally caught or harvested; or~~

- 1431 2. ~~Approved for sale or service.~~
- 1432 *E. ~~Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label~~
 1433 ~~that identifies the:~~
- 1434 1. ~~Name, address, and certification number of the shucker, packer or repacker of the~~
 1435 ~~molluscan shellfish; and~~
- 1436 2. ~~The "sell by" or "best if used by" date for packages with a capacity of less than 1.89~~
 1437 ~~L (one half gallon) or the date shucked for packages with a capacity of 1.89 L (one~~
 1438 ~~half gallon) or more.~~
- 1439 F. ~~Molluscan Shellfish, Original Container.~~
- 1440 1. ~~Except as specified in (G) (H) of this section, molluscan shellfish may not be~~
 1441 ~~removed from the container in which they are received other than immediately~~
 1442 ~~before sale or preparation for service.~~
- 1443 G. ~~For display purposes, shellstock may be removed from the container in which they are~~
 1444 ~~received, displayed on drained ice, or held in a display container, and a quantity specified by~~
 1445 ~~a consumer may be removed from the display or display container and provided to the~~
 1446 ~~consumer if:~~
- 1447 1. ~~The source of the shellstock on display is identified as specified in section 3-201(A);~~
 1448 ~~and~~
- 1449 2. ~~The shellstock are protected from contamination.~~
- 1450 H. ~~Shucked shellfish may be removed from the container in which they were received and held~~
 1451 ~~in a display container from which individual servings are dispensed upon a consumer's~~
 1452 ~~request if:~~
- 1453 1. ~~The labeling information for the shellfish on display as specified in section 3-201(E)~~
 1454 ~~is retained and correlated to the date when, or dates during which, the shellfish are~~
 1455 ~~sold or served; and~~
- 1456 2. ~~The shellfish are protected from contamination.~~

1457 **3-202 Parasite Destruction**

- 1458 *A. ~~Except as specified in (B) of this section, before service or sale in ready to eat form, raw,~~
 1459 ~~raw marinated, partially cooked, or marinated partially cooked fish shall be:~~
- 1460 1. ~~Frozen and stored at a temperature of 4°F (-20°C) or below for a minimum of 168~~
 1461 ~~hours (7 days) in a freezer;~~
- 1462 2. ~~Frozen at 31°F (-35°C) or below until solid and stored at 31°F (-35°C) or below for~~
 1463 ~~a minimum of 15 hours; or~~
- 1464 3. ~~Frozen at 31°F (-35°C) or below until solid and stored at 4°F (-20°C) or below for~~
 1465 ~~a minimum of 24 hours.~~
- 1466 ~~The freezing temperature and time to which the fish are subjected shall be recorded, retained and~~
 1467 ~~made readily available upon request at the food establishment for 90 calendar days after the time of~~
 1468 ~~service or sale of the fish.~~
- 1469 ~~If the fish are frozen by the retail food establishment and/or supplier, a written agreement or~~
 1470 ~~statement from the supplier stipulating that the fish supplied are frozen to the proper temperature and~~
 1471 ~~for a time specified in this section may substitute for the records required.~~

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1474 ~~B. Paragraph (A) of this section does not apply to:~~
- 1475 ~~1. Molluscan shellfish;~~
 - 1476 ~~2. Tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna),~~
1477 ~~Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus~~
1478 ~~(Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern); or~~
 - 1479 ~~3. Aquacultured fish, such as salmon, that:~~
 - 1480 ~~a. If raised in open water, are raised in net pens, or~~
 - 1481 ~~b. Are raised in land-based operations such as ponds or tanks, and~~
 - 1482 ~~c. Are fed formulated feed, such as pellets, that contains no live parasites~~
1483 ~~infective to the aquacultured fish.~~
 - 1484 ~~d. If raw, raw marinated, partially cooked, or marinated partially cooked fish~~
1485 ~~are served or sold in ready to eat form, and the fish are raised and fed as~~
1486 ~~specified in section 3-202(B)(3)(a)(c), a written agreement or statement~~
1487 ~~from the supplier or aquaculturist stipulating that the fish were raised and~~
1488 ~~fed as specified in section 3-202(B)(3)(a)(c) shall be obtained by the~~
1489 ~~person in charge and retained in the records of the food establishment for 90~~
1490 ~~calendar days beyond the time of service or sale of the fish.~~
 - 1491 ~~4. Fish eggs that have been removed from the skein and rinsed.~~

1492 ~~3-3 SOURCES AND SPECIFICATIONS~~

1493 ~~*3-301 Package Integrity~~

1494 ~~Food packages shall be in good condition and protect the integrity of the contents so that the~~
1495 ~~food is not exposed to adulteration or potential contaminants.~~

1496 ~~*3-302 Hermetically Sealed Food~~

1497 ~~A. The use, distribution, or sale of food from hermetically sealed containers that was not prepared in an~~
1498 ~~approved food processing establishment or retail food establishment that is approved for this~~
1499 ~~type of processing, is prohibited.~~

1500 ~~B. Hermetically sealed packages shall be handled so as to maintain product and container integrity.~~
1501 ~~The “Guide to Can Defects and Basic Components of Double Seam Containers”, November~~
1502 ~~2011, published by the Association of Food and Drug Officials, shall be used to determine~~
1503 ~~container integrity. Food items that are spoiled or that are in damaged containers that may~~
1504 ~~affect the product and those food items that have been returned to, or are being detained by,~~
1505 ~~the retail food establishment because of spoilage, container damage, or other public health~~
1506 ~~considerations shall be segregated and held in designated areas pending proper disposition~~
1507 ~~unless disposed of under the supervision of the Department.~~

1508 ~~*3-303 Dry Milk and Dry Milk Products~~

1509 ~~Dry milk and milk products used, served or offered for sale shall be made from pasteurized milk and~~
1510 ~~milk products.~~

1511 ~~*3-304—Reconstitution of Dry Milk, Dry Milk Products and Non-Dairy Products~~

1512 ~~Dry milk, dry milk products and non dairy creaming, whitening, or whipping agents may be~~
 1513 ~~reconstituted with potable water on the premises only when they will be stored in sanitized, covered~~
 1514 ~~containers and cooled to 41°F (7°C) or below within four hours after preparation.~~

1515 ~~Reconstituted dry milk cannot be substituted for use as a Grade A fluid milk product in its final form~~
 1516 ~~(e.g. for drinking, over cereal, etc.).~~

1517 ~~*3-305—Fluid Milk, Fluid Milk Products, and Frozen Dessert Mix~~

1518 ~~A. Fluid milk and fluid milk products used, served or offered for sale shall comply with the~~
 1519 ~~Colorado Grade A Pasteurized Fluid Milk and Milk Products Regulation.~~

1520 ~~B. Only pasteurized mix from an approved licensed dairy plant may be mixed and/or frozen by~~
 1521 ~~a counter freezer.~~

1522 ~~C. Raw milk supplied to and held by retail food establishments for distribution to shareholders~~
 1523 ~~shall meet the requirements of section 25-5.5-117 et. seq., C.R.S.~~

1524 ~~1. Only farms or dairies that are properly registered with the Department may~~
 1525 ~~distribute raw milk.~~

1526 ~~2. Only an owner or shareholder of a cow, goat or dairy herd may distribute raw milk~~
 1527 ~~from a retail food establishment. Distribution of raw milk by management or~~
 1528 ~~employees of a retail food establishment that are not owners or shareholder of a~~
 1529 ~~cow, goat or dairy herd is prohibited.~~

1530 ~~3. Only an owner or shareholder of a cow, goat or dairy herd shall receive raw milk~~
 1531 ~~from the farm or dairy where the cow or goat is located or from a shareholder of the~~
 1532 ~~same cow, goat or dairy herd.~~

1533 ~~4. Containers used to hold raw milk shall have a prominent warning statement that the~~
 1534 ~~milk is not pasteurized, is delivered to the shareholder with the milk or is displayed~~
 1535 ~~on a label affixed to the milk container.~~

1536 ~~5. Storage of raw milk with other food is prohibited. Raw milk must be stored in a~~
 1537 ~~separate refrigerator or cooler that is used only for raw milk and must be stored in a~~
 1538 ~~manner where it cannot be mistaken for pasteurized milk. Display or access of raw~~
 1539 ~~milk to the public is prohibited.~~

1540 ~~*3-306—Wild Mushrooms~~

1541 ~~A. Except as specified in paragraph B of this section, mushroom species picked in the wild shall~~
 1542 ~~be obtained from sources where each mushroom is individually inspected and found to be~~
 1543 ~~safe by a mushroom identification expert approved by the Department. To be approved by~~
 1544 ~~the department an individual must:~~

1545 ~~1. Identify which county(ies) and retail food establishments they will supply wild~~
 1546 ~~mushrooms;~~

1547 ~~2. Provide the genus and species of the wild mushrooms that will be supplied;~~

1548 ~~3. Provide written verification detailing their qualifications that demonstrate their~~
 1549 ~~ability to identify and pick wild mushrooms that are safe for human consumption~~
 1550 ~~such as educational degrees, years of experience, membership to any professional~~
 1551 ~~organizations;~~

- 1552 4. ~~Provide a written letter of reference from a separate individual who can verify the~~
 1553 ~~picker has the expertise. The person supplying the letter of reference must be a~~
 1554 ~~recognized mycologist who can attest the picker has the ability to identify the genus~~
 1555 ~~and species of wild mushrooms they intend to pick;~~
- 1556 5. ~~Maintain records for at least two (2) years identifying the buyers, the type of~~
 1557 ~~mushroom(s) received and the quantity received, and;~~
- 1558 6. ~~Supply an invoice to the buyer with each shipment that identifies:~~
- 1559 a. ~~The variety of mushroom by common name and genus and species;~~
- 1560 b. ~~The quantity;~~
- 1561 c. ~~The suppliers name, address, and date of packing.~~
- 1562 B. ~~This section does not apply to:~~
- 1563 1. ~~Cultivated wild mushroom species that are grown, harvested, and processed in an~~
 1564 ~~operation that is regulated by the regulatory agency that has jurisdiction over the~~
 1565 ~~operation; or~~
- 1566 2. ~~Wild mushroom species if they are in packaged form and are the product of a food~~
 1567 ~~processing plant that is regulated by the food regulatory agency that has jurisdiction~~
 1568 ~~over the plant.~~

1569 ~~*3-307 Meat, Poultry, Game Animals and Exotic Species~~

- 1570 ~~Game animals and exotic species may be received for sale or service provided they are slaughtered~~
 1571 ~~and processed according to laws governing meat and poultry as determined by the agency that has~~
 1572 ~~animal health jurisdiction and the agency that conducts the inspection program.~~
- 1573 A. ~~Meat and poultry are required to come from a USDA FSIS inspected facility.~~
- 1574 1. ~~Meats listed in the Federal Meat Inspection Act that require mandatory USDA~~
 1575 ~~inspection include cattle, swine, sheep, goats, horse, mule, other equine, and any~~
 1576 ~~others as determined by the USDA.~~
- 1577 2. ~~Poultry listed in the Poultry Products Inspection Act that require Mandatory USDA~~
 1578 ~~Inspection include chicken, geese, duck, turkey, guineas, emu, ratite, ostrich, squab~~
 1579 ~~(pigeon), and any others as determined by the USDA.~~
- 1580 B. ~~Game animals indigenous to North America such as reindeer, elk, deer, antelope, water~~
 1581 ~~buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and any others as~~
 1582 ~~determined by the USDA shall go through the USDA Voluntary Meat~~**Error! Bookmark not**
 1583 ~~defined.~~ **defined.** ~~Inspection Program in order to be considered an approved source.~~
- 1584 C. ~~Poultry products that are game animals are required to be inspected under the USDA~~
 1585 ~~Voluntary Poultry Inspection Program. Species include Quail, pheasant, dove, other game~~
 1586 ~~birds and any others as determined by the USDA.~~
- 1587 D. ~~Any other game animal that is obtained from a retail food establishment would fall under~~
 1588 ~~FDA inspection authority. This would include rattlesnake, bear, alligator, and any others as~~
 1589 ~~determined by the USDA.~~
- 1590 E. ~~Game animals obtained from States that have contracts with the FDA or USDA to conduct~~
 1591 ~~inspections of game animal food processing establishments are recognized by the~~
 1592 ~~Department as being an approved regulatory authority and food products received from these~~
 1593 ~~states are considered an approved source.~~

1594 For additional guidance, refer to the Colorado Department of Public Health and Environment issued
 1595 interpretative memo titled “Determining Approved Source for Meat, Poultry, Game Animals, and
 1596 Exotic Animal Species.”

1597 ~~*3-308—Eggs~~

1598 A. Only clean intact, approved shell eggs meeting applicable grade standards or pasteurized shell,
 1599 liquid, frozen or dry eggs, or pasteurized dry egg products shall be used or offered for sale.

1600 B. The egg carton must be new, clean and properly labeled to include the supplier’s name and
 1601 address, egg grade, size and pack date. *FDA Safe Handling Instructions* on the carton are
 1602 required.

1603 C. Eggs can be offered for sale loose or in a basket, but must have an accompanying card or sign
 1604 that contains the required labeling information including the wash and process date versus a
 1605 pack date as indicated on a carton.

1606 D. Pooling of raw shell eggs is allowed only if the eggs are 41°F (5°C) or below when they are
 1607 cracked and maintained at 41°F (5°C) or below until cooked.

1608 ~~3-309—Ice~~

1609 *A. Only ice which has been manufactured from drinking water and handled in a sanitary manner
 1610 shall be used or offered for sale. Ice offered for sale shall be packaged and properly labeled.

1611 B. Ice for human consumption shall be drained.

1612 ~~*3-310—Ice Used as Exterior Coolant, Prohibited as Ingredient~~

1613 Ice used as a cooling medium for food storage, beverage containers, food containers or food utensils
 1614 shall not be used or sold for human consumption.

1615 ~~3-311—Storage or Display of Food in Contact With Water or Ice~~

1616 A. Packaged food may be stored in direct contact with drinking water if the packaging,
 1617 wrapping, or container is not subject to entry of water.

1618 B. Except as specified in C and D of this section, unpackaged food may not be stored in direct
 1619 contact with undrained ice.

1620 C. Whole raw fruits and whole or cut raw vegetables, such as celery or carrot sticks or cut
 1621 potatoes; and tofu may be immersed in ice made with drinking water.

1622 D. Raw chicken and raw fish that are received immersed in ice made with drinking water in
 1623 shipping containers may remain in that condition while in storage awaiting preparation,
 1624 display, service, or sale.

1625 ~~*3-312—Juice~~

1626 A. Pre packaged juice shall be obtained pasteurized; in a sterile shelf stable form in a ; or
 1627 otherwise treated under an approved HACCP plan as specified in 21 CFR section 120.24,
 1628 (2003) to attain a 5-log reduction of the most resistant microorganism of public health
 1629 significance.

1630

1631
 1632 B. — ~~Juice packaged in a retail establishment and sold exclusively and directly to its consumers~~
 1633 ~~does not have to be processed in conformance with an approved HACCP plan, but if~~
 1634 ~~packaged shall bear the phrase: “WARNING: This product has not been pasteurized and,~~
 1635 ~~therefore, may contain harmful bacteria that can cause serious illness in children, the elderly,~~
 1636 ~~and persons with weakened immune systems” and meet the requirements of the Federal Fair~~
 1637 ~~Packaging and Labeling Act.~~

1638 ~~***3-313 Whole Muscle, Intact Beef Steaks**~~

1639 ~~Whole muscle, intact beef steaks that are intended for consumption in an undercooked form~~
 1640 ~~without a consumer advisory as specified in section 3-801 shall be:~~

1641 A. — ~~Obtained from a food processing plant that, upon requested by the purchaser, packages the~~
 1642 ~~steaks and labels them, to indicate that the steaks meet the definition of whole muscle, intact~~
 1643 ~~beef, or~~

1644 B. — ~~Deemed acceptable by the Department based on other evidence, such as written buyer~~
 1645 ~~specifications or invoices, that indicates that the steaks meet the definition of whole muscle,~~
 1646 ~~intact beef; and~~

1647 C. — ~~If individually cut in a food establishment:~~

1648 1. — ~~Cut from a whole muscle intact beef that is labeled by a food processing plant as~~
 1649 ~~specified in part (A) of this section or identified as specified in part (B) of this~~
 1650 ~~section;~~

1651 2. — ~~Prepared so they remain intact; and~~

1652 3. — ~~If packaged for undercooking in a food establishment, labeled as specified in part~~
 1653 ~~(A) of this section or as identified in part (B) of this section.~~

1654 ~~**3-4 PROTECTION FROM CONTAMINATION AFTER RECEIVING**~~

1655 ~~***3-401 Preventing Contamination from Hands**~~

1656 A. — ~~Food employees shall wash their hands as specified in section 2-402 of these rules and~~
 1657 ~~regulations.~~

1658 B. — ~~Food employees shall minimize bare hand and arm contact with exposed food that is not~~
 1659 ~~in a ready to eat form.~~

1660 C. — ~~Except when washing fruits and vegetables as specified in section 3-408(A) of these~~
 1661 ~~rules and regulations or except as specified in (D) of this section, food employees may~~
 1662 ~~not contact exposed, ready to eat food including fruits and vegetables with their bare~~
 1663 ~~hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single use gloves,~~
 1664 ~~or dispensing equipment.~~

1665 D. — ~~Food employees not serving a highly susceptible population may contact exposed, ready-~~
 1666 ~~to eat food with their bare hands if:~~

1667 1. — ~~Written procedures are maintained in the food establishment and made available~~
 1668 ~~to the Department upon request that include:~~

1669 a. — ~~A listing of the ready to eat food categories that are touched by bare~~
 1670 ~~hands;~~

- 1671 b. ~~Handwashing facilities are, equipped, maintained, are easily accessible~~
 1672 ~~and in close proximity to the work station(s) where the bare hand contact~~
 1673 ~~procedure is conducted as specified in section 5-208 (B)–(J) of these~~
 1674 ~~rules and regulations;~~
- 1675 c. ~~A written employee health policy that details how the food establishment~~
 1676 ~~will comply with sections 2-201, 2-202, 2-203, and 2-204 of these rules~~
 1677 ~~and regulations, including health conditions upon which the food~~
 1678 ~~employee will not be allowed to work and acknowledgement of their~~
 1679 ~~responsibilities as specified in sections 2-201 and 2-202;~~
- 1680 d. ~~An employee training program that documents completion of the~~
 1681 ~~following training areas:~~
- 1682 ~~(1) The risks of contacting the ready-to-eat foods with bare hands;~~
 1683 ~~(2) Proper handwashing as specified in section 2-401 and 2-402;~~
 1684 ~~(3) When to wash their hands as specified in section 2-403;~~
 1685 ~~(4) Where to wash their hands as specified in section 2-405;~~
 1686 ~~(5) Proper fingernail maintenance as specified in section 2-406 (A);~~
 1687 ~~(6) Prohibition of jewelry as specified in section 2-408; and~~
 1688 ~~(7) Good hygienic practices as related to section 2-501 and section 2-~~
 1689 ~~502.~~
- 1690 2. ~~Hands are washed prior to food preparation and as necessary to prevent cross~~
 1691 ~~contamination as specified in section 2-401, 2-402, 2-403 and 2-405 by food~~
 1692 ~~employees during all hours of operation when the specific ready-to-eat foods are~~
 1693 ~~prepared.~~
- 1694 3. ~~In addition to the requirements specified in section 2-403 “When to Wash”, food~~
 1695 ~~employees contacting ready-to-eat foods with bare hands utilize two or more of~~
 1696 ~~the following control measures to provide additional safeguards to hazards~~
 1697 ~~associated with bare hand contact:~~
- 1698 a. ~~Double handwashing;~~
 1699 b. ~~Nail brushes;~~
 1700 c. ~~A hand antiseptic after handwashing as specified in section 2-404;~~
 1701 d. ~~Incentive programs that encourage food employees not to work when~~
 1702 ~~they are ill with a communicable disease that can be transmitted by foods~~
 1703 ~~as specified in section 2-201; or~~
 1704 e. ~~Other control measures approved by the Department.~~
- 1705 4. ~~Corrective actions are immediately taken when subparagraphs D (1)–(3) of this~~
 1706 ~~section are not followed. Accompanying monitoring, corrective actions, and~~
 1707 ~~appropriate documentation are required.~~
- 1708 E. ~~If a food establishment is found to be in non-compliance with the requirements listed in~~
 1709 ~~subparagraphs D (1)–(4) and a civil penalty has been issued in accordance with C.R.S.,~~
 1710 ~~§25-4-1611, as a result of this non-compliance, or if a confirmed foodborne illness is~~
 1711 ~~associated with bare hand contact and ill employees, the Department may suspend or~~

1712 ~~revoke the food establishment's allowance for food employees to contact ready-to-eat~~
 1713 ~~foods with their bare hands.~~

1714 F. ~~— If the allowance for a food establishment to contact ready-to-eat foods with bare hands is~~
 1715 ~~voluntarily discontinued by the food establishment, suspended or revoked as provided for~~
 1716 ~~in subparagraph E, a food establishment may not reinstate bare hand contact with ready-~~
 1717 ~~to-eat foods without prior written approval from the Department.~~

1718 ~~3-402—Glove Use~~

1719 ~~*A. — If used, single-use gloves shall be used for only one task, such as working with ready-to-~~
 1720 ~~eat food, or with raw animal food. Single-use gloves shall be used for no other purpose,~~
 1721 ~~and discarded when damaged, when interruptions occur in the operation, or when the task~~
 1722 ~~is completed.~~

1723 ~~B. — Except as specified in (C) slash-resistant gloves that are used to protect the hands during~~
 1724 ~~operations requiring cutting shall be used in direct contact only with food that is~~
 1725 ~~subsequently cooked as specified in part 3-5 such as frozen food or a primal cut of meat.~~

1726 ~~C. — Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently~~
 1727 ~~cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer~~
 1728 ~~surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent~~
 1729 ~~glove, or a single-use glove.~~

1730 ~~D. — Cloth gloves may not be used in direct contact with food unless the food is subsequently~~
 1731 ~~cooked as required under section 3-5 such as frozen food or a primal cut of meat.~~

1732 ~~*3-403—Preventing Contamination When Tasting~~

1733 ~~A food employee may not use a utensil more than once to taste food that is to be sold or served.~~

1734 ~~*3-404—General~~

1735 ~~At all times, including while being stored, prepared, displayed, dispensed, packaged, or transported,~~
 1736 ~~food shall be protected from cross-contamination between foods and from potential contamination by~~
 1737 ~~insects, insecticides, rodents, rodenticides, other toxins, probe-type price tags or probe-type~~
 1738 ~~identification tags, unclean equipment and utensils, unnecessary handling, flooding, draining,~~
 1739 ~~overhead leakage or condensation, or other agents of public health significance. Hanging primal cuts~~
 1740 ~~and quarters or sides of meat, and uncut raw fruits and vegetables do not need to be over-wrapped or~~
 1741 ~~covered. Foods in original individual packages must be over-wrapped or covered if the package has~~
 1742 ~~been torn or broken. During transportation, including transportation to another location for service or~~
 1743 ~~catering operations, food shall meet the requirements of these rules and regulations relating to food~~
 1744 ~~protection, food storage and temperature maintenance of potentially hazardous foods~~
 1745 ~~(time/temperature control for safety foods).~~

1746 ~~*3-405—Cross-Contamination Control~~

1747 ~~Each time there is a change in processing between raw beef, raw pork, other raw meats, raw poultry,~~
 1748 ~~raw fish and molluscan shellfish or from raw to ready-to-eat foods, food contact surfaces and utensils~~
 1749 ~~shall be cleaned and sanitized as specified in 4-403 and 4-404. Salads and other ready-to-eat foods~~
 1750 ~~may also be prepared simultaneously in areas that are separated by a barrier or open space from areas~~
 1751 ~~used for processing potentially hazardous raw products.~~

1752 ~~3-406 — Packaged and Unpackaged Food — Separation, Packaging, and Segregation~~

- 1753 A. ~~Food shall be protected from cross contamination by separating raw animal foods during~~
 1754 ~~storage, preparation, holding, and display from:~~
- 1755 ~~*1. — Raw ready to eat food including other raw animal food such as fish for sushi or~~
 1756 ~~molluscan shellfish, or other raw ready to eat food such as fruits and vegetables;~~
 1757 ~~and~~
- 1758 ~~*2. — Cooked ready to eat food;~~
- 1759 B. ~~Frozen, commercially processed and packaged raw animal food may be~~
 1760 ~~stored or displayed with or above frozen, commercially processed and packaged, ready to~~
 1761 ~~eat food.~~

1762 ~~*3-407 — Pasteurized Eggs, Substitute for Shell Eggs for Certain Recipes~~

1763 ~~Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of foods such as~~
 1764 ~~Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-~~
 1765 ~~fortified beverages that are not cooked as specified in section 3-502 (D). This section does not apply~~
 1766 ~~if there is a Consumer Advisory in place as specified in Section 3-801 excepts as prohibited by~~
 1767 ~~Section 3-702(C).~~

1768 ~~3-408 — Washing Fruits and Vegetables/Additives/Sulfites~~

- 1769 A. ~~Except as specified in (B)–(D) of this section and except for whole, raw fruits and vegetables~~
 1770 ~~that are intended for washing by the consumer before consumption, raw fruits and vegetables~~
 1771 ~~shall be thoroughly washed in running drinking water to remove soil and other contaminants~~
 1772 ~~before being cut, combined with other ingredients, cooked, served, or offered for human~~
 1773 ~~consumption in ready to eat form. Commercially, prewashed raw fruits and vegetables that~~
 1774 ~~are prepackaged to prevent contamination do not require further washing prior to use.~~
- 1775 B. ~~Fruits and vegetables from which rinds, peels, husks, or shells are not removed~~
 1776 ~~before preparation require washing.~~
- 1777 C. ~~Chemicals for washing fruits and vegetables, criteria.~~
- 1778 ~~*1. — Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the~~
 1779 ~~requirements specified in 21 CFR 173.315, “Chemicals used in washing or to assist~~
 1780 ~~in the peeling of fruits and vegetables”.~~
- 1781 ~~2. — Ozone as an antimicrobial agent used in the treatment, storage, and processing of~~
 1782 ~~fruits and vegetables in a food establishment shall meet the requirements specified in~~
 1783 ~~21 CFR 173.368.~~
- 1784 ~~*D. — Application of sulfiting agents to fresh fruits and vegetables intended for raw consumption or~~
 1785 ~~to a food considered to be a good source of vitamin B₁, such as poultry, crab meat (except~~
 1786 ~~canned), mixed nuts, whole grains, whole grain flours, enriched bakery products is~~
 1787 ~~prohibited.~~
- 1788 E. ~~New or extensively remodeled establishments with food items that require washing shall~~
 1789 ~~have a food preparation sink. The food preparation sink must be supplied with both hot and~~
 1790 ~~cold running water, must be indirectly drained to sewer and must be equipped with an~~
 1791 ~~approved eighteen inch (18") [(46 centimeters (cm))] drain board or an alternate drain table or~~
 1792 ~~work space approved by the Department. If a garbage disposal is to be installed at the food~~

1793 preparation sink, it shall be located in the drain board of the sink and must be plumbed in
1794 accordance with section 5-205.

1795 F. ~~In establishments licensed prior to the effective date of these regulations, where vegetable~~
1796 ~~preparation is limited to a few items and in limited quantity, and either single service~~
1797 ~~tableware or a mechanical dishwasher is used, the three compartment warewashing sink~~
1798 ~~may be used for food preparation if the sink is indirectly drained and the sink and drain~~
1799 ~~boards are cleaned and sanitized between changes in use.~~

1800 G. ~~A food preparation sink may only be used for washing food, cooling, thawing and other food~~
1801 ~~preparation activities.~~

1802 ~~3-409~~ **In-Use Utensils, Between Use Storage**

1803 A. ~~To avoid unnecessary manual contact with the food, suitable dispensing utensils and single-~~
1804 ~~service articles shall be used by employees and consumers. Consumer display and self-~~
1805 ~~service of bulk food shall meet the requirements of section 25-4-1301 et seq., C.R.S., (See~~
1806 ~~Appendix H). Except as specified in 5 and 6, dispensing utensils shall be:~~

- 1807 1. ~~Stored in the food with the dispensing utensil handle extended out of the food; or~~
- 1808 2. ~~Stored on a clean and sanitized surface, if washed and sanitized in accordance with~~
1809 ~~section 4-407(C); or~~
- 1810 3. ~~Stored in continuously flowing drinking water such as in a dipper well; or~~
- 1811 4. ~~Stored at temperatures of 135°F (57°C) and above, or 41°F (5°C) and below.~~
- 1812 5. ~~Utensils may not be stored in cracks and crevices between equipment.~~
- 1813 6. ~~In use utensils may not be stored in sanitizing or cleaning solutions.~~

1814 B. ~~Ice for human consumption shall be dispensed only by employees with scoops, tongs, or~~
1815 ~~other ice dispensing utensils, or through automatic self service, ice dispensing equipment.~~
1816 ~~Ice dispensing utensils shall be stored on a clean surface or in the ice with the dispensing~~
1817 ~~utensil's handle extended out of the ice. Between uses, ice transfer receptacles shall be~~
1818 ~~stored in a way that protects them from contamination.~~

1819 ~~3-410~~ **Wiping Cloths**

1820 A. ~~Cloths used for wiping food spills on food contact surfaces shall be cleaned and rinsed~~
1821 ~~frequently in one of the sanitizing solutions permitted in Appendix F of these rules and~~
1822 ~~regulations and used for no other purpose. These cloths shall be held between uses in a~~
1823 ~~clean, chemical sanitizer solution at the proper concentration.~~

1824 B. ~~Cloths used for cleaning nonfood contact surfaces shall be clean and rinsed as specified in~~
1825 ~~paragraph A of this section and used for no other purpose. These cloths shall be held~~
1826 ~~between uses in a clean, chemical sanitizer solution at the proper concentration.~~

1827 C. ~~Cloths that are used with raw foods of animal origin shall be kept separate from cloths used~~
1828 ~~for other purposes. Cloths used with raw foods of animal origin shall be kept in a separate~~
1829 ~~sanitizing solution.~~

1830 D. ~~Dry, single use disposable towels are permitted for wiping food spills in lieu of wiping~~
1831 ~~cloths if discarded after each use.~~

1832 E. ~~Cloths used for wiping food spills on tableware, such as plates and bowls being served to the~~
1833 ~~consumer, shall be clean, dry, and used for no other purpose.~~

- 1834 F. ~~Sponges shall not be used in contact with food contact surfaces.~~
- 1835 G. ~~Wet wiping cloths shall be laundered daily.~~
- 1836 H. ~~Dry wiping cloths shall be laundered as necessary to prevent contamination of food and~~
1837 ~~clean serving utensils.~~

1838 **3-411 — Re-Use of Tableware**

- 1839 A. ~~Except as specified in B, re-use of soiled tableware is prohibited.~~
- 1840 B. ~~Beverage cups and glasses may be refilled where filling equipment is designed to prevent~~
1841 ~~cross-contamination provided that the actuating lever or mechanism and filling device of~~
1842 ~~beverage dispensing equipment is designed to prevent contact with the lip contact surface of~~
1843 ~~glasses or cups that are being refilled.~~

1844 **3-412 — Refilling Returnables**

- 1845 A. ~~A take-home or personal food container shall not be refilled at a retail food establishment~~
1846 ~~with a potentially hazardous food (time/temperature control for safety food).~~
- 1847 B. ~~Returnables refilled with food that is not potentially hazardous shall be clean.~~
- 1848 C. ~~Personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee~~
1849 ~~cups, and promotional beverage glasses, may be refilled by employees or the consumer if~~
1850 ~~refilling is a contamination-free process.~~

1851 **3-413 — Food Storage**

- 1852 A. ~~Containers of food shall be stored a minimum of six inches (6") [15 centimeters (cm)] above~~
1853 ~~the floor or stored on dollies, skids, racks, or open-ended pallets, provided such equipment is~~
1854 ~~easily movable, either by hand or with the use of pallet moving equipment that is on the~~
1855 ~~premises and used. Such storage areas shall be kept clean.~~
- 1856 B. ~~Pressurized beverage containers, cased food in waterproof containers such as bottles or cans,~~
1857 ~~milk containers in plastic crates, and waterproof, easily moveable, covered containers may be~~
1858 ~~stored on a floor that is clean and not exposed to floor moisture.~~
- 1859 C. ~~Packaged food, once the container is opened in the retail food establishment prior to use or~~
1860 ~~retail sale, shall be kept covered. Food, whether raw or prepared, if removed from the~~
1861 ~~container in which it was originally packaged, shall be stored in a clean, covered container,~~
1862 ~~except during necessary periods of preparation or cooling. Foods uncovered during~~
1863 ~~preparation or cooling must be protected from contamination.~~
- 1864 ~~Primal cuts, quarters or sides of meat, or processed meats, such as country hams, slab bacon,~~
1865 ~~and smoked or cured sausages, may be hung uncovered or placed on clean, sanitized metal~~
1866 ~~racks in such a manner as to preclude contamination of any food products in storage.~~

1867 **3-414 — Food Storage, Prohibited Areas**

- 1868 Food may not be stored:
- 1869 A. ~~In locker areas unless the food is completely packaged;~~
- 1870 B. ~~In toilet rooms and their vestibules;~~
- 1871 C. ~~In dressing rooms;~~

- 1872 D. ~~— In rooms designated for garbage, recycling or composting collection;~~
- 1873 E. ~~— In mechanical rooms;~~
- 1874 F. ~~— Under sewer lines that are not shielded to intercept potential drips;~~
- 1875 G. ~~— Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on~~
1876 ~~which water has condensed;~~
- 1877 H. ~~— Under open stairwells;~~
- 1878 I. ~~— Under other sources of contamination; or~~
- 1879 J. ~~— In a private home.~~

1880 **~~3-415 — Food Display~~**

- 1881 A. ~~— Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling,~~
1882 ~~peeling, or washing by the consumer before consumption, food on display shall be protected~~
1883 ~~from contamination by the use of packaging; food shields at counters, service lines, or salad~~
1884 ~~bars; display cases; or other effective means of protection.~~
- 1885 B. ~~— French style, hearth baked or hard crusted loaves and rolls may be considered properly~~
1886 ~~wrapped if contained in an open end bag of sufficient size to enclose the loaves or rolls.~~
- 1887 C. ~~— Bulk food that is available for consumer self dispensing shall meet the requirements of~~
1888 ~~section 25-4-1301 et seq., C.R.S., (See Appendix H).~~

1889 **~~3-416 — Condiments, Protection~~**

- 1890 A. ~~— Condiments shall be protected from contamination by being kept in protective dispensers, in~~
1891 ~~food displays that meet the requirements of section 3-311 (A) and are provided with the~~
1892 ~~proper utensils, in original containers that are designed for dispensing, or in individual~~
1893 ~~packages or portions.~~
- 1894 B. ~~— Adding additional product before the container is emptied, cleaned and sanitized is~~
1895 ~~prohibited.~~

1896 **~~*3-417 — Consumer Self-Service Operations~~**

- 1897 A. ~~— Unpackaged or unwrapped raw animal food, such as beef, lamb, pork, poultry and fish shall~~
1898 ~~not be offered for consumer self service. This does not apply to consumer self service of~~
1899 ~~ready to eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish, or~~
1900 ~~to ready to cook individual portions for immediate cooking and consumption on the~~
1901 ~~premises such as consumer cooked meats or consumer selected ingredients for Mongolian~~
1902 ~~barbecue.~~
- 1903 B. ~~— Consumer self service operations such as buffets and salad bars shall be monitored by food~~
1904 ~~employees trained in safe operating procedures.~~

1905 **~~*3-418 — Reservice~~**

- 1906 ~~Once served to a consumer, portions of leftover food shall not be served again except that packaged~~
1907 ~~food, other than potentially hazardous food (time/temperature control for safety food), that is still in~~
1908 ~~an unopened package and is still in sound condition, may be re-served.~~

1909

1910

1911 **3-5 DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN**

1912 ***3-501 Temperature**

1913 A. The temperature of potentially hazardous foods (time/temperature control for safety foods)
 1914 shall be 41°F (5°C) or below or 135°F (57°C) or above, at all times, except during necessary
 1915 periods of preparation or as otherwise provided in this code.

1916 B. Equipment for cooling, heating and holding food, cold and hot, shall be sufficient in number
 1917 and capacity to provide required food temperatures.

1918 C. Fluid milk and milk products, molluscan shellstock, and shell eggs may be received at their
 1919 respective temperatures according to laws governing their distribution.

1920 D. A food that is labeled frozen and shipped frozen by a food processing plant shall be received
 1921 and stored frozen.

1922 E. Upon receipt, potentially hazardous food (time/temperature control for safety food) shall be
 1923 free of evidence of previous temperature abuse.

1924 ***3-502 Cooking Potentially Hazardous Foods (Time/Temperature Control For Safety Foods)**

1925 Potentially hazardous foods (time/temperature control for safety foods) processed within the retail
 1926 food establishment shall be cooked to a uniform internal temperature of 135°F (57°C), except that:

1927 A. Poultry, stuffed ratite, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, or stuffing
 1928 containing fish, meat or poultry shall be cooked to a minimum internal temperature of at
 1929 least 165°F (74°C) for 15 seconds.

1930 B. Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as
 1931 ham shall be cooked:

1932 1. In an oven that is preheated to the temperature specified for the roast's weight in the
 1933 following chart and that is held at that temperature:

OVEN TYPE	OVEN TEMPERATURE BASED ON ROAST WEIGHT	
	LESS THAN 10 LBS (4.5 KG)	10 LBS(4.5 KG) OR MORE
STILL DRY	350°F (177°C) OR MORE	250°F (121°C) OR MORE
CONVECTION	325°F (163°C) OR MORE	250°F (121°C) OR MORE
HIGH HUMIDITY ¹	250°F (121°C) OR LESS	250°F (121°C) OR LESS

¹RELATIVE 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.

1934

1935 and

1936

1937
1938
1939

2. — 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:

TEMPERATURE °F °C	TIME ¹ IN MINUTES	TEMPERATURE °F °C	TIME ¹ IN SECONDS
130°F (54.4°C)	112	147°F (63.9°C)	134
131°F (55.0°C)	89	149°F (65.0°C)	85
133°F (56.1°C)	56	151°F (66.1°C)	54
135 (57.2°C)	36	153°F (67.2°C)	34
136°F (57.8°C)	28	155°F (68.3°C)	22
138°F (58.9°C)	18	157°F (69.4°C)	14
140°F (60.0°C)	12	158°F (70.0°C)	0
142°F (61.1°C)	8	-	-
144°F (62.2°C)	5	-	-
145°F (62.8°C)	4	-	-

¹~~HOLDING TIME MAY INCLUDE POST-OVEN HEAT RISE.~~

1940

C. — A raw or undercooked whole muscle, intact beef steak may be served or offered for sale in a ready to eat form if:

1943
1944

1. — The food establishment serves a population that is not a highly susceptible population;

1945
1946

2. — The steak is labeled to indicate that it meets the definition of "whole muscle, intact beef"; and

1947
1948

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

1949
1950

D. — Eggs, pork, lamb, fish and other meats as defined in section 1-202 (35) shall be cooked to a minimum internal temperature of 145°F (63°C) for 15 seconds.

1951
1952

E. — Eggs that are not prepared in response to a consumer's order or for immediate service shall be cooked to 155°F (68°C).

1953
1954
1955

F. — Ground beef and ratites shall be cooked to a minimum internal temperature of 155°F (68°C) for 15 seconds, or to 145°F (63°C) for 3 minutes, or 150°F (66°C) for 1 minute, or 158°F (70°C) for less than one second.

1956
1957

G. — Game animals shall be cooked to a minimum internal temperature of 145°F (63°C) for 15 seconds except as specified in section 3-502 (K) of these rules and regulations.

1958
1959
1960

H. — Comminuted fish, meat and game animals and beef including mechanically tenderized or injected meats other than whole muscle intact beef steak, shall be cooked to a minimum internal temperature of 155°F (68°C) for 15 seconds.

1961

I. — Raw animal foods cooked in a microwave oven shall be:

1962
1963

1. — Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat

- 1964 2. — Covered to retain surface moisture
- 1965 3. — Heated to a temperature of at least 165°F (74°C) in all parts of the food; an
- 1966 4. — Allowed to stand covered for 2 minutes after cooking to obtain temperature
- 1967 equilibrium.
- 1968 J. — Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of
- 1969 135°F (57°C).
- 1970 K. — Unless otherwise ordered by the immediate consumer and the consumer is informed as
- 1971 specified in sections 1(a)–(c) below:
- 1972 1. — A raw animal food such as raw egg, raw fish, raw marinated fish, raw molluscan
- 1973 shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft
- 1974 cooked eggs, or rare meat other than whole muscle, intact beef steaks as specified in
- 1975 (c) of this section, may be served or offered for sale upon consumer request or
- 1976 selection in a ready-to-eat form if:
- 1977 a. — As specified in section 3-702(A)–(C) of these rules and regulations, the food
- 1978 establishment serves a population that is not a highly susceptible
- 1979 population;
- 1980 b. — The food, if served or offered for service by consumer selection from a
- 1981 children's menu, does not contain comminuted meat; and
- 1982 c. — The consumer is informed as specified in part 3-8 "*Consumer Advisory*"
- 1983 that to ensure its safety, the food should be cooked as specified in section 3-
- 1984 502(A)–(K) of this section.

1985 ***3-503 Non-Continuous Cooking of Raw Animal Foods**

- 1986 A. — Raw animal foods that are cooked using a non-continuous cooking process shall be:
- 1987 1. — Subject to an initial heating process that is no longer than sixty minutes in
- 1988 duration;
- 1989 2. — Immediately after initial heating, cooled according to the time and temperature
- 1990 parameters specified for cooked potentially hazardous food (time/temperature
- 1991 control for safety food) in section 3-603(A) of these rules and regulations;
- 1992 3. — After cooling, held frozen or cold, as specified for potentially hazardous food
- 1993 (time/temperature control for safety food) in section 3-501(A) of these rules and
- 1994 regulations;
- 1995 4. — Prior to sale or service, cooked using a process that heats all parts of the food to a
- 1996 temperature of at least 165°F (74°C) for 15 seconds;
- 1997 5. — Cooled according to the time and temperature parameters specified for cooked
- 1998 potentially hazardous food (time/temperature control for safety food) in section
- 1999 3-603(A)–(C) if not either hot held as specified in section 3-501(A), served
- 2000 immediately, or held using time as a public health control as specified in section
- 2001 3-605(A)–(B) after complete cooking; and
- 2002 6. — Prepared and stored according to written procedures approved by the Department
- 2003 that:
- 2004 a. Are maintained in the food establishment and are available to the
- 2005 Department upon request;

- 2006 b. Describe how the requirements specified in (1) (5) of this Section are to
 2007 be monitored and documented by the licensee and the corrective actions
 2008 to be taken if the requirements are not met;
- 2009 e. Describe how the foods, after initial heating, but prior to complete
 2010 cooking, are to be marked or otherwise identified as foods that must be
 2011 cooked as specified in (4) of this section prior to being offered for sale or
 2012 service; and
- 2013 d. Describe how the foods, after initial heating but prior to cooking as
 2014 specified in section (4) of this section, are to be separated from ready-to-
 2015 eat foods as specified in section 3-406.

2016 ***3-504—Reheating**

- 2017 A. Except as specified in paragraphs (B) and (C) of this section, potentially hazardous foods
 2018 (time/temperature control for safety foods) that have been cooked and then refrigerated shall
 2019 be rapidly reheated within two hours to a uniform internal temperature of 165°F (74°C) or
 2020 higher before being placed in hot food storage holding units which shall maintain product
 2021 temperature at 135°F (57°C) or above at all times. Food warmers and other hot food holding
 2022 units shall not be used to reheat potentially hazardous foods (time/temperature control for
 2023 safety foods) unless the equipment is specifically designed for that purpose.
- 2024 B. Except as specified in paragraph (C) of this section, food reheated in a microwave oven shall
 2025 be heated to a uniform internal temperature of at least 165°F (74°C) and the food is rotated
 2026 or stirred, covered, and allowed to stand covered for 2 minutes after reheating.
- 2027 C. Ready to eat food taken from a commercially processed, hermetically sealed container, or
 2028 from an intact package from a food processing plant that is inspected by the food Department
 2029 that has jurisdiction over the plant, shall be heated within two hours to a uniform internal
 2030 temperature of at least 135°F (60°C) for hot holding.

2031 ***3-505—Preparation for Immediate Service**

- 2032 Cooked and refrigerated food that is prepared for immediate service in response to an individual
 2033 consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

2034 **3-6—LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC**
 2035 **HEALTH CONCERN**

2036 **3-601—Thawing**

- 2037 Except as specified in subparagraph (D) of this section, potentially hazardous foods
 2038 (time/temperature control for safety foods) shall be thawed:
- 2039 *A. Under refrigeration that maintain the food temperature at 41°F (5°C) or less; or
- 2040 B. Completely submerged and with packaging removed under running water:
- 2041 1. At a water temperature of 70°F (21°C) or below,
- 2042 2. With sufficient water velocity to agitate and float off loose particles in an overflow,
 2043 and

- 2044 ~~*3. For a period of time that does not allow thawed portions of ready-to-eat food to rise~~
 2045 ~~above 41°F (5°C), or~~
- 2046 ~~*4. For a period of time that does not allow thawed portions of a raw animal food~~
 2047 ~~requiring cooking as specified in section 3-502 to be above 41°F (5°C), for more~~
 2048 ~~than 4 hours including:~~
- 2049 ~~a. The time the food is exposed to the running water and the time needed for~~
 2050 ~~preparation for cooking, or~~
- 2051 ~~b. The time it takes under refrigeration to lower the food temperature to 41°F~~
 2052 ~~(5°C);~~
- 2053 ~~C. As part of a cooking process if the food that is frozen is:~~
- 2054 ~~1. Cooked as specified in section 3-502, or~~
- 2055 ~~2. Thawed in a microwave oven and immediately transferred to conventional cooking~~
 2056 ~~equipment, with no interruption in the process; or~~
- 2057 ~~D. Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for~~
 2058 ~~immediate service in response to an individual consumer's order.~~
- 2059 **3-602 — Slacking**
- 2060 ~~A. Frozen potentially hazardous food (time/temperature control for safety food) that is slacked~~
 2061 ~~to moderate the temperature shall be held:~~
- 2062 ~~*1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less, or~~
- 2063 ~~2. At any temperature if the food remains frozen.~~
- 2064 ***3-603 — Cooling**
- 2065 ~~A. Cooked potentially hazardous foods (time/temperature control for safety foods) shall be~~
 2066 ~~cooled from 135°F (57°C) to 41°F (5°C), or below, in 6 hours, provided that the food is~~
 2067 ~~cooled from 135°F (57°C) to 70°F (21°C) within the first 2 hours.~~
- 2068 ~~B. Potentially hazardous foods (time/temperature control for safety foods) that has been~~
 2069 ~~prepared from ingredients at ambient temperature, such as reconstituted milk and canned~~
 2070 ~~products, shall be cooled to 41°F (5°C), or below, within 4 hours.~~
- 2071 ~~C. Fluid milk and milk products, shell eggs, and molluscan shellstock received in compliance~~
 2072 ~~with laws regulating the respective food during shipment from the supplier shall be cooled to~~
 2073 ~~41°F (5°C) or below within 4 hours. —~~
- 2074 **3-604 — Cooling Methods**
- 2075 ~~A. Cooling shall be accomplished as required in section 3-603, by using one or more of the~~
 2076 ~~following methods based on the type of food being cooled:~~
- 2077 ~~1. Placing the food in shallow pans;~~
- 2078 ~~2. Separating the food into smaller or thinner portions;~~
- 2079 ~~3. Using rapid cooling equipment;~~
- 2080 ~~4. Stirring the food in a container placed in an ice water bath;~~

- 2081 5. ~~Using containers that facilitate heat transfer;~~
 2082 6. ~~Adding ice as an ingredient; or~~
 2083 7. ~~Other effective methods that meet the requirements of section 3-603 of these rules~~
 2084 ~~and regulations.~~
- 2085 B. ~~When using food containers to cool food, food shall be:~~
- 2086 1. ~~Arranged in the container to provide maximum heat transfer through the container~~
 2087 ~~walls; and~~
- 2088 2. ~~Loosely covered, or uncovered if protected from overhead contamination during the~~
 2089 ~~cooling period to facilitate heat transfer from the surface of the food.~~

2090 **~~3-605 Time as a Public Health Control~~**

- 2091 *A. ~~Except as specified in paragraph (D) of this section, if time without temperature control is~~
 2092 ~~used as the public health control for a working supply of potentially hazardous food~~
 2093 ~~(time/temperature control for safety food) before cooking, or for ready to eat potentially~~
 2094 ~~hazardous food (time/temperature control for safety food) that is displayed or held for sale or~~
 2095 ~~service:~~
- 2096 1. ~~Written procedures shall be prepared in advance, maintained in the food~~
 2097 ~~establishment and made available to the Department upon request that specify:~~
- 2098 a. ~~Methods of compliance with subparagraphs (B)(1)-(3) or (C)(1)-(5) of this~~
 2099 ~~section; and~~
- 2100 b. ~~Methods of compliance in section 3-501 of these rules and regulations for~~
 2101 ~~food that is prepared, cooked, and refrigerated before time is used as a~~
 2102 ~~public health control.~~
- 2103 *B. ~~If time temperature control is used as the public health control up to a maximum of 4 hours:~~
- 2104 1. ~~The food shall have an initial temperature of 41°F (5°C) or less when removed from~~
 2105 ~~cold holding temperature control, or 135°F (57°C) or greater when removed from~~
 2106 ~~hot holding temperature control;~~
- 2107 2. ~~The food shall be marked or otherwise identified to indicate the time that is 4 hours~~
 2108 ~~past the point in time when the food is removed from temperature control;~~
- 2109 3. ~~The food shall be cooked and served, served at any temperature if ready to eat, or~~
 2110 ~~discarded, within 4 hours from the point in time when the food is removed from~~
 2111 ~~temperature control; and~~
- 2112 4. ~~The food in unmarked containers or packages, or marked to exceed a 4 hour limit~~
 2113 ~~shall be discarded.~~
- 2114 *C. ~~If time without temperature control is used as the public health control up to a maximum of 6~~
 2115 ~~hours:~~
- 2116 1. ~~The food shall have an initial temperature of 41°F (5°C) or less when removed from~~
 2117 ~~temperature control and the food temperature may not exceed 70°F (21°C) within a~~
 2118 ~~maximum time period of 6 hours;~~
- 2119 2. ~~The food shall be monitored to ensure the warmest portion of the food does not~~
 2120 ~~exceed 70°F (21°C) during the 6 hour period, unless an ambient air temperature is~~

- 2121 ~~maintained that ensures the food does not exceed 70°F (21°C) during the 6 hour~~
 2122 ~~holding period;~~
- 2123 3. ~~The food shall be marked or otherwise identified to indicate:~~
- 2124 a. ~~The time when the food is removed from 41°F (5°C) or less cold holding~~
 2125 ~~temperature control, and~~
- 2126 b. ~~The time that is 6 hours past the point in time when the food is removed~~
 2127 ~~from cold holding temperature control;~~
- 2128 4. ~~The food shall be:~~
- 2129 a. ~~Discarded if the temperature of the food exceeds 70°F (21°C), or~~
- 2130 b. ~~Cooked and served, served at any temperature if ready to eat, or discarded~~
 2131 ~~within a maximum of 6 hours from the point in time when the food is removed from~~
 2132 ~~41°F (5°C) or less cold holding temperature control; and~~
- 2133 5. ~~The food in unmarked containers or packages, or marked with a time that exceeds~~
 2134 ~~the 6 hour limit shall be discarded.~~
- 2135 D. ~~A food establishment that serves a highly susceptible population may not use time as~~
 2136 ~~specified in section (A), (B) or (C) of this section as the public health control for raw eggs.~~

2137 ~~*3-606 Specialized Processing Methods~~

- 2138 A. ~~Unless otherwise approved by the Department, a retail food establishment shall develop a~~
 2139 ~~HACCP plan and except in (4) of this section, obtain written approval from the Department~~
 2140 ~~prior to engaging in any of the following:~~
- 2141 1. ~~Smoking food as a method of food preservation rather than as a method of flavor~~
 2142 ~~enhancement;~~
- 2143 2. ~~Curing food;~~
- 2144 3. ~~Using food additives or adding components to alter the pH or Water Activity:~~
- 2145 a. ~~As a method of food preservation rather than as a method of flavor~~
 2146 ~~enhancement, or~~
- 2147 b. ~~To render a food so that it is not potentially hazardous.~~
- 2148 4. ~~Packaging food using a reduced oxygen packaging method except as specified in~~
 2149 ~~section 3-607 where a barrier to clostridium botulinum in addition to refrigeration~~
 2150 ~~exists;~~
- 2151 5. ~~Operating a molluscan shellfish life support system display tank used to store or~~
 2152 ~~display shellfish that are offered for human consumption;~~
- 2153 6. ~~Custom processing animals that are for personal use as food and not for sale or~~
 2154 ~~service in a food establishment;~~
- 2155 7. ~~Sprouting seeds or beans;~~
- 2156 8. ~~Other specialized processing methods.~~
- 2157

2158

2159 ~~*3-607~~ **Reduced Oxygen Packaging**

2160 A. ~~— A retail food establishment that packages potentially hazardous food (time/temperature~~
2161 ~~control for safety food) using a reduced oxygen packaging method shall control the growth~~
2162 ~~and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes and~~
2163 ~~have a HACCP plan that contains the information specified under Appendix G and that:~~

2164 1. ~~— Identifies the food to be packaged;~~

2165 2. ~~— Except as specified in (B)–(D) of this section, requires that the packaged food shall~~
2166 ~~be maintained at 41°F (5°C) or less and meet at least one of the following criteria:~~

2167 a. ~~— Has an a_w of 0.91 or less;~~

2168 b. ~~— Has a pH of 4.6 or less;~~

2169 c. ~~— Is a meat or poultry product cured at a food processing plant regulated by~~
2170 ~~the U.S. Department of Agriculture (USDA) using substances specified in 9~~
2171 ~~CFR 424.21, use of food ingredients and sources of radiation, and is~~
2172 ~~received in an intact package; or~~

2173 d. ~~— Is a food with a high level of competing organisms such as raw meat or raw~~
2174 ~~poultry or raw vegetables.~~

2175 3. ~~— Describes how the package shall be prominently and conspicuously labeled on the~~
2176 ~~principal display panel in bold type on a contrasting background, with instructions~~
2177 ~~to:~~

2178 a. ~~— Maintain the food at 41°F (5°C) or below, and~~

2179 b. ~~— Discard the food if within fourteen (14) calendar days of its packaging it is~~
2180 ~~not served for on-premises consumption, or consumed if served or sold for~~
2181 ~~off-premises consumption;~~

2182 4. ~~— Limits the refrigerated shelf life to no more than fourteen (14) calendar days from~~
2183 ~~packaging to consumption, except the time the product is maintained frozen, or the~~
2184 ~~original manufacturer's "sell by" or "use by" date, whichever occurs first;~~

2185 5. ~~— Includes operational procedures that:~~

2186 a. ~~— Prohibit contacting ready-to-eat food with bare hands as specified in section~~
2187 ~~3-302 of these rules and regulations;~~

2188 b. ~~— Identify a designated work area and the method by which:~~

2189 (1) ~~— Physical barriers or methods of separation of raw foods and ready-~~
2190 ~~to-eat foods minimize cross-contamination, and~~

2191 (2) ~~— Access to the processing equipment is limited to responsible trained~~
2192 ~~personnel familiar with the potential hazards of the operation, and~~

2193 c. ~~— Delineate cleaning and sanitization procedures for food-contact surfaces;~~
2194 ~~and~~

2195

- 2196
2197
2198 6. ~~Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:~~
- 2199 a. ~~Concepts required for a safe operation;~~
- 2200 b. ~~Equipment and facilities, and~~
- 2201 c. ~~Procedures specified under Subparagraph (A)(5) of this section and~~
- 2202 ~~Appendix G.~~
- 2203 B. ~~Except for fish that is frozen before, during, and after packaging, a food establishment may~~
- 2204 ~~not package fish using a reduced oxygen packaging method.~~
- 2205 C. ~~Except as specified in (B) of this section, a food establishment that packages potentially~~
- 2206 ~~hazardous food (time/temperature control for safety food) food using a cook chill or sous~~
- 2207 ~~vide process shall:~~
- 2208 1. ~~Implement a HACCP plan that contains the information as specified in Appendix G;~~
- 2209 2. ~~Ensure the food is:~~
- 2210 a. ~~Prepared and consumed on the premises, or prepared and consumed off the~~
- 2211 ~~premises but within the same business entity with no distribution or sale of~~
- 2212 ~~the packaged product to another business entity or the consumer;~~
- 2213 b. ~~Cooked to heat all parts of the food to a temperature and for a time as~~
- 2214 ~~specified in section 3-502;~~
- 2215 c. ~~Protected from contamination before and after cooking as specified in~~
- 2216 ~~section 3-401 through 3-406;~~
- 2217 d. ~~Placed in a package with an oxygen barrier and sealed before cooking, or~~
- 2218 ~~placed in a package and sealed immediately after cooking and before~~
- 2219 ~~reaching a temperature below 57°C (135°F);~~
- 2220 e. ~~Cooled to 41°F (5°C) in the sealed package or bag as specified in section 3-~~
- 2221 ~~503 and:~~
- 2222 (1) ~~Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held~~
- 2223 ~~at that temperature until consumed or discarded within thirty (30)~~
- 2224 ~~days after the date of packaging;~~
- 2225 (2) ~~Held at 41°F (5°C) or less for no more than 7 days, at which time the~~
- 2226 ~~food must be consumed or discarded; or~~
- 2227 (3) ~~Held frozen with no shelf life restriction while frozen until consumed~~
- 2228 ~~or used.~~
- 2229 f. ~~Held in a refrigeration unit that is equipped with an electronic system that~~
- 2230 ~~continuously monitors time and temperature and is visually examined for~~
- 2231 ~~proper operation twice daily;~~
- 2232 g. ~~If transported off site to a satellite location of the same business entity,~~
- 2233 ~~equipped with verifiable electronic monitoring devices to ensure that times~~
- 2234 ~~and temperatures are monitored during transportation; and~~
- 2235 h. ~~Labeled with the product name and the date packaged; and~~

- 2236 3. ~~Maintain the records required to confirm that cooling and cold holding refrigeration~~
 2237 ~~time/temperature parameters are met as part of the HACCP plan and:~~
- 2238 a. ~~Make such records available to the Department upon request, and~~
 2239 b. ~~Hold such records for at least 6 months; and~~
- 2240 4. ~~Implement written operational procedures as specified in (A)(5) of this section and a~~
 2241 ~~training program as specified in (A)(6) of this section.~~
- 2242 D. ~~A food establishment that packages cheese using a reduced oxygen packaging method shall:~~
- 2243 1. ~~Limit the cheeses packaged to those that are commercially manufactured in a food~~
 2244 ~~processing plant with no ingredients added in the food establishment and that meet~~
 2245 ~~the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR~~
 2246 ~~133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;~~
- 2247 2. ~~Have a HACCP plan that contains the information specified under appendix G and~~
 2248 ~~as specified in (A)(1), (A)(3)(a), (A)(5) and (A)(6) of this section;~~
- 2249 3. ~~Labels the package on the principal display panel with a "use by" date that does not~~
 2250 ~~exceed thirty (30) days from its packaging or the original manufacturer's "sell by" or~~
 2251 ~~"use by" date, whichever occurs first; and~~
- 2252 4. ~~Discards the reduced oxygen packaged cheese if it is not sold for off premises~~
 2253 ~~consumption or consumed within thirty (30) calendar days of its packaging.~~
- 2254 E. ~~When applying a reduced oxygen packaging process, retail food establishments shall notify~~
 2255 ~~the Department in advance and indicate the method proposed (i.e. cook chill, sous vide).~~

2256 **3-608 — Breeding Mixtures**

- 2257 A. ~~Containers of dry breeding mixtures (containing flour, cornmeal, spices, etc.) into which raw~~
 2258 ~~animal foods such as poultry and fish are repeatedly dipped, may be used for a total period of~~
 2259 ~~up to 7 days and stored at room temperature, provided that:~~
- 2260 1. ~~Containers are stored covered in a clean dry area overnight and/or when not in use~~
 2261 ~~as specified in sections 3-413 and 3-414;~~
- 2262 2. ~~The breeding mixture is sifted at a minimum of every 4 hours to remove excess~~
 2263 ~~moisture and doughballs while in use; and~~
- 2264 3. ~~Containers are completely emptied, cleaned and sanitized, and the breeding mixtures~~
 2265 ~~discarded at intervals of no greater than 7 days.~~
- 2266 B. ~~If this procedure is used, the person in charge must have a system in place to indicate the~~
 2267 ~~date the breeding must be discarded.~~
- 2268

2269

2270 **3-7 — ON-PREMISES LABELING**2271 **3-701 — Labeling**

2272 A. ~~When voluntary code date information appears on a retail food establishment or~~
2273 ~~manufacturers' label, it shall not be concealed or altered.~~

2274 B. ~~Bulk food available for consumer self dispensing shall be prominently labeled according to~~
2275 ~~section 25-4-1301 et seq., C.R.S., (See Appendix H).~~

2276 C. ~~If an unpackaged non-bulk food product is manufactured on-site and sold at the site where it~~
2277 ~~was manufactured or sold over the counter at a different site, no labeling is required.~~
2278 ~~However, an ingredient label shall be made available upon request.~~

2279 ~~If a packed food product is manufactured and sold on or off site for customer self service, it~~
2280 ~~must be labeled in accordance with section 25-5-401 et seq., C.R.S. and all labeling~~
2281 ~~regulations authorized therein.~~

2282 D. ~~A food ingredient, such as flour, sugar, salt, spices, dried herbs, potato flakes, baking~~
2283 ~~powder, cooking oil or vinegar, that is not stored in the original package and is not readily~~
2284 ~~identifiable on sight, shall be stored in a container identifying it by a common name.~~

2285 **3-702 — Special Requirements for Highly Susceptible Populations**

2286 A. ~~Ready to Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food)~~
2287 ~~served in facilities providing food to highly susceptible populations shall adhere to the~~
2288 ~~following date marking requirements:~~

2289 *1. ~~Except when packaging food using a reduced oxygen packaging method as specified~~
2290 ~~in section 3-607 of these rules and regulations, and except as specified in (4) and (5)~~
2291 ~~of this section, refrigerated, ready to eat, potentially hazardous food~~
2292 ~~(time/temperature control for safety food) prepared and held in a food establishment~~
2293 ~~for more than 24 hours shall be clearly marked to indicate the date or day by which~~
2294 ~~the food shall be consumed on the premises, sold, or discarded when held at a~~
2295 ~~temperature of 41°F (5°C) or less for a maximum of 7 days.~~

2296 *2. ~~Except as specified in (4) (6) of this section, refrigerated, ready to eat, potentially~~
2297 ~~hazardous food (time/temperature control for safety food) prepared and packaged by~~
2298 ~~a food processing plant shall be clearly marked, at the time the original container is~~
2299 ~~opened in a food establishment and if the food is held for more than 24 hours, to~~
2300 ~~indicate the date or day by which the food shall be consumed on the premises, sold,~~
2301 ~~or discarded, based on the temperature and time combinations specified in (1) of this~~
2302 ~~section and:~~

2303 a. ~~The day the original container is opened in the food establishment shall be~~
2304 ~~counted as Day 1; and~~

2305 b. ~~The day or date marked by the food establishment may not exceed a~~
2306 ~~manufacturer's use-by date if the manufacturer determined the use-by date~~
2307 ~~based on food safety.~~

2308 *3. ~~A refrigerated, ready to eat, potentially hazardous food (time/temperature control~~
2309 ~~for safety food) ingredient or a portion of a refrigerated, ready to eat, potentially~~

- 2310 ~~hazardous food (time/temperature control for safety food) that is subsequently~~
 2311 ~~combined with additional ingredients or portions of food shall retain the date~~
 2312 ~~marking of the earliest prepared or first prepared ingredient.~~
- 2313 4. ~~A date marking system that meets the criteria stated in (1) and (2) of this section~~
 2314 ~~may include:~~
- 2315 a. ~~Using a method approved by the Department for refrigerated, ready-to-eat~~
 2316 ~~potentially hazardous food (time/temperature control for safety food) that is~~
 2317 ~~frequently rewrapped, such as lunchmeat or a roast, or for which date~~
 2318 ~~marking is impractical, such as soft serve mix or milk in a dispensing~~
 2319 ~~machine~~
- 2320 b. ~~Marking the date or day of preparation, with a procedure to discard the food~~
 2321 ~~on or before the last date or day by which the food must be consumed on the~~
 2322 ~~premises, sold, or discarded as specified in (a) of this section;~~
- 2323 c. ~~Marking the date or day the original container is opened in a food~~
 2324 ~~establishment, with a procedure to discard the food on or before the last date~~
 2325 ~~or day by which the food must be consumed on the premises, sold, or~~
 2326 ~~discarded as specified in (b) of this section; or~~
- 2327 d. ~~Using calendar dates, days of the week, color-coded marks, or other~~
 2328 ~~effective marking methods, provided that the marking system is disclosed to~~
 2329 ~~the Department upon request.~~
- 2330 5. ~~Paragraphs (1) and (2) of this section do not apply to individual meal portions served~~
 2331 ~~or repackaged for sale from a bulk container upon a consumer's request.~~
- 2332 6. ~~Paragraph (2) of this section does not apply to the following foods prepared and~~
 2333 ~~packaged by a food processing plant inspected by a Department:~~
- 2334 a. ~~Deli salads, such as ham salad, seafood salad, chicken salad, egg salad,~~
 2335 ~~pasta salad, potato salad, and macaroni salad, manufactured in accordance~~
 2336 ~~with 21 CFR 110 Current good manufacturing practice in manufacturing,~~
 2337 ~~packing, or holding human food;~~
- 2338 b. ~~Hard cheeses containing not more than 39% moisture as defined in 21 CFR~~
 2339 ~~133 Cheeses and related cheese products, such as cheddar, gruyere,~~
 2340 ~~parmesan and reggiano, and romano;~~
- 2341 c. ~~Semi-soft cheeses containing more than 39% moisture, but not more than~~
 2342 ~~50% moisture, as defined in 21 CFR 133 Cheeses and related cheese~~
 2343 ~~products, such as blue, edam, gorgonzola, gouda, and monterey jack;~~
- 2344 d. ~~Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as~~
 2345 ~~yogurt, sour cream, and buttermilk;~~
- 2346 e. ~~Preserved fish products, such as pickled herring and dried or salted cod, and~~
 2347 ~~other acidified fish products defined in 21 CFR 114 Acidified foods;~~
- 2348 f. ~~Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami~~
 2349 ~~that are not labeled "Keep Refrigerated" as specified in 9 CFR 317~~
 2350 ~~Labeling, marking devices, and containers, and which retain the original~~
 2351 ~~casing on the product; and~~

- 2352 g. — Shelf stable salt-cured products such as prosciutto and Parma (ham) that are
 2353 not labeled "Keep Refrigerated" as specified in 9 CFR 317 Labeling,
 2354 marking devices, and containers.
- 2355 *B. — A food establishment that packages potentially hazardous food (time/temperature control for
 2356 safety food) that will be served in facilities providing food to highly susceptible populations
 2357 using a reduced-oxygen packaging method as specified in section 3-607 shall have a HACCP
 2358 plan that contains the information specified under appendix G and that is provided to the
 2359 Department for review and approval prior to implementation.
- 2360 *C. — The following foods may not be served or offered for sale in a ready-to-eat form to persons
 2361 in a highly susceptible population:
- 2362 1. — Raw animal foods such as raw fish, raw marinated fish, raw molluscan shellfish, and
 2363 steak tartare;
- 2364 2. — A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked
 2365 eggs that are made from raw shell eggs and meringue;
- 2366 3. — Raw seed sprouts;
- 2367 4. — Juice that is not pasteurized or treated under an HACCP plan as specified in
 2368 Appendix G of these rules and regulations, or contains a warning label as specified
 2369 in Section 3-312(B) of these rules and regulations;
- 2370 *D. — Food may not be re-served to or from highly susceptible populations under the following
 2371 conditions:
- 2372 1. — Any food served to patients or clients who are under contact precautions in medical
 2373 isolation or quarantine, or protective environment isolation may not be re-served to
 2374 others outside.
- 2375 2. — Packages of food from any patients, clients, or other consumers should not be re-
 2376 served to persons in protective environment isolation.

2377 **3-8 — CONSUMER ADVISORY (Section Effective July 1, 2013)**

2378 ***3-801 — Consumption of Animal Foods That Are Raw, Undercooked, or Not Otherwise Processed**
 2379 **— to Eliminate Pathogens**

- 2380 A. — Except as specified in 3-502(C) and Subparagraph 3-502(K)(1) and in 3-702(A)-(D), if an
 2381 animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish is served or sold
 2382 raw, undercooked, or without otherwise being processed to eliminate pathogens, either in
 2383 ready-to-eat form or as an ingredient in another ready-to-eat food, the licensee shall inform
 2384 consumers of the significantly increased risk of consuming such foods by way of a disclosure
 2385 and reminder, as specified in (B) and (C) of this section using brochures, deli case or menu
 2386 advisories, label statements, table tents, placards, or other effective written means.
- 2387 B. — Disclosure shall include:
- 2388 1. — A description of the animal-derived foods, such as "oysters on the half shell (raw
 2389 oysters)," "undercooked eggs," and "hamburgers (can be cooked to order)," or

- 2390 2. ~~Identification of the animal derived foods by asterisking them to a footnote that~~
2391 ~~states that the items are served raw or undercooked, or contain (or may contain) raw~~
2392 ~~or undercooked ingredients.~~
- 2393 C. ~~Reminder shall include asterisking the animal derived foods requiring disclosure to a~~
2394 ~~footnote that states:~~
- 2395 1. ~~Regarding the safety of these items, written information is available upon request;~~
- 2396 2. ~~Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may~~
2397 ~~increase your risk of foodborne illness; or~~
- 2398 3. ~~Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may~~
2399 ~~increase your risk of foodborne illness, especially if you have certain medical~~
2400 ~~conditions.~~
- 2401

2402

CHAPTER 4

2403

~~WAREWASHING, EQUIPMENT, UTENSILS, AND LINENS~~

2404

~~4-1 — MATERIALS FOR CONSTRUCTION AND REPAIR~~

2405

~~4-101 — General~~

2406

~~All equipment, utensils and single service articles shall be fabricated with safe materials; be of commercial design, that is certified or classified for sanitation by an American National Standards Institute (ANSI) accredited certification program or a design approved by the Department (see Appendix I); fabricated for durability under conditions of normal use; and resistant to denting, buckling, pitting, chipping, and crazing. Equipment, utensils, and single service articles shall not impart odor, color, or taste, nor in any manner contribute to the contamination of food. Equipment and utensils shall be repaired with safe materials and maintained in good repair to comply with the requirements of this code.~~

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~~4-102 — Equipment Requirements~~

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~~All retail food establishments shall have at a minimum:~~

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~~A. — Equipment and utensil washing facilities installed and operated in accordance with section 4-403 except retail food establishments that do not prepare food, package food, or dispense unpackaged food other than whole, uncut raw fruits and vegetables, and whole nuts in the shell;~~

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2420

~~B. — At least one manual handsink accessible to employees involved in food preparation and equipment and utensil washing in accordance with section 5-208; and~~

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2422

~~C. — A utility facility in accordance with section 5-210.~~

2423

~~4-2 — DESIGN AND CONSTRUCTION~~

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~~4-201 — Food Contact Surfaces~~

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~~Multi use food contact surfaces shall be:~~

2426

~~A. — Smooth;~~

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~~B. — Free of breaks, open seams, cracks, chips, pits, and similar imperfections;~~

2428

~~C. — Free of sharp internal angles, corners, and crevices;~~

2429

~~D. — Finished to have smooth welds and joints; and~~

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~~E. — Accessible for cleaning and inspection by one of the following methods:~~

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~~1. — Without being disassembled,~~

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~~2. — By disassembly without the use of tools, or~~

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~~3. — By easy disassembly with the use of only simple tools, such as mallets, screw drivers, or wrenches, that are kept in a readily accessible location near the equipment.~~

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2436 **4-202—Use Limitations**

2437 A. ~~Cast iron may only be used as a cooking surface which can include use in the service of food~~
 2438 ~~when used in an uninterrupted process from cooking through service.~~

2439 *B. ~~Ceramic, china, crystal utensils, and decorative utensils, such as hand-painted ceramic or~~
 2440 ~~china, that are used in contact with food shall be lead-free or contain levels of lead not~~
 2441 ~~exceeding the limits of the following utensil categories:~~

2442

UTENSIL CATEGORY	DESCRIPTION	MAXIMUM LEAD mg/L
Beverage Mugs, Cups, Pitchers	Coffee Mugs	0.5
Large Hollowware (excluding pitchers)	Bowls \geq 1.1 L (1.16 QT)	1
Small Hollowware (excluding cups and mugs)	Bowls $<$ 1.1 L (1.16 QT)	2.0
Flat Tableware	Plates, Saucers	3.0

2443

2444 *C. ~~Copper and copper alloys, such as brass, may not be used in contact with food that has a pH~~
 2445 ~~below 6 (e.g. vinegar, fruit juice, wine, carbonated beverage, etc.).~~

2446 ~~—Copper and copper alloys may be used in contact with beer brewing ingredients that have a~~
 2447 ~~pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such~~
 2448 ~~as a brewpub or microbrewery.~~

2449 D. ~~Enamelware shall not be used for storage or preparation of acidic foods (e.g. vinegar, tomato~~
 2450 ~~based sauces, juices, etc.).~~

2451 *E. ~~Galvanized metal may not be used to fabricate food contact surfaces of equipment that is~~
 2452 ~~used for beverages, moist food, or hygroscopic food.~~

2453 F. ~~Linens and napkins may not be used in contact with food unless they are used to line a~~
 2454 ~~container for the service of foods and the linens and napkins are replaced each time the~~
 2455 ~~container is refilled for a new consumer.~~

2456 G. ~~Clean cloth gloves may be used in direct contact with food that will be subsequently cooked~~
 2457 ~~as required as specified in part 3-5 of these rules and regulations, such as frozen food or a~~
 2458 ~~primal cut of meat.~~

2459 H. ~~Pewter alloys containing lead in excess of 0.05% may not be used as a food contact surface.~~

2460 I. ~~Solder and flux containing lead in excess of 0.2%, and cadmium, antimony, bismuth, or~~
 2461 ~~other toxic chemicals may not be used on surfaces that contact food.~~

2462 J. ~~Except as specified in paragraphs 1, 2, and 3 of this section, wood and wicker may not be~~
 2463 ~~used as a food contact surface.~~

2464 1. ~~Hard maple or an equivalently hard, close-grained, nonabsorbent wood, provided it~~
 2465 ~~is not cracked, pitted or uncleanable, may be used for:~~

- 2466 a. ~~Cutting boards, cutting blocks, bakers' tables, bagel boards, and utensils~~
 2467 ~~such as rolling pins, doughnut dowels, salad bowls, pizza paddles, and~~
 2468 ~~chopsticks; and~~
- 2469 b. ~~Wooden paddles used in confectionery operations for pressure scraping~~
 2470 ~~kettles when manually preparing confections at a temperature of 230°F~~
 2471 ~~(110°C) or above.~~
- 2472 2. ~~Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the~~
 2473 ~~original wood or wicker containers until the fruits, vegetables, or nuts are used.~~
- 2474 3. ~~If the nature of the food requires removal of rinds, peels, husks, or shells before~~
 2475 ~~consumption, the whole, uncut, raw food may be kept in:~~
- 2476 a. ~~Untreated wood or wicker containers; or~~
- 2477 b. ~~Treated wood containers if the containers are treated with a preservative~~
 2478 ~~that meets the requirements specified by the Department in Preservatives for~~
 2479 ~~Wood, 21 CFR section 178.3800, (2008).~~
- 2480 K. ~~Cutting surfaces that are scratched and scored must be resurfaced so as to be easily cleaned,~~
 2481 ~~or be discarded when these surfaces can no longer be effectively cleaned and sanitized.~~
- 2482 L. ~~Wrapping of utensils or equipment handles with absorbent or difficult to clean material, such~~
 2483 ~~as string, wire or tape shall not be allowed.~~
- 2484 M. ~~Newspaper, cloth, paper, oil cloth, cardboard, towels and other nonfood grade surfaces, such~~
 2485 ~~as grocery bags or retail store bags, are not approved food contact surfaces. This does not~~
 2486 ~~preclude the use of grocery bags for retail customers.~~

2487 ~~4-203 — Nonfood Contact Surfaces~~

- 2488 ~~Nonfood contact surfaces shall be constructed of approved materials, in good repair, and be easily~~
 2489 ~~maintained in a clean and sanitary condition.~~
- 2490 A. ~~In new or extensively remodeled retail food establishments, wood interior construction in~~
 2491 ~~walk-in cooler and freezer units shall be prohibited.~~
- 2492 B. ~~Unfinished wood is not acceptable in food preparation, equipment or warewashing, or food~~
 2493 ~~storage areas other than those areas used solely as dry food storage areas.~~
- 2494 C. ~~Surfaces of equipment or other areas, which are exposed to splash, food debris or which~~
 2495 ~~otherwise require frequent cleaning, shall be designed and fabricated to be smooth, durable,~~
 2496 ~~nonabsorbent, washable, free of unnecessary ledges, projections, or crevices, and readily~~
 2497 ~~accessible for cleaning.~~
- 2498 D. ~~Wicker and wicker like materials, in good repair can be used for service and display of~~
 2499 ~~prepackaged food. Service of bread or rolls in wicker or wicker like materials is permissible~~
 2500 ~~if lined with dry linens or napkins, which are replaced each time the container is refilled for a~~
 2501 ~~new customer.~~
- 2502 E. ~~Newspapers, cloth, paper, cardboard, towels, contact paper, foil, oil cloth, or similar~~
 2503 ~~materials shall not be used as liners for shelves, drawers, or drain boards.~~

2504 ~~4-204 — Clean In Place (CIP) Equipment~~

- 2505 A. ~~CIP equipment shall meet the characteristics of food contact surfaces and shall be designed~~
 2506 ~~and constructed so that:~~

- 2507 *1. ~~Cleaning and sanitizing solutions circulate throughout a fixed system and contact all~~
 2508 ~~interior food contact surfaces; and~~
- 2509 2. ~~The system is self draining or capable of being completely drained of cleaning and~~
 2510 ~~sanitizing solutions.~~
- 2511 B. ~~CIP equipment that is not designed to be disassembled for cleaning shall be designed with~~
 2512 ~~inspection access points to ensure that all interior food contact surfaces throughout the fixed~~
 2513 ~~system are being effectively cleaned.~~

2514 **4-205 — “V” Threads, Use Limitation**

- 2515 ~~“V” type threads may not be used on food contact surfaces, except for hot oil cooking or filtering~~
 2516 ~~equipment.~~

2517 **4-206 — Hot Oil Filtering Equipment**

- 2518 ~~Hot oil filtering equipment shall meet the characteristics specified under food contact surfaces as~~
 2519 ~~specified in section 4-201 or CIP equipment as specified in section 4-204 and shall be readily~~
 2520 ~~accessible for filter replacement and cleaning of the filter.~~

2521 **4-207 — Bearings and Gear Boxes, Leakproof**

- 2522 ~~Equipment containing bearings and gears requiring lubricants not made of safe materials shall be~~
 2523 ~~designed, constructed and maintained to ensure that the lubricant cannot leak, drip, or be forced into~~
 2524 ~~food or onto food contact surfaces. Equipment designed to receive lubrication of bearings and gears~~
 2525 ~~on or within food contact surfaces shall be lubricated with materials meeting the requirements of~~
 2526 ~~Lubricants, 21 CFR section 178.3570, (2008). (see Appendix E)~~

2527 **4-208 — Beverage Tubing, Separation**

- 2528 ~~Beverage tubing and cold plate beverage cooling devices shall not be installed in contact with stored~~
 2529 ~~ice. This section does not apply to cold plates that are constructed integrally with an ice storage bin.~~

2530 **4-209 — Ice Units, Separation of Drains**

- 2531 ~~Liquid waste drain lines may not pass through an ice machine or ice storage bin.~~

2532 **4-210 — Condenser Unit, Separation**

- 2533 ~~If a condenser unit is an integral component of equipment, the condenser unit shall be separated from~~
 2534 ~~the food and food storage space by a dustproof barrier.~~

2535 ***4-211 — Molluscan Shellfish Tanks**

- 2536 A. ~~Except as specified in B of this section, molluscan shellfish life support system display tanks~~
 2537 ~~may not be used to store or display shellfish that are offered for human consumption and~~
 2538 ~~shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for~~
 2539 ~~display only.~~
- 2540 B. ~~Molluscan shellfish life support system display tanks that are used to store or display~~
 2541 ~~shellfish that are offered for human consumption shall be operated and maintained in~~
 2542 ~~accordance with an approval granted by the department or an approved HACCP plan that:~~

- 2543 1. ~~Is submitted by the licensee and approved as specified in section 11-403; and~~
- 2544 2. ~~Ensures that:~~
- 2545 a. ~~Water used with fish other than molluscan shellfish does not flow into the~~
- 2546 ~~molluscan tank,~~
- 2547 b. ~~The safety and quality of the shellfish as they were received are not~~
- 2548 ~~compromised by the use of the tank, and~~
- 2549 c. ~~The identity of the source of the shell stock is retained as specified in~~
- 2550 ~~section 3-201(B).~~

2551 **4-212 — ~~Ventilation and Ventilation Hood Systems~~**

2552 ~~All rooms shall have sufficient ventilation to keep them free of excessive heat, steam, condensation,~~

2553 ~~vapors, obnoxious odors, smoke, and fumes. Ventilation systems shall comply with applicable~~

2554 ~~building department and fire prevention bureau requirements, and when vented to the outside shall~~

2555 ~~not create an unsightly, harmful, or unlawful discharge. Ventilation systems shall comply with 2006~~

2556 ~~International Mechanical Code (IMC). When local building and/or fire departments have adopted~~

2557 ~~codes equivalent or more stringent than the above, those codes shall apply.~~

2558 ~~A. Ventilation Hood Systems. Ventilation systems shall be sufficient in number, capacity, and~~

2559 ~~designed and constructed according to 2006 International Mechanical Code, chapter 5,~~

2560 ~~sections 507 and 508. Ventilation systems and devices shall be designed to prevent grease or~~

2561 ~~condensation from collecting on walls and ceilings, and from dripping into food or onto~~

2562 ~~food contact surfaces. Hood filters or other grease extracting equipment shall be easily~~

2563 ~~removable for cleaning and replacement when not designed for in place cleaning. Hood~~

2564 ~~filters shall remain in place whenever the system is in operation.~~

2565 ~~B. Equipment from which aerosols, obnoxious odors, noxious fumes, or vapors may originate~~

2566 ~~shall be effectively vented to the outside air or vented through an approved ventilation~~

2567 ~~system.~~

2568 ~~1. Type I hoods shall be installed where cooking~~

2569 ~~appliances produce grease or smoke such as occurs with grills, fryers, broilers,~~

2570 ~~ranges and woks.~~

2571 ~~2. Type II hoods shall be installed where cooking or~~

2572 ~~dish washing appliances produce heat, steam or products of combustion but do not~~

2573 ~~produce grease or smoke. This includes steamers, pasta cookers and high~~

2574 ~~temperature sanitizing dish washing machines. This does not apply to under-~~

2575 ~~counter type commercial dishwashing machines.~~

2576 ~~3. Intake and exhaust ducts shall be maintained to~~

2577 ~~prevent the entrance of dust, dirt, and other contaminating materials.~~

2578 ~~4. In new or extensively remodeled retail food~~

2579 ~~establishments, restrooms shall be mechanically vented to the outside.~~

2580 ~~C. Except for mobile retail food establishments, make up air must be filtered and mechanically~~

2581 ~~introduced into the establishment at a volume equal to or greater than what is exhausted.~~

2582 ~~D. Fire prevention, extinguishing equipment and lighting systems shall be installed in a~~

2583 ~~ventilation system or hood so as to not create a cleaning problem.~~

2584 **4-3 — LOCATION AND INSTALLATION**

2585 **4-301 — Equipment, and Storage Cabinets, Contamination Prevention**

2586 A. ~~The storage of cleaned and sanitized equipment, utensils, laundered linens, laundered~~
 2587 ~~clothing and single service and single use articles may not be located:~~

2588 1. ~~In locker areas;~~

2589 2. ~~In toilet rooms and their vestibules;~~

2590 3. ~~In dressing rooms;~~

2591 4. ~~In garbage, recycling, or composting rooms;~~

2592 5. ~~In mechanical rooms;~~

2593 6. ~~Under water and sewer lines that are not shielded to intercept potential drips;~~

2594 7. ~~Under leaking automatic fire sprinkler heads, or under lines on which water has~~
 2595 ~~condensed;~~

2596 8. ~~In a private home;~~

2597 9. ~~Under open stairwells; or~~

2598 10. ~~Under other sources of contamination.~~

2599 B. ~~A storage cabinet used for linens or completely packaged single service or single use articles~~
 2600 ~~may be stored in a locker area.~~

2601 **4-302 — Fixed Equipment, Spacing or Sealing**

2602 Equipment, including ice makers and ice storage equipment, shall not be located under sewer lines
 2603 that are not shielded to intercept potential drips or under leaking water lines, including leaking
 2604 automatic fire sprinkler heads, or under lines on which water has condensed.

2605 A. ~~Table Mounted Equipment~~

2606 1. ~~Table mounted equipment shall be installed to facilitate the cleaning of the~~
 2607 ~~equipment and the adjacent areas.~~

2608 2. ~~Equipment that is mounted on tables or counters, unless portable, shall be sealed to~~
 2609 ~~the table or counter, or elevated on legs to provide at least a 4 inch (10 cm)~~
 2610 ~~clearance between the table or counter, except that if no part of the table under the~~
 2611 ~~equipment is more than 18 inches (46 cm) from cleaning access, the clearance space~~
 2612 ~~shall be three (3) inches (8 cm) or more; or if no part of the table under the~~
 2613 ~~equipment is more than three (3) inches (8 cm) from cleaning access, the clearance~~
 2614 ~~space shall be two (2) inches (5 cm) or more.~~

2615 3. ~~Equipment is portable within the meaning of this section if:~~

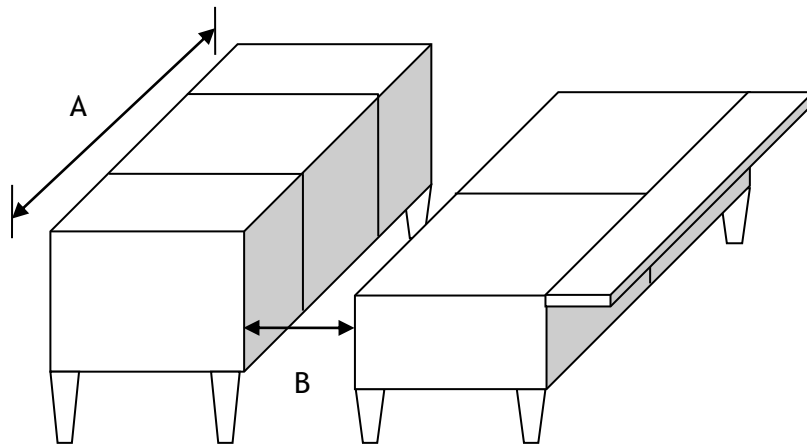
2616 a. ~~It is small and light enough to be moved easily by one person; or~~

2617 b. ~~Is equipped with a mechanical means of safely tilting the unit for cleaning;~~
 2618 ~~and~~

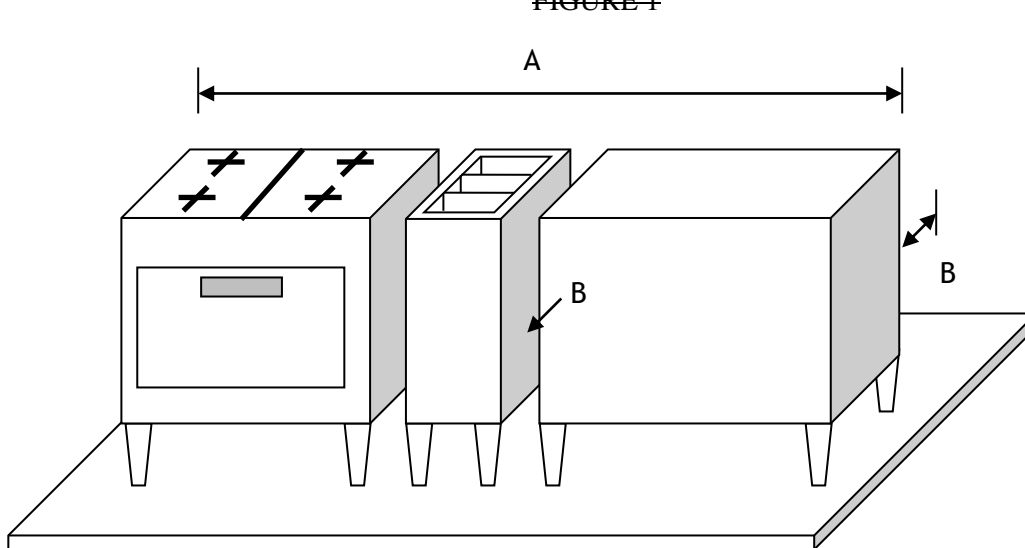
2619 c. ~~It is table mounted, such as powered mixers, grinders, slicers, tenderizers,~~
 2620 ~~and similar equipment; and~~

- 2621 ~~d. It has no utility connection, has a utility connection that disconnects~~
 2622 ~~quickly, or has a flexible utility connection line of sufficient length to~~
 2623 ~~permit the equipment to be moved for easy cleaning.~~
- 2624 ~~B. Floor Mounted Equipment~~
- 2625 ~~1. Floor mounted equipment, unless easily moveable, shall be:~~
- 2626 ~~a. Sealed to the floor; or~~
- 2627 ~~b. Elevated on sanitary legs to provide at least a 6 inch (15 cm) clearance~~
 2628 ~~between the floor and equipment, except that equipment may be elevated to~~
 2629 ~~provide at least a 4 inch (10 cm) clearance between the floor and equipment~~
 2630 ~~if the floor under the equipment is no more than six (6) inches (15 cm) from~~
 2631 ~~cleaning access;~~
- 2632 ~~c. Display shelving units, display refrigeration units, and display freezer units~~
 2633 ~~are exempt from the provisions of Paragraph 1, a and b of this section if~~
 2634 ~~they are installed so that the floor beneath the units can be cleaned.~~
- 2635 ~~2. Equipment is easily moveable if:~~
- 2636 ~~a. It is mounted on commercially designed wheels or casters; and~~
- 2637 ~~b. It has no utility connection, or has a utility connection that disconnects~~
 2638 ~~quickly, or has a flexible utility line of sufficient length to permit the~~
 2639 ~~equipment to be moved for cleaning.~~
- 2640 ~~3. Grease Use Equipment. Grease use equipment, in which fats and oils are utilized as~~
 2641 ~~the heat transfer agent or which is used in preparation of foods that produce grease,~~
 2642 ~~shall be installed to facilitate cleaning around and beneath the equipment by means~~
 2643 ~~of:~~
- 2644 ~~a. Rollers or casters with a utility connection that disconnects quickly, or has a~~
 2645 ~~flexible utility line of sufficient design and length to permit the equipment~~
 2646 ~~to be moved for easy cleaning; or~~
- 2647 ~~b. Mounted on 6 inch (15.24 cm) sanitary legs; or~~
- 2648 ~~c. Cantilever mounted to the wall at least 6 inches (15.24 cm) above the floor.~~
- 2649 ~~C. Space Between Adjoining Units~~
- 2650 ~~1. The space between adjoining units, and between or above a unit and the adjacent~~
 2651 ~~wall or ceiling, shall be closed unless exposed to seepage, in which event it shall be~~
 2652 ~~sealed; or sufficient space shall be provided to facilitate easy cleaning between,~~
 2653 ~~behind, and beside or above all such equipment. (See Figure 1 and Figure 2)~~
- 2654 ~~2. Space required between or behind walls or equipment shall be based on the~~
 2655 ~~following distances: (See Figure 1 and Figure 2)~~
- 2656 ~~a. When distance "A" is 2 feet (0.61 M) or less, distance "B" must be at least 6~~
 2657 ~~inches (15 cm).~~
- 2658 ~~b. When distance "A" is over 2 feet (0.61 M) but less than 6 feet (1.8 M),~~
 2659 ~~distance "B" must be at least 12 inches (30 cm).~~
- 2660 ~~c. When distance "A" is 6 feet (1.8 M) or more, then distance "B" must be at~~
 2661 ~~least 18 inches (46 cm).~~

2662 3. ~~When rollers or casters are installed on equipment, the space requirements between~~
 2663 ~~adjoining units may not apply.~~



2676 FIGURE 1



2689 FIGURE 2

2690

2691 ~~D. Aisles and Working Spaces. Aisles and working spaces between units of equipment and~~
 2692 ~~between equipment and walls shall be unobstructed and of sufficient width to permit~~
 2693 ~~employees to perform their duties readily without contamination of food or food contact~~
 2694 ~~surfaces by clothing or personal contact. All easily moveable storage equipment such as~~
 2695 ~~dollies, skids, racks, and open ended pallets shall be positioned to provide accessibility to~~
 2696 ~~working areas.~~

2697 ~~E. Kick Plates, Removable. Kick plates shall be designed so that the areas behind them are~~
 2698 ~~accessible for inspection and cleaning by being:~~

- 2699 1. ~~Removable by one of the methods specified in section 4-201(E)(1-3) of these rules~~
 2700 ~~and regulations or capable of being rotated open; and~~
 2701 2. ~~Removable or capable of being rotated open without unlocking equipment doors.~~

2702 ~~4-4 EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION TESTING~~
 2703 ~~DEVICES~~

2704 ~~4-401 Temperature Measuring Devices~~

2705 ~~Temperature measuring devices shall be provided and used. Surfaces of food temperature measuring~~
 2706 ~~devices that come in contact with food shall be cleaned and sanitized before use or storage.~~

2707 ~~*A. Temperature measuring devices shall be available, used, capable of reading both hot and cold~~
 2708 ~~temperatures, and shall have a numerical scale that includes the range of (0°–220°F), printed~~
 2709 ~~record, or digital readout in increments no greater than 2°F (1°C). Temperature measuring~~
 2710 ~~devices shall be used to determine required food temperature(s) and shall be accurate to ±2°F~~
 2711 ~~(1°C).~~

2712 ~~*B. A temperature measuring device with a suitable small diameter probe that is capable of~~
 2713 ~~measuring the temperature of thin masses shall be provided and readily accessible to~~
 2714 ~~accurately measure the temperature in thin foods such as meat patties and fish fillets, if this~~
 2715 ~~type of food is prepared.~~

2716 ~~C. Ambient air and warewashing temperature measuring devices shall have a numerical scale,~~
 2717 ~~printed record, or digital readout in increments no greater than 2°F or 1°C and shall be~~
 2718 ~~accurate to ±3°F (2°C).~~

2719 ~~D. Each mechanically refrigerated and each hot food storage unit storing potentially hazardous~~
 2720 ~~food (time/temperature control for safety food) shall be provided with a numerically scaled~~
 2721 ~~indicating temperature measuring device. Temperature measuring devices used to measure~~
 2722 ~~the air temperature of cold holding units shall be conspicuously located in the upper one-~~
 2723 ~~third of the unit. Temperature measuring devices used to measure the air temperature of hot~~
 2724 ~~food storage units shall be conspicuously located in the lower one-third of the unit.~~

2725 ~~E. Temperature measuring devices shall be checked and calibrated as necessary to ensure their~~
 2726 ~~accuracy.~~

2727 ~~F. Where it is impractical to install temperature measuring devices on equipment, such as heat~~
 2728 ~~lamps, calorod units, or insulated food transport carriers, a temperature measuring device, as~~
 2729 ~~required in part A of this section, shall be available and used to check internal food~~
 2730 ~~temperature.~~

2731 ~~4-402 Testing Devices~~

2732 ~~A. An appropriate test kit or other device designed to accurately measure the concentration in~~
 2733 ~~parts per million (mg/L) of the sanitizing solution shall be available and used.~~

2734 ~~B. Where chemicals are used to wash fruits and vegetables in the establishment, the chemicals~~
 2735 ~~shall be prepared and used in accordance with the manufacture's labeled instructions.~~

2736 ~~C. Where heat sanitization is used in mechanical warewashing machines, an accurate machine~~
 2737 ~~or water line mounted temperature gauge must be present. In the event a mounted~~
 2738 ~~temperature gauge is not present, an appropriate irreversible registering temperature~~

2739 indicator, such as a maximum read temperature, measuring device or heat sensitive tape shall
2740 be available and used to verify proper sanitization.

2741 **4-403—Manual Cleaning and Sanitization**

2742 In new or extensively remodeled retail food establishments, equipment and utensil washing facilities
2743 in accordance with section (A) of this section shall be provided for washing, rinsing, and sanitizing
2744 equipment and utensils.

2745 A. — Except as specified in paragraph (C) of this section, a sink with at least three compartments
2746 shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.
2747 Each compartment of the sink shall be supplied with hot and cold drinking running water.

2748 B. — Sink compartments shall be self draining and large enough to accommodate immersion of
2749 the largest equipment and utensils. If equipment or utensils are too large for the sink
2750 compartments, a warewashing machine or alternative equipment as specified in paragraph
2751 (C) of this section shall be used.

2752 C. — Alternative manual warewashing equipment may be used when there are special cleaning
2753 needs or constraints and the Department has approved the use of the alternative equipment.
2754 Alternative manual warewashing equipment may include:

2755 1. — High pressure detergent sprayers;

2756 2. — Low or line pressure spray detergent foamers;

2757 3. — Other task specific cleaning equipment;

2758 4. — Brushes or other implements;

2759 5. — Two compartment sinks as specified in paragraph D of this section.

2760 6. — Mechanical cleaning and sanitization as specified in Sections 4-404, 4-405 and 4-
2761 406.

2762 D. — A two compartment sink may be used in an existing retail food establishment only if:

2763 1. — The Department has approved its use; and

2764 2. — The nature of warewashing is limited to batch operations such as between cutting
2765 one type of raw meat and another or cleanup at the end of a shift, where the number
2766 of items cleaned is limited, and where the cleaning and sanitizing solutions are made
2767 up immediately before use and drained immediately after use. *If a detergent
2768 sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is not
2769 a distinct water rinse between the washing and sanitizing steps, then the detergent
2770 sanitizer shall be approved and used according to the manufacturer's specifications.

2771 3. — A two compartment sink may not be used for warewashing operations such as where
2772 cleaning and sanitizing solutions are used for a continuous or intermittent flow of
2773 kitchenware or tableware in an ongoing warewashing process.

2774 E. — In manual warewashing operations, a temperature measuring device shall be provided and
2775 readily accessible for frequently measuring the washing and sanitizing temperatures. The
2776 temperature of the wash solution shall be maintained at not less than 110°F (43°C) unless a
2777 different temperature is specified on the cleaning agent manufacturer's label instructions.

2778 F. — Equipment and utensils shall be pre-flushed or pre-scraped, and when necessary, pre-soaked
2779 to remove gross food particles and soil.

- 2780 ~~G. When a three compartment sink is utilized for warewashing or when equipment such as~~
 2781 ~~slicers, grinders, kettles, and mixers are cleaned and sanitized in place, the operation shall be~~
 2782 ~~conducted in the following sequence:~~
- 2783 ~~1. The sinks or equipment used for warewashing shall be cleaned and sanitized before~~
 2784 ~~use; and~~
 - 2785 ~~2. Equipment and utensils shall be thoroughly cleaned in the first compartment with a~~
 2786 ~~clean detergent solution that is mixed in accordance with the manufacturer's label~~
 2787 ~~and a temperature of at least 110°F (43°F).~~
 - 2788 ~~3. Equipment and utensils shall be rinsed free of detergent and abrasive with clean~~
 2789 ~~water in the second compartment; and~~
 - 2790 ~~*4. Equipment and utensils shall be sanitized in the third compartment according to one~~
 2791 ~~of the methods included in section 4-403(I)(1-4).~~
- 2792 ~~*H. When pressure spray methods are utilized for cleaning and sanitizing, the equipment and~~
 2793 ~~utensils shall be thoroughly flushed with a detergent sanitizer solution until the article is free~~
 2794 ~~of food particles and soil. The detergent sanitizer shall be used in accordance with the~~
 2795 ~~manufacturer's instructions and shall be of the type that does not require a potable water rinse~~
 2796 ~~when used according to those instructions.~~
- 2797 ~~*I. The food contact surfaces of all equipment and utensils shall be sanitized by:~~
- 2798 ~~1. Immersion for at least ½ minute in clean, hot water of a temperature of at least~~
 2799 ~~170°F (77°C); or~~
 - 2800 ~~2. Immersion for at least 1 minute in a clean solution containing a minimum of 50 parts~~
 2801 ~~per million (mg/L) and no more than 200 parts per million (mg/L) of available~~
 2802 ~~chlorine as a hypochlorite and having a temperature of at least 75°F (24°C); or~~
 - 2803 ~~3. Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per~~
 2804 ~~million (mg/L) of available iodine, having a pH range not higher than 5.0, unless~~
 2805 ~~otherwise certified to be effective by the manufacturer, and at a temperature of at~~
 2806 ~~least 68°F (20°C); or~~
 - 2807 ~~4. Immersion in a clean solution containing a quaternary ammonia product at a~~
 2808 ~~minimum of 75°F (24°C) or any other chemical sanitizing agent allowed under~~
 2809 ~~Sanitizers, 40 CFR 180.940 (2005).~~
 - 2810 ~~5. Treatment with steam that is free from materials or additives other than those~~
 2811 ~~specified in 21 CFR section 173.310, (2003) in the case of equipment too large to~~
 2812 ~~sanitize by immersion, but in which steam can be confined; or~~
 - 2813 ~~6. Rinsing, spraying, or swabbing with a chemical sanitizing solution containing at~~
 2814 ~~least the strength required for that particular sanitizing solution in section 4-~~
 2815 ~~403(I)(2-4) for equipment too large to sanitize by immersion.~~
 - 2816 ~~7. If a chemical not specified in paragraphs (2) (4) of this section is used, the licensee~~
 2817 ~~shall demonstrate to the Department that the solution achieves sanitization and the~~
 2818 ~~use of the solution shall be approved; or~~
 - 2819 ~~8. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium~~
 2820 ~~compound is used, it shall be registered with EPA and applied in accordance with~~
 2821 ~~the EPA registered label use instructions.~~
- 2822 ~~*J. When hot water is used for sanitizing, the following equipment shall be provided and used:~~

- 2823 1. ~~An integral heating device or fixture installed in, on, or under the sanitizing~~
 2824 ~~compartment of the sink which is capable of maintaining the water at a temperature~~
 2825 ~~of at least 170°F (77°C); and~~
- 2826 2. ~~A numerically scaled indicating temperature measuring device, accurate to ±3°F~~
 2827 ~~(±2°C), located convenient to the sink for frequent checks of water temperature; and~~
- 2828 3. ~~Utensil racks, baskets, or other appropriate means to permit complete immersion of~~
 2829 ~~utensils and equipment in the hot water.~~
- 2830 *K. ~~Chemicals used for sanitization, shall not have concentrations higher than the maximum~~
 2831 ~~permitted under Sanitizers, 40 CFR 180.940 (2005).~~

2832 ~~4-404 Mechanical Cleaning and Sanitization~~

- 2833 A. ~~Cleaning and sanitizing may be done by spray type, immersion warewashing, or by any~~
 2834 ~~other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes~~
 2835 ~~equipment and utensils. These machines and devices shall be properly installed and~~
 2836 ~~maintained in good repair. Machines and devices shall be operated in accordance with~~
 2837 ~~manufacturer's instructions. Utensils and equipment placed in the machine shall be exposed~~
 2838 ~~to all warewashing cycles. Automatic detergent dispensers, wetting agent dispensers, and~~
 2839 ~~liquid sanitizer injectors shall be properly installed and maintained.~~
- 2840 B. ~~The pressure of final rinse water supplied to spray type warewashing machines shall not be~~
 2841 ~~less than 15 pounds per square inch (1.05 kg per sq cm) nor more than 25 pounds per square~~
 2842 ~~inch (1.76 kg per sq cm) measured in the water line immediately upstream from the final~~
 2843 ~~rinse control valve. A 1/4 inch (6.4 millimeters) Iron Pipe Size (IPS) valve shall be provided~~
 2844 ~~immediately upstream from the final control valve to permit checking the flow pressure of~~
 2845 ~~the final rinse water. In all new installations, a pressure gauge shall be provided for use with~~
 2846 ~~the IPS valve. This section does not apply to a machine that uses only a pumped sanitizing~~
 2847 ~~rinse.~~
- 2848 C. ~~Machine or water line mounted numerically scaled indicating temperature monitoring~~
 2849 ~~device, accurate to ± 3°F (± 2°C), shall be provided to indicate the temperature of the water~~
 2850 ~~in each tank of the machine and the temperature of the final rinse water as it enters the~~
 2851 ~~manifold.~~
- 2852 D. ~~Rinse water tanks shall be protected by baffles, curtains, or other effective means to~~
 2853 ~~minimize the entry of wash water into the rinse water. Conveyors in warewashing machines~~
 2854 ~~shall be accurately timed to ensure proper exposure times in wash and rinse cycles in~~
 2855 ~~accordance with manufacturer's specifications attached to the machines.~~
- 2856 E. ~~Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove~~
 2857 ~~gross food particles and soil prior to being washed in a warewashing machine unless a pre-~~
 2858 ~~wash cycle is a part of the warewashing machine operation. Equipment and utensils shall be~~
 2859 ~~placed in racks, trays, or baskets, or on conveyors, in a way that exposes food contact~~
 2860 ~~surfaces to the unobstructed application of detergent wash and clean rinse waters, and that~~
 2861 ~~permits free draining.~~
- 2862 F. ~~Chemical sanitizing warewashing machines (single tank, stationary tank, door type~~
 2863 ~~machines, and spray type glass washers) may be used provided that:~~
- 2864 1. ~~The temperature of the wash water shall not be less than 120°F (49°C);~~
- 2865 2. ~~The wash water shall be kept clean; and~~

- 2866 3. ~~Chemicals added for washing and sanitization purposes shall be automatically~~
2867 ~~dispensed; and~~
- 2868 *4. ~~Utensils and equipment shall be exposed to the final chemical sanitizing rinse in~~
2869 ~~accordance with the manufacturer's specifications for time and concentration; and~~
- 2870 *5. ~~The chemical sanitizing rinse water temperature shall not be less than 75°F (24°C)~~
2871 ~~nor less than the temperature specified by the machine's manufacturer; and~~
- 2872 *6. ~~Chemical sanitizers shall meet the requirements specified 40 CFR 180.940 (2005)~~
2873 ~~and be applied in accordance with the EPA registered label use instructions.~~
- 2874 *G. ~~Hot water sanitizing warewashing machines may be used, provided that wash water and~~
2875 ~~pumped rinse water is kept clean and the wash solution temperature is maintained at not less~~
2876 ~~than the temperatures stated in this section 4-404(G)(1-5).~~
- 2877 Achieving a utensil and/or equipment surface temperature of 160°F (71°C) is an acceptable
2878 means of testing the sanitization process of a hot water sanitizing warewashing machine.
- 2879 1. ~~Single tank, stationary rack, dual temperature machines:~~
2880 ~~Wash temperature 150°F (66°C)~~
- 2881 2. ~~Single tank, stationary rack, single temperature machine:~~
2882 ~~Wash temperature 165°F (74°C)~~
- 2883 3. ~~Single tank, conveyor machine:~~
2884 ~~Wash temperature 160°F (72°C)~~
- 2885 4. ~~Multi tank, conveyor machine:~~
2886 ~~Wash temperature 150°F (66°C)~~
2887 ~~Pumped rinse temperature 160°F (72°C)~~
- 2888 5. ~~Single tank, pot, pan, and utensil washer (either stationary or moving rack):~~
2889 ~~Wash temperature 140°F (60°C)~~
- 2890 *H. ~~Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures~~
2891 ~~In mechanical warewashing machines the temperature of the fresh hot water sanitizing rinse~~
2892 ~~as it enters the manifold may not be more than 194°F (90°C), or less than:~~
- 2893 1. ~~For a stationary rack, single temperature machine, 165°F (74°C); or~~
2894 2. ~~For all other machines 180°F (82°C).~~
- 2895 I. ~~All warewashing machines shall be thoroughly cleaned daily and as needed to maintain them~~
2896 ~~in a satisfactory operating condition.~~
- 2897 J. ~~A warewashing machine shall be provided with an easily accessible and readable data plate~~
2898 ~~affixed to the machine which includes:~~
- 2899 1. ~~Temperatures required for washing, rinsing, and sanitizing;~~
2900 2. ~~Pressure required for the fresh water sanitizing rinse unless the machine is designed~~
2901 ~~to use only a pumped sanitizing rinse;~~
- 2902 3. ~~Conveyor speed required for conveyor machines or cycle time required for~~
2903 ~~stationary rack machines; and~~

- 2904 4. Required type and concentration of sanitizing solutions.
- 2905 K. After being cleaned and sanitized, equipment and utensils shall not be rinsed before air
- 2906 drying or use unless:
- 2907 1. The rinse is applied directly from a drinking water supply by a warewashing
- 2908 machine that is maintained and operated as specified in sections 4-404; and
- 2909 2. The rinse is applied only after the equipment and utensils have been sanitized by the
- 2910 application of hot water or by the application of a chemical sanitizer solution whose
- 2911 EPA registered label use instructions call for rinsing off the sanitizer after it is
- 2912 applied in a commercial warewashing machine.

2913 **4-405 Drainboard and Dishtable Requirements**

- 2914 A. Drainboards and dishtables shall be self draining and shall have a minimum pitch of 1/8 inch
- 2915 (3.2mm) per foot (304.8mm). Drainage shall be directed to warewashing sink bowls, pre-
- 2916 rinse sinks, scuppers or warewashing machines.
- 2917 B. Drainboards and dishtables shall be supported as needed to prevent sagging and shall have
- 2918 edges turned up at least 1/2 inch (12.7 mm).
- 2919 C. When provided on warewashing sinks, drainboards shall be integrally welded to the sink
- 2920 bowl(s).
- 2921 D. Drainboards and dishtables shall be large enough to accommodate for the staging of soiled
- 2922 equipment, dishes, glasses, mugs, kitchenware, tableware and utensils so they may be
- 2923 adequately pre scraped and pre flushed prior to warewashing and large enough to
- 2924 accommodate the air drying of sanitized items that may accumulate during hours of
- 2925 operation. Drainboard and dishtable's length shall be measured from right to left.
- 2926 1. Drainboards and dishtables installed on the establishment's primary means for
- 2927 warewashing shall be sized in accordance with the following:

FACILITY TYPE	SOILED DRAINBOARDS	CLEAN DRAINBOARDS
Single Service	Twenty four (24)	Twenty four (24)
	Inches (64 cm)	Inches (64 cm)
Multi use Service	Thirty six (36)	Thirty six (36)
With Manual Warewashing	Inches (91 cm)	Inches (91 cm)
Multi use Service	Forty eight (48)	Forty eight (48)
With Mechanical Warewashing	Inches (122 cm)	Inches (122 cm)

- 2940 2. Bar sinks shall be equipped with an eighteen (18") inch (46 cm) drainboard for
- 2941 staging soiled tableware, utensils, glasses and mugs and an eighteen (18") inch (46
- 2942 cm) drainboard for air drying sanitized items.
- 2943 3. Under counter warewashing machines shall be provided with drainboards or
- 2944 dishtables that are large enough to accommodate staging of soiled equipment,
- 2945 dishes, glasses, mugs, kitchenware, tableware and utensils and large enough for air
- 2946 drying of sanitized items. A common drainboard, dishtable or the open door of the
- 2947 warewashing machine may be utilized.

- 2948 4. ~~Multi tank conveyor warewashing machines equipped with both, a powered pre-~~
 2949 ~~wash unit and a powered blower dryer unit shall be equipped with dishtables sized~~
 2950 ~~in accordance with the warewashing machine's manufacture.~~
- 2951 5. ~~Alternate equipment or methods, such as wall mounted drainboards, wire shelving~~
 2952 ~~or bus carts, may be provided for staging of soiled equipment, dishes, glasses, mugs,~~
 2953 ~~and utensils for pre scraping and pre flushing prior to warewashing and to~~
 2954 ~~accommodate air drying of sanitized items may be utilized if approved by the~~
 2955 ~~Department. Alternate equipment shall not be located or constructed in a manner~~
 2956 ~~that interferes with the proper use of the warewashing facilities.~~
- 2957 E. ~~Except for under counter warewashing machines, prerinse sprayers or other approved means~~
 2958 ~~shall be provided and used for pre scraping and pre flushing of soiled equipment, dishes and~~
 2959 ~~utensils when a warewashing machine is installed.~~
- 2960 F. ~~Scuppers when installed shall transverse the entire flat section of the drainboard or dishtable~~
 2961 ~~to prevent soiled water and debris from draining into the warewashing sink bowl or~~
 2962 ~~warewashing machine. Scuppers shall be equipped with a readily removable strainers or~~
 2963 ~~strainer baskets.~~

2964 **4-406 — Drying**

- 2965 ~~Unless used immediately after sanitization, all equipment and utensils shall be air dried. Towel~~
 2966 ~~drying shall not be permitted. Utensils that have been air dried may be polished with cloths which~~
 2967 ~~are maintained clean and dry.~~

2968 **4-407 — Food Contact Surfaces of Equipment and Utensils**

- 2969 A. ~~Equipment food contact surfaces and utensils shall be clean to sight and touch.~~
- 2970 *B. ~~Utensils and food contact surfaces of equipment shall be cleaned and sanitized:~~
- 2971 1. ~~Before each use with a different type of raw animal food, such as beef, fish, lamb,~~
 2972 ~~pork, or poultry;~~
- 2973 2. ~~Each time there is a change from working with raw animal foods to working with~~
 2974 ~~ready to eat foods;~~
- 2975 3. ~~Between uses with raw fruits or vegetables and with potentially hazardous food~~
 2976 ~~(time/temperature control for safety food);~~
- 2977 4. ~~At any time during the operation when contamination may have occurred; and~~
- 2978 5. ~~After final use each working day.~~
- 2979 *C. ~~Where equipment and utensils are used for the preparation of potentially hazardous food~~
 2980 ~~(time/temperature control for safety food) on a continuous or production line basis, utensils~~
 2981 ~~and the food contact surfaces of equipment shall be cleaned and sanitized at intervals not to~~
 2982 ~~exceed four (4) hours.~~
- 2983 D. ~~Surfaces of utensils and equipment contacting potentially hazardous food (time/temperature~~
 2984 ~~control for safety food) may be cleaned less frequently than every 4 hours if:~~
- 2985 1. ~~Utensils and equipment such as skillets, omelet pans and woks used on a production~~
 2986 ~~line basis in continuous use for the heating/cooking of potentially hazardous foods~~
 2987 ~~(time/temperature control for safety foods) shall be cleaned and sanitized after final~~
 2988 ~~use each working day and at least every 24 hours;~~

- 2989 2. Containers in serving situations such as salad bars, delis, and cafeteria lines holding
- 2990 ready-to-eat potentially hazardous food (time/temperature control for safety food)
- 2991 that is maintained at the temperature specified in chapter 3 and are intermittently
- 2992 combined with the additional supplies of the same food that is at the required
- 2993 temperature, and the containers are cleaned and sanitized at least every 24 hours;
- 2994 3. Utensils and equipment used to prepare food in a refrigerated room or area that is
- 2995 maintained at one of the temperatures in Figure 3 shall be cleaned and sanitized at
- 2996 the frequency that corresponds to the ambient temperatures:
- 2997

<u>Temperature</u>	<u>Cleaning Frequency</u>
41°F (5.0°C) or less	24 hours
>41°F – 45°F (>5.0°C – 7.2°C)	20 hours
>45°F – 50°F (>7.2°C – 10.0°C)	16 hours
>50°F – 55°F (>10.0°C – 12.8°C)	10 hours

FIGURE 3

- 2998
- 2999 4. The food contact surfaces of cooking and baking utensils and equipment, such as
- 3000 grills, woks, hot sandwich presses, waffle irons, as well as baking equipment and the
- 3001 cavities and door seals of microwave ovens shall be cleaned at least every 24 hours
- 3002 and shall be kept free of encrusted grease deposits and other accumulated soil. This
- 3003 shall not apply to hot oil cooking equipment and hot oil filtering systems.

3004 4-408 — Nonfood-Contact Surfaces

3005 Nonfood contact surfaces of equipment, including transport vehicles, shall be cleaned as often as
 3006 necessary to keep the equipment free from the accumulation of dust, dirt, food particles, and other
 3007 debris.

3008 4-409 — Dry Equipment Cleaning Methods

3009 Dry equipment cleaning methods, such as brushing, scraping, and vacuuming shall contact only
 3010 surfaces that are soiled with dry food residues that are not potentially hazardous; this cleaning
 3011 equipment shall not be used for any other purpose.

3012 4-5 — LAUNDRY FACILITIES

3013 4-501 — Laundry Facilities

3014 A. If provided, laundry facilities shall be restricted to the washing and drying of linens and work
 3015 clothes used in the operation. If such items are laundered on the premises, an electric or gas
 3016 clothes dryer shall be provided and used, except that it is not necessary to provide a clothes
 3017 dryer provided that:

- 3018 1. On premise laundering is limited to wiping cloths intended to be used moist, and
- 3019 2. The laundered wiping cloths are stored in an approved sanitizing solution; or

- 3020 3. ~~The laundered wiping cloths are air dried in a laundry room or other approved~~
3021 ~~locations.~~
- 3022 B. ~~Laundry facilities shall not be located in food preparation areas. If located in food storage~~
3023 ~~areas, it shall be operated in a manner that prevents the contamination of food, equipment,~~
3024 ~~utensils, linens, single service and single use articles and wiping cloths.~~
- 3025 C. ~~Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry~~
3026 ~~bags. Soiled linens shall be stored and transported to prevent contamination of food, clean~~
3027 ~~equipment, clean utensils, single service and single use articles.~~

3028 ~~4-6~~ ~~EQUIPMENT AND UTENSIL HANDLING AND STORAGE~~

3029 ~~4-601~~ ~~Equipment and Utensil Storage~~

- 3030 A. ~~Cleaned and sanitized equipment and utensils shall be handled in a way that protects them~~
3031 ~~from contamination. Spoons, knives, and forks shall be touched only by their handles.~~
3032 ~~Cups, glasses, bowls, plates, and similar items shall be handled without contact with inside~~
3033 ~~surfaces or surfaces that contact the user's mouth.~~
- 3034 B. ~~Cleaned and sanitized utensils and equipment shall be stored at least 6 inches (15.24 cm)~~
3035 ~~above the floor in a clean, dry location in a way that protects them from contamination by~~
3036 ~~splash, dust, and other means. The food contact surfaces of fixed equipment shall also be~~
3037 ~~protected from contamination. Equipment and utensils shall not be placed under sewer lines~~
3038 ~~or water lines that are not protected to intercept potential drips, including leaking automatic~~
3039 ~~fire protection sprinkler heads, or under lines on which water has condensed.~~
- 3040 C. ~~Utensils shall be air dried, in accordance with section 4-406, before being stored or shall be~~
3041 ~~stored in a self-draining position.~~
- 3042 D. ~~Glasses and cups shall be stored inverted. Other stored tableware shall be covered or~~
3043 ~~inverted, wherever practical. Facilities for the storage of knives, forks and spoons shall be~~
3044 ~~designed and used to present the handle to the employee or consumer. Unless pre-wrapped,~~
3045 ~~holders for knives, forks and spoons at self-service locations shall protect these articles from~~
3046 ~~contamination and present the handle of the utensil to the consumer.~~

3047 ~~4-602~~ ~~Single-Service and Single-Use Articles~~

- 3048 A. ~~Single service articles shall be stored at least 6 inches (15.24 cm) above the floor in closed~~
3049 ~~cartons or containers which protect them from contamination. They shall not be placed~~
3050 ~~under exposed sewer lines or water lines, except for automatic fire protection sprinkler heads~~
3051 ~~that may be required by law.~~
- 3052 B. ~~Single service articles shall be handled and dispensed in a manner that prevents~~
3053 ~~contamination of surfaces which may come in contact with food or with the mouth of the~~
3054 ~~user.~~
- 3055 C. ~~Single service knives, forks, and spoons packaged in bulk shall be inserted into holders or be~~
3056 ~~wrapped prior to dispensing by employees who have washed their hands immediately prior~~
3057 ~~to sorting or wrapping the utensils. Holders shall be provided to protect these items from~~
3058 ~~contamination and present the handle of the utensil to the consumer.~~
- 3059 D. ~~Single service and single use articles may not be reused.~~
- 3060 E. ~~Mollusk and crustacea shells may not be used more than once as serving containers.~~

3061 ~~4-603~~ **Preset Tableware**

3062 Tableware may be preset if:

3063 A. ~~Except as specified in paragraph (B) of this section, tableware that is preset shall be~~
3064 ~~protected from contamination by being wrapped, covered or inverted;~~

3065 B. ~~Preset tableware may be exposed if unused settings are removed when a consumer is seated~~
3066 ~~and cleaned and sanitized before further use.~~

3067

3068

CHAPTER 5

3069

~~WATER, PLUMBING, AND WASTE~~3070 **~~5-1 — WATER SUPPLY~~**3071 **~~*5-101 — General~~**

3072 A. ~~Adequate, uncontaminated, safe drinking water for the needs of the retail food establishment~~
 3073 ~~shall be provided from a source constructed, maintained, and operated according to the~~
 3074 ~~*Colorado Primary Drinking Water Regulations* and regulations adopted pursuant to Title 25-~~
 3075 ~~1.5-203 C.R.S., or~~

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3080

1. ~~If the retail food establishment does not meet the definition of a public water system pursuant to the *Colorado Primary Drinking Water Regulations*, promulgated pursuant to 25-1.5-101, and 25-1.5-203, C.R.S., the retail food establishment shall provide:~~

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a. ~~Adequate treatment on a continuous basis; and~~

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b. ~~Bacteriological samples at a minimum of once per quarter or at a frequency determined by the department; and~~

3084

3085

c. ~~A DPD colorimetric drinking water test kit capable of testing free chlorine at an accuracy of 0.1 mg/Liter; and~~

3086

3087

d. ~~Free chlorine shall range from a trace amount to 4 mg/Liter (0.2 to 1.2 mg/Liter recommended) at any fixture; and~~

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e. ~~Most recent required water sample reports shall be retained on file at the retail food establishment and shall be available for review by the department when requested; and~~

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3095

2. ~~Retail food establishments with water supplies determined to be surface water or determined to be under the direct influence of surface water shall be required to filter their water to 1µm (micron) absolute using National Sanitation Foundation approved equipment and maintain a residual disinfectant concentration to ensure inactivation and/or removal of giardia and other parasitic cysts and viruses.~~

3096 **~~*5-102 — System Flushing and Disinfection~~**

3097 ~~A drinking water system shall be flushed and disinfected before being placed in service after~~
 3098 ~~construction, repair, or modification and after an emergency situation, such as a flood, that may~~
 3099 ~~introduce contaminants to the system.~~

3100 **~~*5-103 — Bottled Drinking Water~~**

3101 ~~Bottled drinking water used or sold in a retail food establishment shall be obtained from approved~~
 3102 ~~sources in accordance with Processing and Bottling of Bottled Drinking Water, 21 CFR section 129,~~
 3103 ~~(2009).~~

3104

3105

3106 ~~*5-104—Transportation~~

3107 All drinking water not provided directly by pipe to the retail food establishment from the source shall
3108 be transported in a bulk water transport system and shall be delivered to a closed water system. Both
3109 of these systems shall be constructed and operated according to law and operated as approved by the
3110 Department.

3111 ~~*5-105—Emergency Alternative Water Supply~~

3112 A.—— Establishments intending to operate when there is a temporary interruption of water service
3113 or an upset in the supply of treated drinking water, with approval by the Department prior to
3114 implementation, the establishment may continue operation if the temporary water supply
3115 meets the requirements of sections 5-101, 5-102, 5-103, 5-104 and 5-105 and drinking water
3116 is made available through:

3117

3118

1.—— A supply of commercially bottled drinking water;

3119

2.—— One or more closed portable water containers;

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3.—— An enclosed vehicular drinking water tank;

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4.—— An on-premises drinking water storage tank; or

3122

5.—— Piping, tubing, or hoses connected to an adjacent approved source.

3123 ~~*5-106—Non-Drinking Water~~

3124 A non-drinking water system is permitted for air conditioning, non-food equipment cooling,
3125 landscape irrigation and fire protection, and shall be installed according to law. Non-drinking water
3126 shall not directly or indirectly contact food or equipment or utensils that contact food. The piping of
3127 any non-drinking water system shall be identified so that it is readily distinguishable from piping that
3128 carries drinking water.

3129 ~~*5-107—Pressure and Temperature~~

3130 A.—— Water under pressure of at least 15 pounds per square inch (psi) (1.05 kg per sq. cm) at the
3131 required temperature shall be provided to all fixtures and equipment that use water.

3132

B.—— Hot and cold water shall be provided to all sinks.

3133 ~~*5-108—Hot Water~~

3134 Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands
3135 throughout the retail food establishment. (see Appendix C)

3136 ~~*5-109—Steam~~

3137 Steam used in contact with food or food contact surfaces shall be free from any unsafe materials or
3138 additives not listed in Specific Usage Additives, 21 CFR section 173.310, (2003). (see Appendix D)

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3140

3141 **5-2 — PLUMBING SYSTEM**3142 **5-201 — General**

3143 Plumbing shall be sized, installed, and maintained in accordance with applicable state and local
 3144 plumbing codes, ordinances, regulations, and standards. Plumbing shall be designed and constructed
 3145 according to the 2009 International Plumbing Code. Where local building departments have adopted
 3146 codes equivalent to or more stringent than the above, those codes shall apply. The Department shall
 3147 work in collaboration with the local building and/or fire department with regard to enforcement and
 3148 compliance activities. Plumbing fixtures shall be easily cleanable and kept clean.

3149 ***5-202 — Backflow**3150 ***A. — General**

3151 The drinking water system shall be constructed to prevent backflow. There shall be no unprotected
 3152 cross-connections between the drinking water supply and any non-drinking water supply, or any
 3153 sources of contamination. Devices or assemblies installed shall meet the appropriate application for
 3154 the hazard of the cross-connection to prevent backflow of a solid, liquid or gas contaminant into the
 3155 drinking water supply system at each point of use within the retail food establishment.

3156 ***B. — Backflow prevention devices and installation requirements**

3157 1. — An air gap between the water supply inlet and the flood level rim of the plumbing
 3158 fixture, equipment, or nonfood equipment shall be at least twice the diameter of the
 3159 water supply inlet and may not be less than one (1) inch (25 mm).

3160 2. — An atmospheric vacuum breaker shall be located on the discharge side of the last
 3161 valve and not less than six (6) inches (154.4 mm) above the flood rim of plumbing
 3162 fixture or equipment. A shutoff valve downstream of the atmospheric vacuum
 3163 breaker is prohibited.

3164 3. — Backsiphonage and backflow prevention devices shall meet American Society of
 3165 Sanitary Engineering (A.S.S.E.) standards for construction, installation,
 3166 maintenance, inspection and testing for that specific application and type of device.

3167 **C. — Applications**

3168 *1. — Inlets to tanks, vats, garbage disposals, troughs, fixtures, warewashing machines and
 3169 other equipment with submerged inlets shall be protected by an approved backflow
 3170 prevention device or with an approved air gap at the inlet.

3171 ***2. — Carbonated Beverage Dispensers**

3172 — The drinking water supply connection to carbonated beverage dispensers shall be
 3173 protected against backflow by at least one of the following:

3174 a. — An approved air gap; or

3175 b. — A dual check valve constructed of a material not affected by carbon dioxide
 3176 with an intermediate vent installed upstream of the carbonator and
 3177 downstream of any copper and copper alloy piping or fixture; or

- 3178 e. ~~A reduced pressure zone backflow prevention assembly constructed of~~
 3179 ~~material impervious to attack by carbon dioxide, and installed upstream of~~
 3180 ~~the carbonator and downstream of any copper and copper alloy piping or~~
 3181 ~~fixture.~~
- 3182 3. ~~Non-Carbonated Beverage Dispensers~~
- 3183 ~~The drinking water supply connection to non-carbonated beverage dispensers shall~~
 3184 ~~be protected against backflow by at least one of the following:~~
- 3185 a. ~~An approved air gap; or~~
- 3186 b. ~~A dual check valve constructed of a material not affected by carbon dioxide~~
 3187 ~~with an intermediate vent installed downstream of any copper and copper~~
 3188 ~~alloy piping or fixture.~~
- 3189 *4. ~~Hose bibs, sillcocks, and threaded faucets where a hose can be attached shall be~~
 3190 ~~equipped with a proper backflow prevention device in accordance with 5-202 (B) (2)~~
 3191 ~~and (3). This paragraph shall not apply to water heater and boiler drain valves that~~
 3192 ~~are provided with hose connection threads and that are intended only for tank or~~
 3193 ~~vessel draining, or to water supply valves intended for connection of clothes~~
 3194 ~~washing machines where backflow prevention is otherwise provided or is integral~~
 3195 ~~with the machine.~~
- 3196 5. ~~In all new or extensively remodeled facilities, a dedicated hot and cold water supply~~
 3197 ~~shall be provided for chemical dispensing towers.~~

3198 **5-203 — Conditioning Device, Design**

- 3199 ~~Water filters, screens, and other water conditioning devices installed on water lines shall be made of~~
 3200 ~~safe materials and designed and located to facilitate disassembly for periodic servicing and cleaning.~~
 3201 ~~A water filter element shall be of the replaceable type.~~

3202 **5-204 — Grease Trap / Grease Interceptor**

- 3203 ~~If required by the local building, water or sanitation authority, when possible, a grease trap, grease~~
 3204 ~~interceptor, or solids interceptor should be located outside the establishment. When installed inside~~
 3205 ~~the establishment, a grease trap, grease interceptor, or solids interceptor shall be located away from~~
 3206 ~~the food preparation area and be easily accessible for cleaning.~~

3207 **5-205 — Food Waste Grinders/Garbage Disposals**

- 3208 A. ~~In new or extensively remodeled retail food establishments, food waste grinders or garbage~~
 3209 ~~disposals, if provided, shall be installed in the soiled drainboard of the warewashing sink,~~
 3210 ~~food preparation sink, or warewashing machine. The installation will be approved under the~~
 3211 ~~following conditions:~~
- 3212 1. ~~The disposal shall be directly connected to the sanitary sewer unless otherwise required~~
 3213 ~~by law; or~~
- 3214 2. ~~When installed in the drainboard of a food preparation sink, the drainboard shall be~~
 3215 ~~equipped with an indirectly drained scupper/scrap basket or similar device to~~
 3216 ~~prevent contamination of food contact surfaces. A second approved eighteen inch~~
 3217 ~~(18") (46 cm) self-draining drain board or alternate approved methods shall be~~
 3218 ~~provided to prevent contamination of food.~~

3219 B. ~~Food waste grinders or garbage disposals may be installed in the basin of the sink if the sink~~
3220 ~~is used solely for the disposal of food wastes.~~

3221 ~~*5-206 Drainage Of Equipment.~~

3222 A. ~~Warewashing machines, refrigerators, walk in refrigerators, freezers, walk in freezers,~~
3223 ~~warewashing sinks, food/vegetable preparation sinks, steam kettles, potato peelers, ice bins,~~
3224 ~~containers of ice for use in food and beverages, ice machines, and similar types of equipment~~
3225 ~~in which food, portable equipment or utensils are placed shall be indirectly connected to the~~
3226 ~~waste line and shall drain into an approved receptor of such size, shape, and capacity to~~
3227 ~~prevent splashing or flooding. The receptor shall be readily accessible for cleaning and~~
3228 ~~inspection.~~

3229 B. ~~Warewashing sinks and dishmachines installed prior to the effective date of these Regulations~~
3230 ~~may be directly connected to the plumbing waste system provided there is a floor drain or~~
3231 ~~floor sink installed within five (5) feet (1.5 M) immediately downstream of the sink waste~~
3232 ~~line, and the fixture shall be connected on the sewer side of the floor drain or floor sink, and~~
3233 ~~no other fixtures are connected to the waste line. The fixture and floor drain shall be trapped~~
3234 ~~and vented as required by the 2009 International Plumbing Code or where local building~~
3235 ~~departments have adopted codes equivalent or more stringent than the above, those codes~~
3236 ~~shall apply (see Figure 4).~~

3237 C. ~~In new or extensively remodeled retail food establishments, each walk in refrigerator used for~~
3238 ~~iced products, hanging meats or which requires flushing shall either be equipped with a floor~~
3239 ~~drain installed only with indirect waste and discharged through an air gap into an approved~~
3240 ~~receptor or constructed so all parts of the floor of such walk in refrigerator shall be graded to~~
3241 ~~drain to the outside of the refrigerator through a waste pipe, doorway or other opening.~~

3242

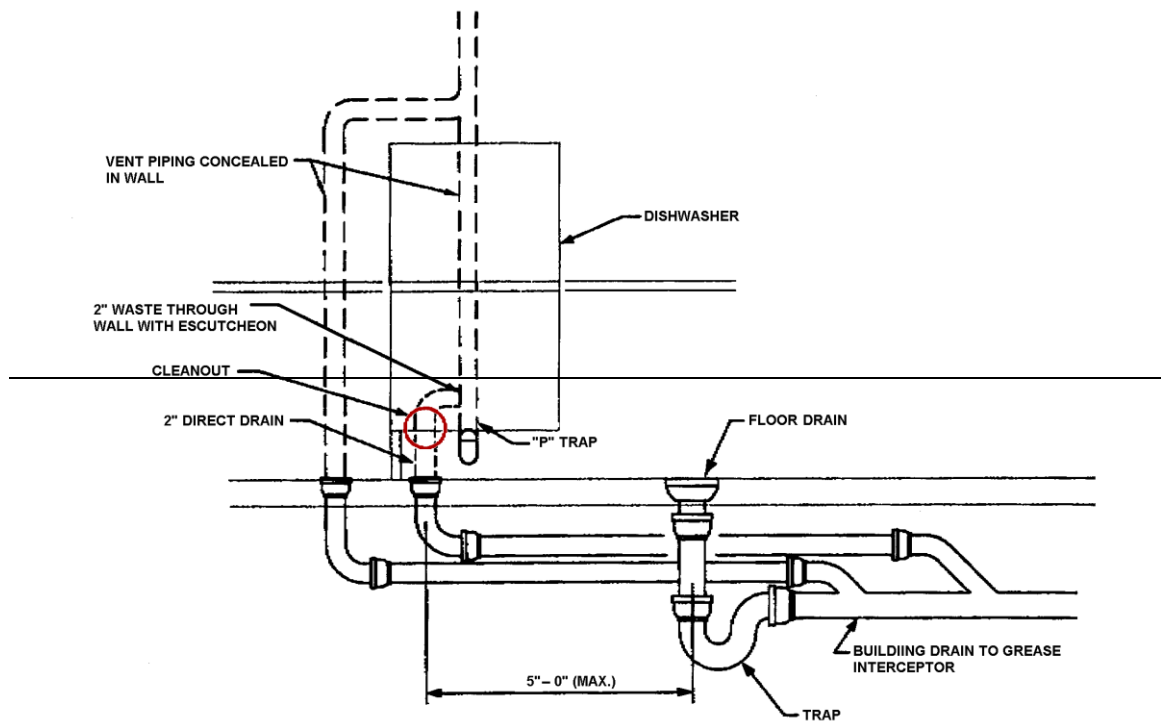


FIGURE 4

3243
32443245 **5-207 — Drainage System Installation**

3246 Drain lines from equipment shall not discharge liquid waste in a manner that permits the flooding of
 3247 floors, or the flowing of water across working or walking areas, or into difficult to clean areas that
 3248 create a nuisance.

3249 **5-208 — Handwashing Lavatory, Water Temperature, and Flow**

3250 *A. — The number of fixtures shall comply with the requirements of the plumbing code adopted by
 3251 the respective local jurisdiction, or in the absence of such local requirements with the
 3252 minimum plumbing fixtures listed in the 2009 International Plumbing Code.

3253 *B. — Handsinks shall be conveniently located to employees involved in food preparation, food
 3254 dispensing, warewashing and utensil handling. Handsinks shall be unobstructed and
 3255 accessible to employees at all times and used only for handwashing. Sinks used for food
 3256 preparation or for washing equipment shall not be used for handwashing. Handsinks used
 3257 for toilet rooms shall be located in the toilet rooms.

3258 *C. — Handwashing sink water temperatures. Each handsink shall be provided with water at least
 3259 100°F (38°C) by means of a mixing valve or combination faucet. Any self-closing, slow-
 3260 closing, or metering faucet used shall be designed to provide a flow of water for at least 15
 3261 seconds without the need to reactivate the faucet.

3262 *D. — A supply of hand-cleansing soap or detergent shall be available at each handsink or group of
 3263 two (2) adjacent handwashing sinks. A continuous cloth towel system that supplies the user
 3264 with a clean towel, individual disposable towels, or a hand-drying device providing heated or

- 3265 high velocity pressurized air shall be conveniently located near each handsink or group of
3266 adjacent handwashing sinks.
- 3267 *E. Common towels are prohibited for the drying of hands.
- 3268 F. Hand towels shall be stored to protect unused towels from becoming contaminated.
- 3269 G. If disposable towels are used, an easily cleanable waste receptacle shall be conveniently
3270 located near the handsink.
- 3271 H. Handsinks, soap dispensers, hand drying devices and all related fixtures shall be kept clean
3272 and in good repair.
- 3273 I. Automatic Handwashing Facilities:
- 3274 1. If the model, installation, location, and conditions of use are approved, and the unit
3275 is capable of removing the types of soils encountered in the food operations
3276 involved, automatic handwashing facilities may be substituted for handwashing
3277 sinks in a food establishment that has at least one additional handwashing sink that
3278 is easily accessible.
- 3279 2. An automatic handwashing facility shall be installed and used in accordance with
3280 manufacturer's instructions.
- 3281 J. Handwashing Sink Specifications for New or Extensively Remodeled Establishments
- 3282 1. The height of the sink's flood rim shall be between 30 inches (76cm) and 48 inches
3283 (122 cm) above the floor.
- 3284 2. The diameter of the handwashing sink basin shall be a minimum of 10 inches (25
3285 cm) in any direction.
- 3286 3. When installed in a counter top, handwashing sink faucets shall be within 24 inches
3287 (61cm) of the front edge of the counter top.
- 3288 4. The clearance between the flood rim of handwashing sink and the base or underside
3289 of any overhead cabinets, shelves, or other equipment shall be a minimum of 24
3290 inches (61cm).
- 3291 5. Handwashing sink faucets shall be installed on the side of the sink basin directly
3292 opposite the user.

3293 ~~5-209~~ **Toilets and Urinals**

- 3294 *A. Toilet facilities shall be installed according to law, shall be the number required by law, shall
3295 be conveniently located, and shall be accessible to employees and patrons.
- 3296 B. Separate toilet facilities shall be required for each sex in establishments with seating capacity
3297 in excess of 20 patrons or more than 20 employees. In all new or extensively remodeled
3298 retail food establishments, these facilities shall be installed to comply with the requirements
3299 of the Plumbing Code adopted by the respective local jurisdictions, or in the absence of such
3300 local requirements, with the minimum numbers of plumbing fixtures listed in the 2009
3301 International Plumbing Code.
- 3302 C. Separate toilet facilities are not required for each sex in places of 15 or fewer seating
3303 capacity for patrons, or 20 or fewer employees where there is no seating capacity, provided
3304 the toilet is a single occupancy facility and the door can be secured from the inside.

- 3305 ~~D. — Retail food establishments with no space on the premises for consumption of food by patrons~~
 3306 ~~are required to provide toilet facilities only for employees. Patron facilities shall be available~~
 3307 ~~where parking is provided primarily for consumption of food on the premise. In all new or~~
 3308 ~~extensively remodeled retail food establishments where parking is provided primarily for~~
 3309 ~~consumption of food on the premise, the number of necessary fixtures shall comply with the~~
 3310 ~~minimum plumbing fixtures required by the Plumbing Code or Building Code adopted by~~
 3311 ~~the respective local jurisdiction, or in the absence of such local requirements, with the~~
 3312 ~~numbers listed in 2009 International Plumbing Code, table 403.1.~~
- 3313 ~~E. — Employees and patrons may use the same toilet facility provided that patrons have access to~~
 3314 ~~them without entering the food preparation, food storage, or warewashing or utensil storage~~
 3315 ~~areas of the establishment.~~
- 3316 ~~F. — Public toilets in multiple activity areas such as shopping centers, sports centers, etc., may~~
 3317 ~~suffice for the use of retail food establishment patrons and employees, if fixtures are~~
 3318 ~~provided in adequate numbers conveniently located to the retail food establishment and~~
 3319 ~~available at all times the retail food establishment is in operation.~~
- 3320 ~~G. — Except where a toilet room is located outside a food establishment and does not open directly~~
 3321 ~~into the food establishment such as a toilet room that is provided by the management of a~~
 3322 ~~shopping mall, a toilet room located on the premises shall be completely enclosed and~~
 3323 ~~provided with a tight fitting and self-closing door.~~
- 3324 ~~H. — Toilet facilities, including toilet fixtures and any related vestibules, shall be kept clean and in~~
 3325 ~~good repair. A supply of toilet tissue in a permanently mounted dispenser shall be provided~~
 3326 ~~at each toilet at all times.~~
- 3327 ~~I. — Easily cleanable trash receptacles shall be provided. A toilet room used by females shall be~~
 3328 ~~provided with a covered trash receptacle for sanitary products. Trash receptacles shall be~~
 3329 ~~emptied at least once a day, and more frequently when necessary to prevent excessive~~
 3330 ~~accumulation of refuse.~~

3331 **5-210 — Utility Facility**

- 3332 ~~A. — In new or extensively remodeled retail food establishments, at least one conveniently located~~
 3333 ~~utility sink or curbed cleaning facility with a floor drain and hot and cold water shall be~~
 3334 ~~provided and used for the cleaning of mops or similar wet floor cleaning tools and for the~~
 3335 ~~disposal of mop water or similar liquid wastes.~~
- 3336 ~~B. — Suitable cleaning equipment and supplies, such as high pressure pumps, hot water, steam,~~
 3337 ~~and detergent, shall be provided as necessary for effective cleaning of equipment and~~
 3338 ~~receptacles for refuse, recyclables, and returnables. If approved by the Department, off-~~
 3339 ~~premise cleaning services may be used.~~
- 3340 ~~*C. — A utility sink cannot be used for food preparation or warewashing.~~
- 3341 ~~D. — Dump Sinks~~
- 3342 ~~— In new or extensively remodeled establishments, bars, juice bars, coffee bars, drink stations,~~
 3343 ~~wait stations or other areas where soiled drinking glasses and mugs are emptied and staged~~
 3344 ~~for warewashing, a dump sink shall be provided and used for the sanitary disposal of liquid~~
 3345 ~~drink waste, ice and/or collection of debris emptied from glasses and mugs.~~
- 3346 ~~1. — Dump sinks shall be fitted with a removable strainer basket, and shall be plumbed with hot~~
 3347 ~~and cold running water.~~
- 3348 ~~2. — Blender station sinks and food preparation sinks shall not be utilized as dump sinks.~~

3349 3. ~~Other methods may be used if approved by the Department.~~

3350 ~~*5-211 Sewage~~

3351 All sewage shall be disposed of by a sewage disposal system constructed, maintained and operated
3352 according to law.

3353 ~~*5-212 Water Reservoir of Fogging Devices, Cleaning~~

3354 A. ~~A reservoir used to supply water to a device, such as a produce fogger shall be:~~

3355 1. ~~Installed and maintained in accordance with manufacturer's specifications; and~~

3356 2. ~~Cleaned in accordance with manufacturer's specifications or according to the~~
3357 ~~procedures specified in paragraph B of this section, whichever is more stringent.~~

3358 B. ~~Cleaning procedures shall include at least the following steps and shall be conducted at least~~
3359 ~~once a week:~~

3360 1. ~~Draining and complete disassembly of the water and aerosol contact parts;~~

3361 2. ~~Brush cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable~~
3362 ~~detergent solution;~~

3363 3. ~~Flushing the complete system with water to remove the detergent solution and~~
3364 ~~particulate accumulation; and~~

3365 4. ~~Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and~~
3366 ~~discharge nozzles with at least 50 ppm (mg/L) hypochlorite solution.~~

3367 ~~5-3 REFUSE, RECYCLABLES, AND RETURNABLES~~

3368 ~~5-301 Containers~~

3369 A. ~~Garbage, refuse, compost, and recyclables shall be held in durable, easily cleanable~~
3370 ~~containers that do not leak and do not absorb liquids. Plastic bags and/or wet strength paper~~
3371 ~~bags shall be used to line these containers. Such bags and durable plastic garbage and refuse~~
3372 ~~containers shall be used for storage inside the food establishment.~~

3373 B. ~~Containers stored in food preparation and utensil washing areas shall be emptied when full.~~

3374 C. ~~Containers stored outside the food establishment, including dumpsters, compactors, and~~
3375 ~~compactor systems, shall be easily cleanable, shall be insect and rodent proof, shall be~~
3376 ~~provided with tight fitting lids, doors, or covers, and shall be kept covered when not in actual~~
3377 ~~use. Drains in receptacles and waste handling units for refuse, recyclables and returnables~~
3378 ~~shall have drain plugs in place.~~

3379 D. ~~There shall be a sufficient number of containers to hold all the garbage, refuse, compost and~~
3380 ~~recyclables that accumulate.~~

3381 E. ~~Soiled containers, including dumpsters, compactors, and compactor systems, shall be cleaned~~
3382 ~~at a frequency to prevent insect and rodent attraction. Each container shall be thoroughly~~
3383 ~~cleaned on the inside and outside in a way that does not contaminate food, equipment,~~
3384 ~~utensils, or food preparation areas. Suitable facilities, detergent, and hot water or steam,~~
3385 ~~shall be provided and used for cleaning containers. Liquid waste from compacting or~~
3386 ~~cleaning operations shall be disposed of as sewage.~~

3387 **5-302 — Storage**

3388 A. ~~Garbage, refuse, compost and recyclables, on the premises, shall be stored in a manner to be~~
3389 ~~inaccessible to insects and rodents. Cardboard or other packaging material not containing~~
3390 ~~garbage or food wastes need not be stored in covered containers provided such materials do~~
3391 ~~not create a nuisance.~~

3392 B. ~~Indoor garbage or refuse storage rooms, compost and recycling areas if provided, shall be~~
3393 ~~constructed of easily cleanable, nonabsorbent, washable materials, shall be kept clean, and~~
3394 ~~shall be insect and rodent resistant. These areas shall be large enough to store all garbage~~
3395 ~~and refuse containers.~~

3396 C. ~~Outside storage areas or enclosures, if provided, shall be kept clean and shall be large enough~~
3397 ~~to store all the garbage and refuse containers. Garbage, refuse, compost, recycling~~
3398 ~~containers, dumpsters, and compactor systems located outside, shall be stored on a smooth~~
3399 ~~surface of nonabsorbent material, such as concrete or machine laid asphalt, that is kept clean~~
3400 ~~and maintained in good repair.~~

3401 **5-303 — Disposal**

3402 A. ~~Garbage, refuse, compost and recyclable materials shall be removed often enough to prevent~~
3403 ~~the development of objectionable odors and the attraction of insects and rodents.~~

3404 B. ~~Where garbage or refuse is burned on the premises, it shall be done by controlled~~
3405 ~~incineration in accordance with the law. Areas around incineration units shall be kept clean~~
3406 ~~and orderly.~~

3407 **5-304 — Storage Areas, Redeeming Machines, Equipment, and Receptacles, Location**

3408 A. ~~An area designated for refuse, recyclables, compost, returnables and, a redeeming machine~~
3409 ~~for recyclables or returnables, except as specified in paragraph B of this section, shall be~~
3410 ~~located separate from food, equipment, utensils, linens, and single service and single use~~
3411 ~~articles, and a public health nuisance is not created.~~

3412 B. ~~A redeeming machine may be located in the packaged food storage area or consumer area of~~
3413 ~~a retail food establishment if food, equipment, utensils, linens, and single service and single-~~
3414 ~~use articles are not subject to contamination from the machines and a public health nuisance~~
3415 ~~is not created.~~

3416 C. ~~The location of equipment and receptacles for refuse, recyclables, compost and returnables~~
3417 ~~may not create a public health nuisance or interfere with the cleaning of adjacent space.~~

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CHAPTER 6

3420

PHYSICAL FACILITIES3421 **6-1 — FLOORS**3422 **6-101 — Floor Construction**

3423 A. — Floors and floor coverings in all food preparation, food storage, warewashing areas, walk-in
3424 refrigeration units, dressing rooms, locker rooms, utility sink areas, toilet rooms, garbage
3425 rooms, and around permanently installed buffets, salad bars and soft drink dispensers shall
3426 be constructed of smooth, durable, nonabsorbent and easily cleanable material and shall be
3427 maintained in good repair. Areas subject to spilling or dripping of grease or fatty substances
3428 shall be of grease resistant material. Nothing in this section shall prohibit the use of anti-slip
3429 floor coverings in areas where necessary for safety reasons.

3430 B. — Floors which are water flushed or which receive discharges of water or other fluid wastes or
3431 are in areas where pressure spray methods for cleaning are used, shall be provided with
3432 properly installed trapped drains and graded to drain. In all new establishments, floor drains
3433 and floor sinks shall be installed to be accessible for cleaning.

3434 **6-102 — Floor Carpeting**

3435 Carpeting, if used as a floor covering, shall be of closely woven construction, properly installed,
3436 easily cleanable, and maintained in good repair. Carpeting shall not be used in food preparation,
3437 warewashing, food storage, utility sink areas, or in toilet room areas where urinals or fixtures are
3438 located. Carpeting is permitted in the retail sales area provided it is maintained in good repair and
3439 kept clean.

3440 **6-103 — Utility Line Installation**

3441 Exposed utility service lines and pipes shall be installed in a way that does not obstruct or prevent
3442 cleaning of the floor. In all new or extensively remodeled food establishments, installation of
3443 exposed horizontal utility service lines and pipes on the floor is prohibited.

3444 **6-104 — Floor Junctures**

3445 All floors installed in food preparation, food storage and warewashing areas, and in walk-in
3446 refrigerators, dressing or locker rooms, utility sink areas, and toilet rooms, shall provide a coved
3447 juncture between the floor and wall. In all cases, the juncture between the floor and wall shall be
3448 closed and sealed.

3449 **6-105 — Prohibited Floor Covering**

3450 Cardboard, newspapers, sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or
3451 similar materials shall not be used as floor coverings; however, these materials may be used in
3452 amounts necessary for immediate spot clean-up of spills or drippage on floors.

3453 **6-106 — Mats and Duckboards**

3454 Mats and duckboards shall be designed to be removable, easily cleanable, and be maintained clean
3455 and in good repair.

3456 **6-2 — WALLS AND CEILINGS**

3457 **6-201 — Construction**

3458 A. — Walls, wall coverings, and ceilings shall be designed, constructed and installed to be smooth,
3459 durable and easily cleanable.

3460 B. — Except for in dry storage units, walls, including non-supporting partitions, wall coverings
3461 and ceilings of walk-in refrigerating units, food preparation areas, food storage areas,
3462 equipment washing and warewashing areas shall be smooth, nonabsorbent, easily cleanable,
3463 and maintained in good repair. Concrete or pumice blocks used for interior wall construction
3464 in these locations shall be finished and sealed to provide an easily cleanable surface.
3465 Acoustical material, free of porous perforations, smooth and durable enough to be washed
3466 with a cloth or sponge, may be used. Walls, including non-supporting partitions and wall
3467 coverings in toilet rooms shall be smooth, nonabsorbent, and easily cleanable. Porous
3468 acoustical ceilings are permitted in toilet rooms and their vestibules.

3469 **6-202 — Attachments, Exposed Construction**

3470 A. — Except as specified in paragraph C of this section, attachments to walls and ceilings such as
3471 light fixtures, mechanical room ventilation system components, vent covers, wall-mounted
3472 fans, decorative items, and other attachments shall be easily cleanable.

3473 B. — Studs, joists, and rafters shall not be exposed in those areas listed in section 6-201(B) of
3474 these rules and regulations. If exposed in other rooms or areas, they shall be kept clean.

3475 C. — In consumer and backbar areas limited to beverage service and the heating of pre-prepared
3476 foods for immediate service, wall and ceiling surfaces and decorative items and attachments
3477 that are provided for ambiance need not meet this requirement if they are kept clean.

3478 D. — Exposed utility service lines and pipes shall not obstruct or prevent cleaning of walls and
3479 ceilings. Utility service lines or pipes shall not be unnecessarily exposed on walls or ceilings
3480 in those areas listed in section 6-201(B) of these rules and regulations.

3481 **6-3 — LIGHTING**

3482 **6-301 — Light Intensity**

3483 A. — Permanently fixed artificial light sources shall be installed to provide at least 50 foot candles
3484 (540 lux) of light on all food preparation surfaces and at warewashing work levels.

3485 B. — Permanently fixed artificial light sources shall be installed to provide, at a distance of 30
3486 inches (76 cm) from the floor:

3487 1. — At least 20 foot candles (215 lux) of light in sales areas, at consumer service areas
3488 such as buffets and salad bars, utensil and equipment storage areas, and in lavatory
3489 and toilet areas; and

3490 2. ~~At least 10 foot candles (108 lux) of light throughout walk-in refrigeration and~~
3491 ~~freezer units, dry food storage areas, and in all other areas.~~

3492 **6-302 — Light Bulbs, Protective Shielding**

3493 A. ~~Except as specified in paragraph B of this section, light bulbs shall be shielded, coated, or~~
3494 ~~otherwise shatter resistant in areas where there is exposed food, clean equipment, utensils,~~
3495 ~~linens, or unwrapped single-service and single-use articles.~~

3496 B. ~~Shielded, coated or otherwise shatter-resistant bulbs are not required in areas used only for~~
3497 ~~storing food in unopened packages if:~~

3498 1. ~~The integrity of the packages cannot be affected by broken glass falling onto them;~~
3499 ~~and~~

3500 2. ~~The packages are capable of being cleaned of debris from broken bulbs before the~~
3501 ~~packages are opened.~~

3502 C. ~~An infrared or other heat lamp shall be protected against breakage by a shield surrounding~~
3503 ~~and extending beyond the bulb so that only the face of the bulb is exposed.~~

3504 **6-4 — OPERATION AND MAINTENANCE**

3505 **6-401 — Cleaning Physical Facilities**

3506 A. ~~Cleaning of floors, walls, and ceilings shall be done as needed, preferably during periods~~
3507 ~~when the least amount of food is exposed, such as after closing.~~

3508 B. ~~Only dustless methods for cleaning floors, walls, and ceilings shall be used, such as vacuum~~
3509 ~~cleaning, wet cleaning, treated dust mops, or the use of dust-arresting sweeping compounds~~
3510 ~~with brooms.~~

3511 C. ~~Floors, mats, duckboards, walls, ceilings, and attachments (e.g., light fixtures, vent covers,~~
3512 ~~wall and ceiling-mounted fans, and similar equipment), and decorative materials (e.g., signs~~
3513 ~~and advertising materials), shall be kept clean.~~

3514 D. ~~Mop water shall be changed as needed to prevent the recontamination of cleaned surfaces.~~

3515 **6-402 — Cleaning Equipment Storage**

3516 ~~Maintenance and cleaning tools, such as brooms, mops, vacuum cleaners, and similar equipment,~~
3517 ~~shall be maintained in good repair and stored in a way that does not contaminate food, utensils,~~
3518 ~~equipment, or linens. Maintenance and cleaning tools shall be stored in an orderly manner to~~
3519 ~~facilitate the cleaning of the storage area. After use, mops shall be placed in a position that allows~~
3520 ~~them to air-dry without soiling walls, equipment, or supplies.~~

3521 **6-5 — PREMISES**

3522 **6-501 — General**

3523 A. ~~Retail food establishments and all parts of the property used in connection with operations of~~
3524 ~~the retail food establishment shall be kept free of litter, maintained clean and in good repair,~~
3525 ~~and shall comply with local ordinances.~~

3526 B. ~~The outdoor walking and driving areas shall be surfaced with concrete, asphalt, gravel or~~
3527 ~~other materials that have been effectively treated to minimize dust, facilitate maintenance,~~
3528 ~~and minimize muddy conditions. These surfaces shall be graded to drain and kept free of~~
3529 ~~litter. Exterior surfaces of buildings shall be of weather-resistant materials and shall comply~~
3530 ~~with law.~~

3531 C. ~~Only articles necessary to the operation and maintenance of the retail food establishment~~
3532 ~~shall be stored on the premises.~~

3533 **6-502 — Living Areas**

3534 ~~No retail food establishment operation shall be conducted in any area used as living or sleeping~~
3535 ~~quarters. A retail food establishment operation shall be separated from any living or sleeping~~
3536 ~~quarters by complete partitioning and solid, self-closing doors, and shall comply with local~~
3537 ~~requirements.~~

3538 **6-503 — Dressing Rooms and Locker Areas**

3539 A. ~~Dressing rooms or dressing areas shall be designated if employees routinely change their~~
3540 ~~clothes in the establishment.~~

3541 B. ~~Designated areas or other suitable facilities shall be provided for the orderly storage of~~
3542 ~~employees' clothing and other possessions.~~

3543 C. ~~If the retail food establishment provides a storage area for any food belonging to employees~~
3544 ~~it shall be inside a covered, leakproof container designated for the storage of employee food~~
3545 ~~and maintained by the facility.~~

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CHAPTER 7

3548

~~POISONOUS OR TOXIC MATERIALS~~3549 **~~7-1 LABELING AND IDENTIFICATION~~**3550 **~~*7-101 Identifying Information, Prominence~~**

3551 Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's
3552 label.

3553 **~~*7-102 Working Containers~~**

3554 Working containers used for storing poisonous or toxic material, such as cleaners and sanitizers taken
3555 from bulk supplies, shall be clearly and individually identified with at least the name of the material.

3556 **~~*7-103 Separation~~**

3557 Poisonous or toxic materials shall be stored so they do not contaminate food, equipment, utensils,
3558 linens, or single service and single use articles by:

3559 A. ~~Separating the poisonous or toxic materials by spacing or partitioning; and~~

3560 B. ~~Locating the poisonous or toxic materials in an area that is not above food, equipment,~~
3561 ~~utensils, linens, and single service or single use articles. Except that equipment and utensil~~
3562 ~~cleaners and sanitizers may be stored in warewashing areas for availability and convenience~~
3563 ~~if such materials are stored to prevent contamination of food, equipment, utensils, linens, or~~
3564 ~~single service and single use articles.~~

3565 C. ~~Poisonous or toxic materials stored or displayed for retail sale shall be separated from food~~
3566 ~~and single service articles by spacing, partitioning, or dividers. These materials shall not be~~
3567 ~~stored or displayed above food or single service articles.~~

3568 **~~*7-104 Restriction~~**

3569 A. ~~Only those poisonous or toxic materials required for the operation and maintenance of a~~
3570 ~~retail food establishment, such as for the cleaning and sanitizing of equipment and utensils~~
3571 ~~and the control of insects and rodents, shall be allowed in a retail food establishment.~~

3572 B. ~~Paragraph A of this section does not apply to packaged poisonous or toxic materials that are~~
3573 ~~for retail sale.~~

3574 **~~*7-105 Use of Materials~~**

3575 A. ~~Sanitizers, disinfectants, cleaning compounds, or other compounds intended for use on food-~~
3576 ~~contact surfaces shall not be used in a way that leaves a toxic residue on such surfaces in~~
3577 ~~accordance with 40 CFR 180.940 (2005).~~

3578 B. ~~Poisonous or toxic materials shall not be used in a way that contaminates food, food contact~~
3579 ~~surfaces, equipment, utensils, or single service articles, nor in a way other than in full~~
3580 ~~compliance with the manufacturer's labeling.~~

3581 ~~*7-106—Food Containers~~

3582 ~~A container previously used to store poisonous or toxic materials shall not be used as a food contact~~
3583 ~~surface. A container previously used to store food shall not be used as a container to store toxic~~
3584 ~~materials.~~

3585 ~~*7-107—Chemicals for Washing Fruits and Vegetables, Criteria~~

3586 ~~Chemicals used to wash whole fruits and vegetables shall meet the requirements of Chemicals Used~~
3587 ~~In Washing Or To Assist In The Lye Peeling Of Fruits And Vegetables, 21 CFR section 173.315,~~
3588 ~~(2003).~~

3589 ~~*7-108—Boiler Water Additives, Criteria~~

3590 ~~Chemicals used as boiler water additives shall meet the requirements specified in Boiler Water~~
3591 ~~Additives, 21 CFR section 173.310, (2003) (see Appendix D).~~

3592 ~~*7-109—Drying Agents, Criteria~~

3593 ~~Drying agents used in conjunction with sanitization shall be approved by the Department.~~

3594 ~~*7-110—Personal Medications~~

3595 ~~Only those medications necessary for the health of employees shall be present in the retail food~~
3596 ~~establishment. Medications and cosmetics shall be stored in properly labeled containers and located~~
3597 ~~so that food and food contact surfaces of equipment, utensils, linens, single service and single use~~
3598 ~~articles cannot be contaminated. Medications requiring refrigeration and stored in a food refrigerator~~
3599 ~~shall be properly identified, double packaged and located on the lowest shelf. This paragraph does~~
3600 ~~not apply to medications that are stored or displayed for retail sale.~~

3601 ~~*7-111—First Aid Supplies~~

3602 ~~First aid supplies shall be properly labeled and stored in a way that prevents them from contaminating~~
3603 ~~food and food contact surfaces, equipment, utensils, linens, single service and single use articles.~~

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CHAPTER 8

3606

INSECT, RODENT AND ANIMAL CONTROL3607 **8-1 — PREVENTION**3608 **8-101 — Outer Openings, Protected**3609 A. — ~~Openings to the outdoors shall be protected against the entry of insects and rodents by:~~3610 1. — ~~Closed, tight fitting windows; and~~3611 2. — ~~Solid self closing, tight fitting doors; or~~3612 B. — ~~If windows or doors are kept open, the openings shall be protected against the entry of~~
3613 ~~insects and rodents by:~~3614 1. — ~~16 mesh to 1 inch (16 mesh to 25.4 mm) screens,~~3615 2. — ~~Properly designed and installed air curtains to control flying insects, or~~3616 3. — ~~Other effective means.~~3617 C. — ~~Paragraph B of this section does not apply in customer areas if flying insects and other pests~~
3618 ~~are absent due to the location of the retail food establishment, the weather, or other limiting~~
3619 ~~conditions.~~3620 D. — ~~Doors used only for delivery or emergency exit are not required to be equipped with self-~~
3621 ~~closing devices, but shall remain closed at all other times.~~3622 E. — ~~All foundations shall be rodent proof. Openings between the floor and bottom of outer doors,~~
3623 ~~when closed, shall be no greater than one fourth inch (1/4") (0.635 cm).~~3624 **8-102 — Controlling Pests**3625 ~~The presence of insects, rodents, and other pests shall be controlled to minimize their presence on~~
3626 ~~the premises by:~~3627 A. — ~~Routinely inspecting incoming shipments of food and supplies;~~3628 B. — ~~Routinely inspecting the premises for evidence of pests;~~3629 *C. — ~~Using methods, if pests are found, such as trapping devices or other means of pest control as~~
3630 ~~specified in sections 8-103 and 8-104;~~3631 D. — ~~Eliminating harborage conditions; and~~3632 E. — ~~Eliminating infestations.~~3633 **8-103 — Insect Control Devices, Design and Installation**3634 A. — ~~Devices used to electrocute flying insects and that may impel insects or insect fragments~~
3635 ~~shall be:~~3636 1. — ~~Designed to have escape resistant trays; and~~3637 *2. — ~~Installed so that:~~

- 3638 a. ~~The devices are not located over a food preparation area; and~~
- 3639 b. ~~Dead insects and insect fragments are prevented from falling on or being~~
- 3640 ~~impelled onto exposed food, clean equipment, utensils, linens, and~~
- 3641 ~~unwrapped single service and single use articles.~~
- 3642 *B. ~~Devices used to trap insects by adherence may not be installed above exposed food, clean~~
- 3643 ~~equipment, utensils, linens, or unwrapped single service and single use articles unless the~~
- 3644 ~~device is designed to completely contain the trapped insects.~~

3645 ***8-104 Pesticide Application**

- 3646 A. ~~Only pesticides registered for application in a food establishment are permitted and shall be~~
- 3647 ~~applied according to label directions.~~
- 3648 B. ~~A pesticide shall be applied so that direct or indirect contact with food, equipment, utensils,~~
- 3649 ~~linens, and single service and single use articles is prevented by protecting those items as~~
- 3650 ~~follows:~~
- 3651 1. ~~Removing the items;~~
- 3652 2. ~~Covering the items with impermeable covers; or~~
- 3653 3. ~~Taking other appropriate preventive actions; and~~
- 3654 4. ~~Cleaning and sanitizing equipment and utensils after the application of a pesticide.~~
- 3655 C. ~~Bait shall be contained in a covered tamper proof bait station.~~
- 3656 D. ~~Only nontoxic tracking powder such as talcum or flour may be used provided it does not~~
- 3657 ~~contaminate food, equipment, utensils, linens, single service or single use articles.~~

3658 ***8-105 Removing Birds, Insects, Rodents, and Other Pests**

- 3659 ~~Birds, insects, rodents, and other pests shall be removed from control devices and the premises at a~~
- 3660 ~~frequency that prevents their accumulation, decomposition, or the attraction of pests.~~

3661 ***8-106 Prohibiting of Animals**

- 3662 *A. ~~Except as specified in (B) and (C) of this section, live animals may not be allowed on the~~
- 3663 ~~premises of a food establishment.~~
- 3664 B. ~~Provided that the contamination of food; clean equipment, utensils, and linens; and~~
- 3665 ~~unwrapped single service and single use articles is controlled, live animals are allowed in the~~
- 3666 ~~following situations:~~
- 3667 1. ~~Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under~~
- 3668 ~~refrigeration, and shellfish and crustacea in display tank systems;~~
- 3669 2. ~~Patrol dogs accompanying police or security officers in offices and dining, sales, and~~
- 3670 ~~storage areas, and sentry dogs running loose in outside fenced areas;~~
- 3671 3. ~~In areas that are not used for food preparation and that are usually open for~~
- 3672 ~~customers, such as dining and sales areas, service animals that are controlled by the~~
- 3673 ~~disabled employee or person. This does not apply to incidental food contact~~
- 3674 ~~surfaces including dining tables, grocery carts and baskets;~~

- 3675 ~~4. Pets in the common dining areas of institutional care facilities such as nursing~~
3676 ~~homes, assisted living facilities, group homes, or residential care facilities at times~~
3677 ~~other than during meals if:~~
- 3678 ~~a. Effective partitioning and self-closing doors separate the common dining~~
3679 ~~areas from food storage or food preparation areas;~~
- 3680 ~~b. Condiments, equipment, and utensils are stored in enclosed cabinets or~~
3681 ~~removed from the common dining areas when pets are present; and~~
- 3682 ~~c. Dining areas including tables, countertops, and similar surfaces are~~
3683 ~~effectively cleaned before the next meal service; and~~
- 3684 ~~5. In areas that are not used for food preparation, storage, sales, display, or dining, in~~
3685 ~~which there are caged animals or animals that are similarly confined, such as in a~~
3686 ~~variety store that sells pets or a tourist park that displays animals.~~
- 3687 ~~C. Live fish bait shall be stored to prevent contamination of food; clean equipment, utensils, and~~
3688 ~~linens; and unwrapped single-service and single-use articles.~~
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CHAPTER 9

3694

MOBILE RETAIL FOOD ESTABLISHMENTS OR PUSHCARTS3695 **9-1 — MOBILE RETAIL FOOD ESTABLISHMENT**3696 **9-101 — General**

3697 A. — Mobile retail food establishments and pushcarts shall comply with the requirements of these
3698 rules and regulations except as otherwise provided in this chapter. The Department may
3699 impose additional requirements to protect against health hazards related to the conduct of the
3700 mobile retail food establishment or pushcart and may prohibit the sale of any potentially
3701 hazardous foods (time/temperature control for safety foods). This may include maintaining
3702 receipts, logs, or any other records. If restrictions are imposed by the Department, they shall
3703 be in writing with a copy provided on the mobile unit at all times. A list of menu items
3704 prepared and/or served by the operator shall be submitted to the Department and available at
3705 all times. The original retail food establishment license shall be posted on the unit at all
3706 times as per Section 11-101.

3707 — When no apparent health hazard will result, the Department may waive or modify
3708 requirements of these rules and regulations relating to physical facilities, except those
3709 requirements of sections 9-104 and 9-105.

3710 B. — Mobile retail food establishments shall have equipment installed and/or mounted, according
3711 to Section 4-302, within the mobile retail food establishment with the exception of a grill
3712 and/or a smoker, approved by the Department, which shall be allowed outside of the mobile
3713 retail food establishment for cooking of food only. *All foods shall be prepared, assembled
3714 and served from within the mobile retail food establishment and not from the external piece
3715 of cooking equipment.

3716 C. — Pushcarts shall be limited to cooking approved menu items and serving commercially
3717 prepared or commissary prepared food that will result in simple assembly. All items related
3718 to the operation of the pushcart shall be kept on the unit, except for those items specified in
3719 Section 9-108(A).

3720 **9-102 — Exemptions**

3721 Mobile retail food establishments and pushcarts are exempt from requirements for self-contained
3722 water or sewage systems, and cleaning and sanitization of equipment under the following conditions:

3723 A. — The menu is limited to commercially packaged potentially hazardous foods
3724 (time/temperature control for safety foods) or food that is prepared, then packaged in
3725 individual servings, transported and stored and served without further handling under
3726 conditions meeting the requirements of these rules and regulations; and

3727 B. — Beverages served are dispensed from covered urns or other protected equipment; and

3728 C. — The required equipment for cleaning and sanitization exists at the commissary.

3729 **9-103 — Single-service Articles**

3730 Mobile retail food establishments and pushcarts shall provide only single-service articles for use by
 3731 the consumer.

3732 **9-104 — Water System**

3733 *A. — A mobile retail food establishment or a pushcart that does not meet the exemptions of section
 3734 9-102 of these rules and regulations shall provide hot and cold drinking water under pressure
 3735 with sufficient capacity for food preparation, utensil cleaning and sanitizing, in accordance
 3736 with the requirements of these rules and regulations.

3737 B. — The water supply tank shall be designed so that it can be flushed and with a drain that
 3738 permits complete drainage of the tank. The drinking water tank shall have no common
 3739 interior partition with the tank holding non-potable water or other liquids. The water tank
 3740 overflow or vent shall terminate in a downward direction and shall be located and
 3741 constructed so as to prevent the entrance of contaminants.

3742 *C. — When a mobile retail food establishment or pushcart is equipped with a three-compartment
 3743 warewashing sink, the water supply shall be sized to adequately fill warewashing sinks at
 3744 least once every four (4) hours of operation. In addition, the mobile retail food establishment
 3745 or pushcart must supply three (3) gallons of water to each hand-washing sink for each hour
 3746 of operation. Where other water-using fixtures such as toilets, utility sinks, food preparation
 3747 sinks, coffee, espresso and soft drink machines are provided, the water supply shall be sized
 3748 in accordance with the manufacturer's specification for each fixture.

3749 *D. — The water supply tank for push-carts shall have a minimum capacity of at least five (5)
 3750 gallons.

3751 *E. — Adequate water pressure must be provided at all fixtures at all times. A minimum flow rate
 3752 of one (1) gallon per minute or thirty-two (32) ounces per fifteen (15) seconds shall be
 3753 provided.

3754 *F. — Water heating systems shall be adequate to fill the warewashing sink with 110°F water
 3755 without interruptions and to supply hand-sinks with three (3) gallons per hour of 100°F water
 3756 at all times and other hot water-using fixtures and equipment with a continuous supply of hot
 3757 water. Standard tank-type heating systems shall be sized in accordance with Section 5-108.

3758 G. — The water inlet shall be located so that it will not be contaminated by waste discharge, road
 3759 dust, oil, or grease, and it shall be kept capped unless being filled. The water inlet shall be
 3760 provided with a connection of a size or type that will prevent its use for any other service.
 3761 All water distribution pipes or tubing shall be constructed and installed in accordance with
 3762 the requirements of these rules and regulations.

3763 *H. — When a mobile retail food establishment is connected to a pressurized water supply, it shall
 3764 be provided with approved backflow prevention devices. This shall include the protection of
 3765 the water source as well as protection of each individual water service connection.

3766 *I. — The water supply hose and couplings shall be of a size and type compatible with the water
 3767 supply tank inlet fixture and shall be free of cracks and checks. Hose couplings shall be
 3768 constructed to permit a tight connection between the mobile retail food establishment
 3769 coupling and the water supply hose bib. Hose ends must be capped, connected or otherwise
 3770 fully protected when not in use. Only food-grade hoses shall be used to fill or transfer
 3771 drinking water to or within a mobile retail food establishment or a pushcart.

3772 ~~*J. Water systems and components shall be disinfected and flushed in accordance with 25-1.5-2,~~
 3773 ~~C.R.S., Colorado Primary Drinking Water Regulations, prior to use, if the mobile retail food~~
 3774 ~~establishment or pusheart is not in daily use.~~

3775 ~~9-105 Wastewater Retention~~

3776 ~~*A. A mobile retail food establishment or pusheart that does not meet all the restrictions of~~
 3777 ~~section 9-102 of these rules and regulations must provide a waste water retention tank. All~~
 3778 ~~liquid waste, except drainage from clean ice made with drinking water, generated by a~~
 3779 ~~mobile retail food establishment or pusheart shall be stored in a retention tank that is at least~~
 3780 ~~15 percent larger than the water supply tank. Liquid waste shall be discharged from the~~
 3781 ~~retention tank to an approved sewage disposal system and flushed as often as necessary to~~
 3782 ~~maintain sanitary conditions. Discharge onto the surface of the ground shall be strictly~~
 3783 ~~prohibited. Drainage from uncontaminated ice made with drinking water can be discharged~~
 3784 ~~onto the surface of the ground provided it does not create a nuisance.~~

3785 ~~B. All connections on the vehicle for servicing mobile food unit waste disposal facilities shall~~
 3786 ~~be of a different size or type than those used for supplying potable drinking water to the~~
 3787 ~~mobile food establishment. The waste water outlet connection shall be located lower than~~
 3788 ~~the drinking water inlet connection to prevent contamination of the drinking water system.~~

3789 ~~C. Liquid waste discharge piping and the drinking water hose shall not be stored in a manner~~
 3790 ~~that may result in contamination.~~

3791 ~~*9-106 Handwashing Facilities~~

3792 ~~A mobile retail food establishment or pusheart that does not meet all the exemptions of section 9-102~~
 3793 ~~of these rules and regulations must be equipped with a convenient, accessible handsink installed as~~
 3794 ~~specified in Section 5-208(J) for employee handwashing. The handsink must be capable of providing~~
 3795 ~~a hands free, continuous flow of 100°F water as specified in Section 9-104(F). Soap and individually~~
 3796 ~~dispensed paper towels must also be provided at the handsink.~~

3797 ~~9-107 Commissary~~

3798 ~~A. The commissary is considered to be an essential part of the mobile food retail food~~
 3799 ~~establishment and push cart operation. The commissary shall be constructed and operated in~~
 3800 ~~compliance with the requirements of these rules and regulations. Mobile retail food~~
 3801 ~~establishments and pushearts shall operate from a commissary or other fixed retail food~~
 3802 ~~establishment and shall report every 24 hours (on operational days) to that location for~~
 3803 ~~supplies, cleaning and servicing operations.~~

3804 ~~— The use of the proposed commissary for each mobile retail food establishments or pushearts~~
 3805 ~~shall be submitted and approved by the department. The mobile retail food establishment or~~
 3806 ~~pusheart shall provide an agreement from the commissary operator to the department each~~
 3807 ~~calendar year and upon change of a commissary location.~~

3808 ~~— The agreement shall specify the mobile retail food establishment or push cart is allowed to~~
 3809 ~~report to the commissary daily, and is allowed to use the facility's warewashing equipment,~~
 3810 ~~refrigeration, food preparation equipment and storage areas as a base for operation. The~~
 3811 ~~agreement shall also specify how and where the commissary use log will be maintained.~~
 3812 ~~These commissary records shall be made available to the Department when requested.~~

3813 ~~B. Accommodations for a servicing area shall be available with a drinking water supply for the~~
 3814 ~~mobile retail food establishment or push cart. Servicing may include vehicle and equipment~~

- 3815 ~~cleaning, discharging liquid or solid wastes, refilling water tanks, and restocking of ice bins,~~
 3816 ~~and food.~~
- 3817 1. ~~Drinking water servicing equipment shall be installed according to the law and shall be~~
 3818 ~~stored and handled to protect the water and equipment from contamination~~
 3819 ~~according to section 5-101 and 5-102.~~
- 3820 2. ~~The mobile retail food establishment and push cart liquid waste retention tank shall be~~
 3821 ~~thoroughly drained and flushed during servicing. All liquid waste shall be~~
 3822 ~~discharged to a sanitary sewage system in accordance with section 5-211 of these~~
 3823 ~~rules and regulations.~~
- 3824 3. ~~There shall be a location provided for the flushing and drainage of liquid wastes that is~~
 3825 ~~separate from the location provided for obtaining drinking water and for the loading~~
 3826 ~~and unloading of food and related supplies.~~
- 3827 ~~C. When servicing areas are provided as part of the commissary, the floor surfaces of the~~
 3828 ~~servicing area shall be constructed of a smooth, nonabsorbent material such as concrete or~~
 3829 ~~machine laid asphalt and shall be maintained in good repair, kept clean, and be graded to~~
 3830 ~~drain.~~
- 3831 ~~The construction of the walls and ceilings of the servicing area is exempt from the provisions~~
 3832 ~~of sections 6-201 and 6-202 of these rules and regulations.~~
- 3833 ~~D. A self-contained mobile retail food establishment is not required to report to a commissary~~
 3834 ~~if:~~
- 3835 1. ~~Adequate storage areas are provided within the mobile retail food establishment for~~
 3836 ~~food, dry goods, single service articles and cleaning supplies; and~~
- 3837 2. ~~Adequate facilities including a hand sink, food preparation sink, warewashing~~
 3838 ~~facilities, mop sink, mechanical refrigeration, and any additional equipment are~~
 3839 ~~provided as required by the menu.~~
- 3840 3. ~~Adequate accommodations for food preparation, storage of food, equipment, utensils~~
 3841 ~~and other supplies; and~~
- 3842 4. ~~Approved arrangements and facilities are provided and used to supply drinking~~
 3843 ~~water to the mobile unit and for the disposal of wastewater generated by the~~
 3844 ~~establishment; and~~
- 3845 5. ~~A written operational plan is submitted by the mobile retail food establishment,~~
 3846 ~~which demonstrates that this process can be accomplished in compliance with these~~
 3847 ~~rules and regulations. Review and approval of this plan must include the menu and~~
 3848 ~~standard operating procedures for the mobile unit. Once an operational plan is~~
 3849 ~~approved, any additions or changes to the approved plan must be approved by the~~
 3850 ~~Department prior to implementation. The approved operational plan must be~~
 3851 ~~available on the mobile retail food establishment at all times.~~
- 3852 ~~E. A mobile retail food establishment is prohibited from acting as a commissary for another~~
 3853 ~~retail food establishment.~~

3854 **9-108 Additional Requirements**

- 3855 A. ~~Spare tires, tools, and other equipment relating to the mechanical operation of the vehicle~~
 3856 ~~shall be stored in a way that does not contaminate food, food equipment, or utensils.~~

- 3857 ~~B. — Except for service windows, any openable windows and doors must be screened. Service~~
3858 ~~windows must be self-closing.~~
- 3859 ~~C. — Restroom facilities shall be available to employees at all times that the mobile retail food~~
3860 ~~establishment or pushcart is in operation.~~
- 3861 ~~*D. — Equipment shall be adequate to maintain potentially hazardous foods (time/temperature~~
3862 ~~control for safety foods) at required temperatures in accordance with Parts 3-5 and 3-6. In~~
3863 ~~addition:~~
- 3864 ~~1. — Mobile retail food establishments shall utilize mechanical refrigeration to hold and~~
3865 ~~serve potentially hazardous foods (time/temperature control for safety foods).~~
- 3866 ~~2. — Pushcarts may use no more than two (2) hard-sided coolers to maintain food at~~
3867 ~~required temperatures. One cooler shall be used for all raw animal foods and the~~
3868 ~~other cooler for all other potentially hazardous foods (time/temperature control for~~
3869 ~~safety foods). If the facility needs additional refrigeration space, the pushcart shall~~
3870 ~~provide commercial mechanical refrigeration.~~
- 3871 ~~*E. — Mobile retail food establishments and pushcarts shall provide enough clean utensils to satisfy~~
3872 ~~the requirements of section 4-407(C).~~
- 3873 ~~F. — Items for customer self-service shall be adequately protected from contamination.~~
- 3874

3875

CHAPTER 10

3876

TEMPORARY RETAIL FOOD ESTABLISHMENTS

3877

10-1 TEMPORARY RETAIL FOOD ESTABLISHMENTS

3878

10-101 General

3879

~~A temporary retail food establishment shall comply with all requirements of these rules and regulations, except as otherwise provided in this chapter.~~

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~~A temporary event vendor application, which shall include a list of food items to be sold, shall be submitted to the Department for each event. The vendor application shall be submitted at least ten (10) working days prior to the event. Approval will be based upon menu, equipment, setup and the ability to protect against public health hazards.~~

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~~Mobile retail food establishments and pushcarts operating at temporary events shall operate according to chapter 9 of these rules and regulations.~~

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10-102 Operations

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~~*A. Food preparation at the event shall be limited to seasoning, cooking, assembly of pre-prepared foods and service of packaged foods stored at required temperatures.~~

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~~*B. All slicing, chopping, peeling, dicing, shredding and washing of produce shall be done at an approved commissary.~~

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~~C. Food and food contact surfaces of equipment shall be protected from contamination by consumers or other sources. Appropriate coverings, packaging, shields, barriers, or other means shall be provided as necessary to prevent contamination.~~

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~~*D. Equipment shall be maintained and operated per its intended use and design.~~

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~~E. Equipment shall be located and installed to facilitate cleaning. No grease from grease producing equipment shall discharge onto the ground or into any storm drainage system.~~

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3898

10-103 Commissary

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~~A. Temporary Retail Food Establishment vendors shall operate from a commissary approved by the Department and shall provide a commissary agreement to the Department for each event. Vendors with limited menus operating from licensed self-contained mobile units in accordance with section 9-107(D) may be allowed to operate without a commissary.~~

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~~B. The commissary for vendors operating at an event of more than one (1) day in duration shall be within 30 minutes or 30 miles of the event.~~

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~~C. All foods, utensils, and single use articles shall be transported from the commissary to the event site in a manner that protects them from contamination. Food product temperature shall be maintained as required in section 3-501.~~

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 3910 ~~D. The commissary shall be constructed and operated in compliance with the requirements of~~
 3911 ~~these rules and regulations. Temporary retail food establishments shall operate from a~~
 3912 ~~commissary or other fixed retail food establishment and shall report at a minimum of every~~
 3913 ~~24 hours (on operational days) to that location for all supplies, all cleaning, advanced food~~
 3914 ~~preparation, and servicing operations. The commissary operator, as requested by the~~
 3915 ~~Department, shall verify to the Department when the temporary retail food establishment~~
 3916 ~~reports to the commissary.~~

3917 1. ~~The agreement shall specify the temporary retail food establishment is allowed to~~
 3918 ~~report to the commissary daily, is allowed to use the facility's warewashing~~
 3919 ~~equipment, refrigeration, food preparation equipment and storage areas as a base for~~
 3920 ~~operation. The commissary operator shall maintain written documentation or a log~~
 3921 ~~as to when the temporary retail food establishment utilizes the commissary. These~~
 3922 ~~records shall be made available to the Department when requested.~~

3923 2. ~~Temporary retail food establishment operators shall maintain written records of~~
 3924 ~~purchases detailing the source of all foods being held, stored, offered for sale, sold~~
 3925 ~~and distributed and expenses including receipts for expenditures such as servicing~~
 3926 ~~operations. These records shall be made available to the Department when~~
 3927 ~~requested.~~

3928 ~~10-104 Minimum Event Site Equipment Requirements~~

3929 *A. ~~Equipment for heating and holding food cold and hot, shall be sufficient in number and~~
 3930 ~~capacity to maintain foods at required temperatures. Equipment utilizing fuel gel canister is~~
 3931 ~~prohibited at outdoor venues unless approved by the Department.~~

3932 *B. ~~A conveniently located hand washing station shall be provided within the Temporary Retail~~
 3933 ~~Food Establishment.~~

3934 *C. ~~Extra utensils and in use food contact surfaces (cutting boards, tongs, knives, etc.) shall be~~
 3935 ~~provided to allow soiled items to be replaced at a minimum of every four (4) hours.~~
 3936 ~~Warewashing of equipment and utensils shall be conducted at an approved facility. Onsite~~
 3937 ~~warewashing is prohibited unless otherwise approved by the Department.~~

3938 D. ~~A sufficient number of smooth, non absorbent, and easily cleanable work surfaces shall be~~
 3939 ~~provided where food is being handled.~~

3940 E. ~~Coolers and containers used to store food shall be durable, smooth, non absorbent and easily~~
 3941 ~~cleanable. Styrofoam and soft sided coolers are prohibited.~~

3942 F. ~~A clean trash receptacle shall be provided.~~

3943 ~~*10-105 Ice~~

3944 ~~Only ice which has been manufactured from drinking water and handled in a sanitary manner shall be~~
 3945 ~~used or offered for sale. Ice used as a cooling medium for food storage, beverage containers, food~~
 3946 ~~containers or food utensils shall not be used or sold for human consumption.~~

3947 ~~10-106 Single Service Articles~~

3948 ~~All temporary retail food establishments shall provide only single service articles for use by the~~
 3949 ~~consumer.~~

3950 ~~*10-107 Water~~

3951 A sufficient quantity of drinking water shall be available for food preparation, wiping cloth solutions,
3952 and sanitization of food contact surfaces. The water supply system hoses, piping, and fixtures shall be
3953 fabricated of approved food contact materials. The water supply system must be installed to preclude
3954 the backflow of contaminants into the drinking water supply.

3955 ~~10-108 Wet Storage~~

3956 Packaged food may be stored in direct contact with drinking ice or drinking water if the packaging,
3957 wrapping, or container is not subject to entry of water. The storage of food and/or beverage, in
3958 undrained ice is prohibited.

3959 ~~*10-109 Waste~~

3960 All sewage, including liquid waste, shall be disposed of according to law. Waste water shall not be
3961 discharged onto ground or into storm drainage system. Drainage from clean drinking ice may be
3962 discharged onto the surface of the ground provided it does not create a nuisance.

3963 ~~*10-110 Handwashing~~

3964 A. ~~— A minimum of five (5) gallons of drinking water shall be provided for hand washing. The~~
3965 ~~required volume of water will be based upon menu, equipment, and hours of operation. Push~~
3966 ~~button spigots on the water supply containers are not permitted.~~

3967 B. ~~— Soap and dispensed paper towels shall be provided at each hand washing station.~~

3968 C. ~~— A hand washing station that is capable of providing hands free continuous flowing warm~~
3969 ~~water of adequate pressure shall be provided.~~

3970 D. ~~— A basin that is capable of capturing hand washing waste water and conveying it into a closed~~
3971 ~~waste water container shall be provided.~~

3972 ~~*10-111 Screening and Enclosures~~

3973 Screening or other provisions may be required to prevent the entrance of pests and debris.

3974 ~~*10-112 Grounds~~

3975 Areas within the Temporary Retail Food Establishment shall be free from standing water, mud, dust
3976 and fecal material. Additional ground covering material may be required such as removable
3977 platforms, duckboards, wood chips or other suitable material.

3978 ~~*10-113 Overhead Protection~~

3979 Overhead protection shall be provided and be made of wood, canvas, or other materials that protect
3980 the interior of the establishment from weather, or other contamination. Any grease producing
3981 equipment or equipment with open flames shall not be located under overhead protection.

3982

3983

CHAPTER 11

3984

COMPLIANCE PROCEDURES3985 **11-1—COMPLIANCE**3986 **11-101—General**

3987 ~~A person shall have a valid retail food establishment license, certificate of license, as defined in~~
 3988 ~~section 25-4-1602, C.R.S. and administration and inspection fees pursuant to sections 25-4-1607,~~
 3989 ~~C.R.S., to operate a retail food establishment. A person operating a retail food establishment without~~
 3990 ~~a valid license, certificate of license or appropriate administration and inspection fees may be~~
 3991 ~~prosecuted under sections 16-13-305, 25-4-1609, and 25-14-1610 C.R.S. Only a person who~~
 3992 ~~complies with the requirements of these rules and regulations shall be entitled to receive or retain~~
 3993 ~~such a license or certificate. Licenses, certificates, or administration and inspection fees are not~~
 3994 ~~transferable. When issued, a valid license or certificate shall be posted in every retail food~~
 3995 ~~establishment.~~

3996 **11-102—Issuance of License or Certificate of License**

3997 ~~A. Any person desiring to operate a retail food establishment shall make written application for~~
 3998 ~~a license or certificate of license or pay administration and inspections fees using forms~~
 3999 ~~provided by the Department. Each application form shall include the name and address of~~
 4000 ~~each applicant, the location and type of the proposed retail food establishment, and the~~
 4001 ~~signature of each applicant.~~

4002 ~~B. Prior to approval of an application for a license or certificate of license, the Department may~~
 4003 ~~inspect the proposed retail food establishment to determine compliance with the rules and~~
 4004 ~~regulations.~~

4005 ~~C. The Department shall approve a license or certificate of license for the applicant if its~~
 4006 ~~inspection reveals that the proposed retail food establishment complies with the requirements~~
 4007 ~~of these rules and regulations.~~

4008 ~~D. An existing Retail Food Establishment shall be required to obtain a new Retail Food~~
 4009 ~~Establishment license when there is a change of ownership that requires a new Colorado~~
 4010 ~~Department of Revenue Sales Tax Account Number, or if the physical location of the~~
 4011 ~~establishment changes.~~

4012 **11-103—License Renewal**

4013 ~~The Department may refuse to renew a retail food establishment license or certificate of license for~~
 4014 ~~any violation of sections 25-4-1601 et seq., C.R.S., of these rules and regulations, or as otherwise~~
 4015 ~~provided by law. This notification shall be presented to license or certificate holders during the last~~
 4016 ~~quarter of each calendar year. Denial of a license renewal shall be treated in all respects as a~~
 4017 ~~revocation and, hence, procedures for revocation shall be followed. In a case in which the license or~~
 4018 ~~certificate holder has made timely and sufficient application for renewal of license, the existing~~
 4019 ~~license shall not expire until such application has been finally acted upon by the Department.~~

4020 **11-104—Judicial Review**

4021 A license or certificate holder adversely affected or aggrieved by a Departmental action may appeal
4022 the final action of the Department as provided in section 24-4-106, C.R.S. Suspension or revocation
4023 of a license may be reviewed, upon application for an order in the nature of mandamus or otherwise,
4024 by any court of general jurisdiction as provided in section 25-4-1609, C.R.S.

4025 **11-105—Closure Without Suspension**

4026 Acting under sections 25-1.5-101(1)(a) and 25-1.5-102(1)(a) & (d), C.R.S., the Department, or its
4027 authorized representative, shall have the power and duty to close retail food establishments and forbid
4028 the gathering of people therein to protect the public health from the cause of epidemic and
4029 communicable diseases. Immediate closure shall be used only when the situation imperatively
4030 requires emergency action or the operator has been guilty of deliberate and willful violation that is
4031 injurious or creates an imminent public health hazard as defined in Section 1-201(A)(57).

4032 **11-106—Injunctive Relief**

4033 When serious or repeated violations of these rules and regulations have been found, the Department
4034 or its authorized agents may abate the nuisance by seeking injunctive relief through judicial means, as
4035 provided under section 16-13-308 and 309, C.R.S.

4036 **11-2—INSPECTIONS**

4037 **11-201—Inspection Frequency**

4038 A. An inspection of a retail food establishment shall be performed at least twice every calendar or
4039 fiscal year; or

4040 B. The *Colorado Retail Food Establishment Risk Based Inspectional Frequency Methodology*
4041 *Guidance Document* may be used as a model for an alternative method for determining
4042 inspectional frequency. If this model is modified by an agency, the agency must be able to
4043 defend the modifications utilizing the public health risk factors contained in the model. The
4044 public health risk factors include: 1) food served, 2) operations, 3) weekly meal volume, and
4045 4) inspectional history including critical and non-critical violations. The minimum inspection
4046 frequency for an establishment falling in the low risk category is once every two years.

4047 C. Additional inspections may be performed based upon additional assessments of potential risks of
4048 foodborne illness including a history of non-compliance with these rules and regulations; the
4049 hazards associated with the particular foods being prepared, stored or served; the method and
4050 extent of food storage, preparation and service; and the number and demographic
4051 characteristics of the consumers.

4052 **11-202—Access**

4053 Agents of the Department, after proper identification, shall be permitted to enter any retail food
4054 establishment during business hours and at other times during which activity is evident in accordance
4055 with 25-4-1604(1)(e) to determine compliance with these rules and regulations. The agents shall be
4056 permitted to examine documents or true copies of documents, excluding prices, that pertain directly
4057 to food and supplies purchased, received or used, information pertinent to their HACCP plan, or to
4058 persons employed in food and beverage operations when such examination is expected to produce

4059 information necessary to protect the public health, enforce these rules and regulations or investigate
4060 suspected incidents of foodborne illnesses.

4061 **11-203—Report of Inspections**

4062 Whenever an inspection of a retail food establishment or commissary is made, the findings shall be
4063 recorded on an inspection report form. The inspection report form shall summarize the requirements
4064 of these rules and regulations. The Department shall document, on the inspection report form,
4065 specific factual observations of violative conditions or other deviations from these rules and
4066 regulations. Once the inspection has been completed and the inspection report form is finalized, a
4067 copy of the completed inspection report form shall be furnished to the person in charge of the
4068 establishment. The completed inspection report form is a public document that shall be made
4069 available for public disclosure to any person who requests it according to law.

4070 **11-204—Correction of Violations**

4071 A. The inspection report form shall specify a reasonable period of time for the correction of the
4072 violations found and correction of the violations shall be accomplished within the period
4073 specified, in accordance with the following provisions:

4074 1. If an imminent health hazard exists, such as, but not limited to, absence of adequate
4075 of refrigeration, no water supply, non-functional water heating system, severe and
4076 active pest infestation, or sewage backup into the establishment, the establishment
4077 shall immediately cease food operations. Operations shall not be resumed until
4078 authorized by the Department.

4079 2. All critical violations are to be corrected as soon as possible, but in any event, by the
4080 date and time specified by the Department, but in no case to exceed ten (10) days.

4081 3. All non-critical violations shall be corrected by the date and time agreed to or
4082 specified by the Department based upon the severity of potential health hazards,
4083 which could result from the non-critical violation. The Department is not required
4084 to conduct follow-up activities on non-critical violations.

4085 B. The inspection report shall state that failure to comply with any time limits may result in the
4086 initiation of administrative or legal regulatory action. An opportunity for appeal of the
4087 inspection findings and time limitation will be provided if a written request for an
4088 administrative hearing is filed with the Department within thirty (30) days following the date
4089 of receipt of inspection. If the request for a hearing is received, a hearing shall be held no
4090 sooner than twenty (20) days after the operator is notified of the hearing.

4091 C. Whenever a retail food establishment is required under the provisions of these rules and
4092 regulations to cease operations, it shall not resume operations until a re-inspection
4093 determines that conditions responsible for the requirement to cease operations no longer
4094 exists. Opportunity for re-inspection shall be offered within a reasonable time.

4095

4096 **11-205 Inspection Report**

4097 The format of an inspection form shall be based upon critical and non-critical categories. The
 4098 following items must be included:

Item	Category
FOOD SOURCE DATE MARKING AND CONSUMER ADVISORY — a. Approved source — b. Wholesome, free of spoilage — c. Cross Contamination — d. Specialized Processes/HACCP plan — e. Date marking — f. Consumer Advisory	CRITICAL
PERSONNEL Employee Health — a. Personnel with infections restricted — b. Wounds properly covered Hygienic Practices — c. Hands washed as needed — d. Hygienic practices — e. Smoking, eating, drinking Demonstration of knowledge — f. Training needed — g. Preventing food contamination from bare hands	CRITICAL
FOOD TEMPERATURE CONTROL Temperature Control Procedures — a. Rapidly cool foods to 41° F or less — b. Rapidly reheat to 165° F or greater — c. Hot hold at 135° F or greater — d. Required cook temperature — e. Cold hold at 41° F or less Temperature Control Equipment — f. Use of Food thermometer (probe type) — g. Adequate equipment to maintain food temperatures	CRITICAL
SANITIZATION RINSE — a. Clean — b. Temperature — c. Concentration — d. Exposure	CRITICAL

Item	Category
WATER, SEWAGE, PLUMBING SYSTEMS	CRITICAL
<ul style="list-style-type: none"> a. Safe water source b. Hot and cold water under pressure c. Backflow, backsiphonage d. Sewage disposal 	
HANDWASHING FACILITIES	CRITICAL
<ul style="list-style-type: none"> a. Adequate number, location b. Accessible c. Soap and drying devices available 	
PEST CONTROL	CRITICAL
<ul style="list-style-type: none"> a. Evidence of insects or rodents b. Pesticide application c. Animals prohibited 	
POISONOUS OR TOXIC ITEMS	CRITICAL
<ul style="list-style-type: none"> a. Properly stored b. Properly labeled c. Properly used 	
FOOD LABELING , FOOD PROTECTION	NON CRITICAL
<ul style="list-style-type: none"> a. Original container, properly labeled b. Food protected from contamination 	
EQUIPMENT DESIGN CONSTRUCTION	NON CRITICAL
<ul style="list-style-type: none"> a. Food contact surfaces b. Nonfood contact surfaces c. Dishwashing facilities 	
TESTING DEVICES	NON CRITICAL
<ul style="list-style-type: none"> a. Refrigeration units provided with accurate, conspicuous thermometers b. Dishmachines provided with accurate thermometer and gauge cock c. Chemical test kits provided, accessible 	
CLEANING OF EQUIPMENT AND UTENSILS	NON CRITICAL
<ul style="list-style-type: none"> a. Food contact surfaces b. Nonfood contact surfaces c. Dishwashing operations d. Wiping cloths 	

Item	Category
UTENSILS, SINGLE SERVICE ARTICLES	NON CRITICAL
— a. Utensils provided, used, stored	
— b. Single service articles stored, dispensed, used	
— c. No reuse of single service articles	
PHYSICAL FACILITIES	NON CRITICAL
— a. Plumbing: installed, maintained	
— b. Garbage and refuse	
— c. Floors, walls, ceiling	
— d. Lighting	
— e. Ventilation	
— f. Locker rooms	
— g. Premises maintained	
— h. Separation of living, laundry	
— i. Restroom facilities	
OTHER OPERATIONS	NON CRITICAL
— a. Personnel: clean clothes, hair restraints, authorized	
— b. Linen properly stored	

4099 ~~11-3 CONDEMNATION AND EMBARGO OF FOOD~~

4100 ~~11-301 General~~

4101 ~~The power and duty to condemn and embargo food that the Department finds probable cause to~~
 4102 ~~believe is in violation of section 3-101 of these rules and regulations has been given to the~~
 4103 ~~Department under the statutory authority of sections 25-1.5-104(a) and 25-5-406 et. seq., C.R.S.~~

4104 ~~11-302 Voluntary Condemnation~~

4105 ~~When the Department finds food that it has probable cause to believe is in violation of section 3-101~~
 4106 ~~of these rules and regulations, the Department shall bring the fact to the attention of the person in~~
 4107 ~~charge and request that the food be voluntarily destroyed. If the person in charge agrees to destroy~~
 4108 ~~the suspect food, a voluntary condemnation agreement shall be completed and signed. The person in~~
 4109 ~~charge shall denature the food under the supervision of the Department. A copy of the voluntary~~
 4110 ~~condemnation agreement shall be left with the person in charge.~~

4111 ~~11-303 Embargo Placement~~

4112 ~~When the Department finds food that it has probable cause to believe is in violation of section 3-101~~
 4113 ~~of these rules and regulations, the Department shall bring the fact to the attention of the person in~~
 4114 ~~charge and request that the food be voluntarily destroyed. Should the person in charge refuse to~~
 4115 ~~voluntarily destroy the food, the Department shall embargo the remainder of the food. An embargo~~
 4116 ~~notice shall be completed and signed. A copy of the embargo notice shall be left with the person in~~
 4117 ~~charge. The remainder of the food product shall be set aside for storage in a container sealed with~~

4118 ~~sampling tape to prevent usage. No person shall remove or dispose of such embargoed article by sale~~
4119 ~~or otherwise.~~

4120 ~~11-304—Embargo Release~~

4121 ~~A. The Department shall complete and sign an embargo release which dictates the subsequent~~
4122 ~~disposition of the product by:~~

4123 ~~1. Use of the product in the establishment where it was found if demonstrated to be in~~
4124 ~~compliance with section 3-101 of these rules and regulations; or~~

4125 ~~2. Use of the product by other approved means; or~~

4126 ~~3. Destruction of the product.~~

4127 ~~B. A copy of this release shall be given to the person in charge.~~

4128 ~~C. Neither the Department nor the State shall be held liable for damages because of such~~
4129 ~~embargo.~~

4130 ~~11-305—Condemnation of Product~~

4131 ~~Should the food be found to be not sound or contaminated with filth and a voluntary destruction~~
4132 ~~cannot be obtained, the Department shall petition the court of jurisdiction for seizure and disposition~~
4133 ~~of the food.~~

4134 ~~11-4—REVIEW OF PLANS~~

4135 ~~11-401—Submission of Plans~~

4136 ~~It shall be necessary to submit to the Department detailed plans and specifications of a proposed~~
4137 ~~newly constructed retail food establishment and or the affected areas of any proposed extensively~~
4138 ~~remodeled retail food establishment. Each retail food operator, or person intending to become a retail~~
4139 ~~food operator, shall be responsible for submitting all plans and specifications. Those assisting an~~
4140 ~~operator may submit plans and specifications on the operator's authority. The Department shall be~~
4141 ~~consulted before preparation of plans and specifications. Approval of both plans and specifications is~~
4142 ~~necessary before construction begins. A minimum of two (2) weeks shall be necessary for the~~
4143 ~~Department to review the plans. Any revision of plans shall be submitted to the Department for~~
4144 ~~review and modification or approval.~~

4145 ~~11-402—Contents of Plans and Specifications~~

4146 ~~Contents of the plans and specifications shall show evidence that the facility complies with applicable~~
4147 ~~portions of these rules and regulations. A plan view scale drawing of the establishment shall be~~
4148 ~~provided. The plans shall include the location of all retail food equipment, plumbing fixtures and~~
4149 ~~connections, ventilation systems, menu and other pertinent information. A dimensional sketch of the~~
4150 ~~entrance, exits, streets, roadways and alleys shall also be included. Specifications shall be provided~~
4151 ~~on a form supplied by the Department.~~

4152 ~~11-403—Contents of a HACCP Plan~~

4153 ~~A. For a food establishment that is required in section 3-506 to have a HACCP plan, the plan~~
4154 ~~and specifications shall indicate:~~

- 4155 1. ~~A categorization of the types of potentially hazardous foods (time/temperature~~
 4156 ~~control for safety foods) that are specified in the menu such as soups and sauces,~~
 4157 ~~salads, and bulk, solid food such as meat roasts, or of other foods that are specified~~
 4158 ~~by the Department;~~
- 4159 2. ~~A flow diagram by specific food or category type identifying critical control points~~
 4160 ~~and providing information on the following:~~
- 4161 a. ~~Ingredients, materials, and equipment used in the preparation of that food;~~
 4162 ~~and~~
- 4163 b. ~~Formulations or recipes that delineate methods and procedural control~~
 4164 ~~measures that address the food safety concerns involved;~~
- 4165 3. ~~Food employee and supervisory training plan that addresses the food safety issues of~~
 4166 ~~concern.~~
- 4167 4. ~~A statement of standard operating procedures for the plan under consideration~~
 4168 ~~including clearly identifying:~~
- 4169 a. ~~Each critical control point;~~
- 4170 b. ~~The critical limits for each critical control point;~~
- 4171 c. ~~The method and frequency for monitoring and controlling each critical~~
 4172 ~~control point by the food employee designated by the person in charge;~~
- 4173 d. ~~The method and frequency for the person in charge to routinely verify that~~
 4174 ~~the food employee is following standard operating procedures and~~
 4175 ~~monitoring critical control point;~~
- 4176 e. ~~Action to be taken by the person in charge if the critical limits for each~~
 4177 ~~critical control point are not met; and~~
- 4178 f. ~~Records to be maintained by the person in charge to demonstrate that the~~
 4179 ~~HACCP plan is properly operated and managed; and~~
- 4180 5. ~~Additional scientific data or other information, as required by the Department,~~
 4181 ~~supporting the determination that food safety is not compromised by the proposal.~~

4182 ~~11-404—Pre-Operational Inspection~~

4183 ~~Whenever plans and specifications are required by section 11-401 of these rules and regulations to be~~
 4184 ~~submitted to the Department, the Department shall inspect the retail food establishment prior to its~~
 4185 ~~beginning operation to determine compliance with the approved plans and specifications and with the~~
 4186 ~~requirements of these rules and regulations. It shall be necessary to arrange for a pre-opening~~
 4187 ~~inspection fourteen (14) days in advance of the date of the intended inspection. For areas of the state~~
 4188 ~~without a Local Health Department, it shall be necessary to arrange for a pre-opening inspection~~
 4189 ~~twenty-one (21) days in advance of the date of the intended inspection.~~

4190 ~~11-5—PROCEDURE WHEN INFECTION IS SUSPECTED~~

4191 ~~11-501—General~~

4192 ~~When the Department has reasonable cause to suspect the possibility of disease transmission from~~
 4193 ~~any retail food establishment employee, it may secure a morbidity history of the suspected employee~~

- 4194 ~~or make any other investigation as necessary and shall take appropriate action. The Department may~~
 4195 ~~require any or all of the following measures:~~
- 4196 A. ~~— The immediate exclusion of the employee from all retail food establishments in accordance~~
 4197 ~~with 2-202;~~
- 4198 B. ~~— The immediate closing of the retail food establishment concerned until, in the opinion of the~~
 4199 ~~Department, no further danger of disease outbreak exists;~~
- 4200 C. ~~— Restriction of the employee's services to some area of the establishment where there would~~
 4201 ~~be no danger of disease transmission in accordance with 2-203;~~
- 4202 D. ~~— Adequate medical and laboratory examination of the employee and other employees in~~
 4203 ~~accordance with 2-203.~~

4204 ~~11-6~~ **VARIANCE PROCEDURE**

4205 ~~11-601~~ **Variance Procedure**

- 4206 A. ~~— Any retail food establishment may request a variance from any requirement of these rules~~
 4207 ~~and regulations when such an establishment believes that the requirement results in an undue~~
 4208 ~~economic hardship or when it is believed a standard may not apply to the specific situation.~~
- 4209 B. ~~— Requests shall be submitted in writing to the Colorado Department of Public Health and~~
 4210 ~~Environment and shall include the name and location of the business, the name of the~~
 4211 ~~licensee or prospective licensee when applicable, and the section for which a variance is~~
 4212 ~~being requested. This request must be accompanied with a recommendation for approval or~~
 4213 ~~denial from the health agency of jurisdiction. Evidence of undue economic hardship should~~
 4214 ~~include estimates and costs for compliance. If it is believed that a standard may not apply to~~
 4215 ~~the specific situation, an explanation shall be included.~~
- 4216 C. ~~— Any person who requests a variance for the provisions of these regulations shall have the~~
 4217 ~~burden of supplying the Department with information that demonstrates the conditions exist~~
 4218 ~~which warrant the granting of a variance. All doubts shall be resolved in favor of denial.~~
- 4219 D. ~~— The Colorado Department of Public Health and Environment may grant a variance if:~~
- 4220 1. ~~— Such variance is consistent with the purpose and intent of the act and these~~
 4221 ~~regulations; and~~
- 4222 2. ~~— It is consistent with the protection of the public health; and~~
- 4223 3. ~~— The circumstances of the retail food establishment are unique; and~~
- 4224 4. ~~— The cost of compliance is so great that it would threaten economic viability of the~~
 4225 ~~retail food establishment or the retail food establishment would be in grave jeopardy~~
 4226 ~~if compliance were enforced; and~~
- 4227 5. ~~— The damage to the retail food establishment's economic viability is in fact caused by~~
 4228 ~~compliance.~~
- 4229 E. ~~— A variance shall expire upon a change of circumstances from those supporting the variance~~
 4230 ~~or upon a change of ownership of the retail food establishment. The approved variance and~~
 4231 ~~all associated documentation shall be located at the establishment and made available to the~~
 4232 ~~Department when requested.~~

4233 F. ~~After review and in circumstances where the Department intends to deny a variance, the~~
 4234 ~~Department shall refer the request to an advisory panel of three persons, two persons who~~
 4235 ~~represent the retail food industry and a representative from a local health department, to~~
 4236 ~~make recommendations to the Department.~~

4237 G. ~~Any retail food establishment for which a variance has been denied may appeal such denial~~
 4238 ~~by requesting a hearing which will be held in accordance with section 24-4-105 (15), C.R.S.~~

4239 ~~11-7~~ **REFERENCE CITATIONS**

4240 ~~11-701~~ **General**

4241 ~~These regulations incorporated by reference (as indicated within) materials originally published~~
 4242 ~~elsewhere. Such incorporation does not include later amendments to or editions of the referenced~~
 4243 ~~material. The Department maintains certified copies of the complete text of any material incorporated~~
 4244 ~~by reference for public inspection during regular business hours and shall provide certified copies of~~
 4245 ~~the incorporated material at cost upon request. Information regarding how to obtain or examine the~~
 4246 ~~incorporated material is available from the Division Director, Division of Environmental Health and~~
 4247 ~~Sustainability, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive~~
 4248 ~~South, Denver, CO 80246-1530.~~

4249 ~~Copies of the incorporated materials have been provided to the State Publications Depository and~~
 4250 ~~Distribution Center, and are available for interlibrary loan. Any incorporated material may be~~
 4251 ~~examined at any State Publications Depository Library.~~

4252 ~~11-702~~ **Safe Materials**

4253 ~~The Colorado Pure Food and Drug Law, the Federal Food, Drug and Cosmetic Act and applicable~~
 4254 ~~regulations of the U.S. Food and Drug Administration used for the determination of material safety in~~
 4255 ~~section 1-202(56) of these rules and regulations may be obtained from the Division Director, Division~~
 4256 ~~of Environmental Health and Sustainability, Colorado Department of Public Health and Environment,~~
 4257 ~~4300 Cherry Creek Drive South, Denver, CO 80246-1530 and/or the U.S. Federal Food and Drug~~
 4258 ~~Administration.~~

4259 ~~11-703~~ **Food Protection Act**

4260 ~~Copies of section 25-4-1601 et seq., C.R.S may be obtained from the Director of the Division of~~
 4261 ~~Environmental Health and Sustainability of the Colorado Department of Public Health and~~
 4262 ~~Environment.~~

4263 ~~11-704~~ **Milk Standards**

4264 ~~Copies of the Grade A Standards referenced in section 3-305 of these regulations may be obtained~~
 4265 ~~from the Director of the Division of Environmental Health and Sustainability of the Colorado~~
 4266 ~~Department of Public Health and Environment.~~

4267 ~~11-705~~ **Ventilation Requirements**

4268 ~~Copies of the 2006 International Mechanical Code or Local Ventilation Codes referenced in section~~
 4269 ~~4-212 of these rules and regulations may be obtained from the International Conference of Building~~

4270 ~~Officials, 503 Alhambra Avenue, Los Angeles, California 90032-3490 or the Local Building~~
4271 ~~Department of jurisdiction, respectively.~~
4272

4273

4274 **11-706—Code of Federal Regulations**

4275 Copies of the ~~(2005) Code of Federal Regulations~~ referenced in sections ~~3-101, 3-312, 3-408, 3-607,~~
4276 ~~3-702, 4-202, 4-207, 4-403, 4-404, 5-103, 5-108, 7-105, 7-107, 7-108~~ may be obtained from the
4277 Director, Office of the Federal Register, National Archives and Records Administration, Washington
4278 DC 20408.

4279 **11-707—Plumbing Requirements**

4280 Copies of the ~~2009 International Plumbing Code or Local Plumbing Codes~~ referenced in sections ~~5-~~
4281 ~~201, 5-208, and 5-209~~ may be obtained from the ~~International Association of Plumbing and~~
4282 ~~Mechanical Officials, 20001 Walnut Drive South, Walnut, California, 91789-2825 and/or the Local~~
4283 ~~Building Department of jurisdiction, respectively.~~

4284 **11-708—Administrative Statutes**

4285 Copies of sections ~~16-13-305, 306 and 308, C.R.S.; 24-4-106, C.R.S.; 25-1.5-101(1)(a), C.R.S.;~~
4286 ~~25-1-108(1)(k), C.R.S.; 25-1-506(1)(d), C.R.S.; 25-4-401 et seq., C.R.S.; 25-4-1301 et seq., C.R.S.;~~
4287 ~~25-4-105, C.R.S.; 25-4-1608, C.R.S.; and 25-5-406(1) and (4) C.R.S.,~~ referenced in sections ~~1-202,~~
4288 ~~3-305, 3-401, 3-409, 3-410, 3-701, 5-101, 9-104, 11-101, 11-103, 11-104, 11-105, 11-106, 11-301,~~
4289 ~~and 11-601~~ of these rules and regulations may be obtained from the ~~Director of the Division of~~
4290 ~~Environmental Health and Sustainability of the Colorado Department of Public Health and~~
4291 ~~Environment.~~

4292 **11-709—American National Standards Institute (ANSI)**

4293 Copies of the ~~National Sanitation Foundation Standards for food equipment that are classified for~~
4294 ~~sanitation by an American National Standards Institute (ANSI) accredited certification program~~
4295 ~~referenced in section 4-101~~ of these rules and regulations may be obtained from the ~~Director of~~
4296 ~~the Division of Environmental Health and Sustainability of the Colorado Department of Public~~
4297 ~~Health and Environment.~~

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- 4649 65, 66, 67, 68, 69, 70, 72, 75, 76, 77, 79, 80,
- 4650 82, 83, 85, 86, 88, 89, 91, 93, 94, 95, 96
- 4651 Utility Line Installation, 81
- 4652 Utility sink, 24, 78, 81, 91
- 4653 **Variance**, 15, 106
- 4654 Ventilation, 57, 82, 104, 107
- 4655 Voluntary condemnation, 103
- 4656 Walls, 9, 57, 59, 60, 81, 82, 83, 93
- 4657 **Warewashing**, 16, 19, 23, 24, 36, 53, 55, 62,
- 4658 63, 64, 65, 66, 67, 74, 75, 76, 77, 78, 81, 82,
- 4659 85, 91, 92, 93, 96, *See*
- 4660 Washing fruits and vegetables, 32, 35, 86
- 4661 Wastewater retention tank, 92
- 4662 **Water activity**, 16, 45
- 4663 Water conditioning device, 74
- 4664 Water pressure, 72
- 4665 **Whole-muscle, intact beef**, 16, 32, 40
- 4666 Wicker, 54, 55
- 4667 Wiping cloth, 7, 36, 37, 69, 97
- 4668 Wood, 54, 55, 81, 97

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4670

APPENDIX A—Potentially Hazardous Foods

4671 Potentially hazardous food (PHF/TCS food) is defined in terms of whether or not it requires time/temperature
4672 control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not
4673 support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a
4674 level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is
4675 considered whether slow or rapid.

4676 The definition of PHF/TCS food takes into consideration pH, a_w , pH and a_w interaction, heat treatment, and
4677 packaging for a relatively simple determination of whether the food requires time/temperature control for
4678 safety. If the food is heat treated to eliminate vegetative cells, it needs to be addressed differently than a raw
4679 product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to
4680 destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or
4681 a_w can be tolerated because remaining spore forming bacteria are the only microbial hazards of concern.
4682 While foods will need to be cooled slightly to prevent condensation inside the package, they must be
4683 protected from contamination in an area with limited access and packaged before temperatures drop below
4684 135°F (57°C). In some foods, it is possible that neither the pH value nor the a_w value is low enough by itself
4685 to control or eliminate pathogen growth; however, the interaction of pH and a_w may be able to accomplish it.
4686 This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used
4687 together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone.
4688 When no other inhibitory factors are present and the pH and/or a_w values are unable to control or eliminate
4689 bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut
4690 tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth
4691 once pathogens are exposed to the cellular fluids and nutrients after cutting.

4692 In determining if time/temperature control is required, combination products present their own challenge. A
4693 combination product is one in which there are two or more distinct food components and an interface between
4694 the two components may have a different property than either of the individual components. A determination
4695 must be made about whether the food has distinct components such as pie with meringue topping, focaccia
4696 bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform consistency such as gravies,
4697 puddings, or sauces. In these products, the pH at the interface is important in determining if the item is a
4698 PHF/TCS food.

4699 A well designed inoculation study or other published scientific research should be used to determine whether
4700 a food can be held without time/temperature control when:

- 4701 ● process technologies other than heat are applied to destroy foodborne pathogens (e.g.,
4702 irradiation, high pressure processing, pulsed light, ozonation);
- 4703 ● combination products are prepared; or
- 4704 ● other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential,
4705 salt content, and antimicrobials) are used to control or eliminate pathogen growth.

4706 Before using Tables A and B listed in the definition section under item 79 for "potentially hazardous food
4707 (time/temperature control for safety food)" in determining whether a food requires time/temperature control
4708 for safety (TCS), answers to the following questions should be considered:

- 4709 ● Is the intent to hold the food without using time or temperature control?
 - 4710 ○ If the answer is No, no further action is required. The decision tree later in this
4711 Appendix is not needed to determine if the item is a PHF/TCS food.
- 4712 ● Is the food raw, or is the food heat treated?
- 4713 ● Does the food already require time/temperature control for safety utilizing the definition of
4714 "potentially hazardous food (time/temperature control for safety food)"?

- 4715 ● ~~Does a product history with sound scientific rationale exist indicating a safe history of use?~~
- 4716 ● ~~Is the food processed and packaged so that it no longer requires TCS such as ultra-high temperature~~
- 4717 ~~(UHT) creamers or shelf-stable canned goods?~~
- 4718 ● ~~What is the pH and a_w of the food in question using an independent laboratory and Association of~~
- 4719 ~~Official Analytical Chemists (AOAC) methods of analysis?~~

4720 A food designated as product assessment required (PA), in either table should be considered PHF/TCS Food
 4721 until further study proves otherwise. The PA means that based on the food's pH and a_w and whether it was raw
 4722 or heat-treated or packaged, it has to be considered PHF until inoculation studies or some other acceptable
 4723 evidence shows that the food is a PHF/TCS food or not. The Rules and Regulations require a variance request
 4724 to the regulatory authority with the evidence that the food does not require time/temperature control for
 4725 safety.

4726 The Rules and Regulations definition designates certain raw plant foods as PHF/TCS food because they have
 4727 been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack
 4728 intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these
 4729 designations are supported by Tables A and B. For example:

4730 For cut cantaloupe (pH 6.2-7.1, $a_w > 0.99$, not heat treated), fresh sprouts (pH > 6.5 , $a_w > 0.99$, not heat-
 4731 treated), and cut tomatoes (pH 4.23-5.04, $a_w > 0.99$, not heat treated), Table B indicates that they are
 4732 considered PHF/TCS Foods unless a product assessment shows otherwise. Maintaining these products under
 4733 the temperature control requirements prescribed in this code for PHF/TCS food will limit the growth of
 4734 pathogens that may be present in or on the food and may help prevent foodborne illness.

4735 If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than flavor
 4736 enhancement, a HACCP plan and approval from the department is required under 3-606. A HACCP plan is
 4737 required whether the food is a PHF/TCS food as in Section 3-606(A)(3)(a) of these rules and regulations or
 4738 not a PHF/TCS food, as in Section 3-606(A)(3)(a) of these rules and regulations. A standardized recipe
 4739 validated by lab testing for pH and a_w would be an appropriate part of the approval process with annual (or
 4740 other frequency as specified by the regulatory authority) samples tested to verify compliance with the
 4741 conditions of the variance.

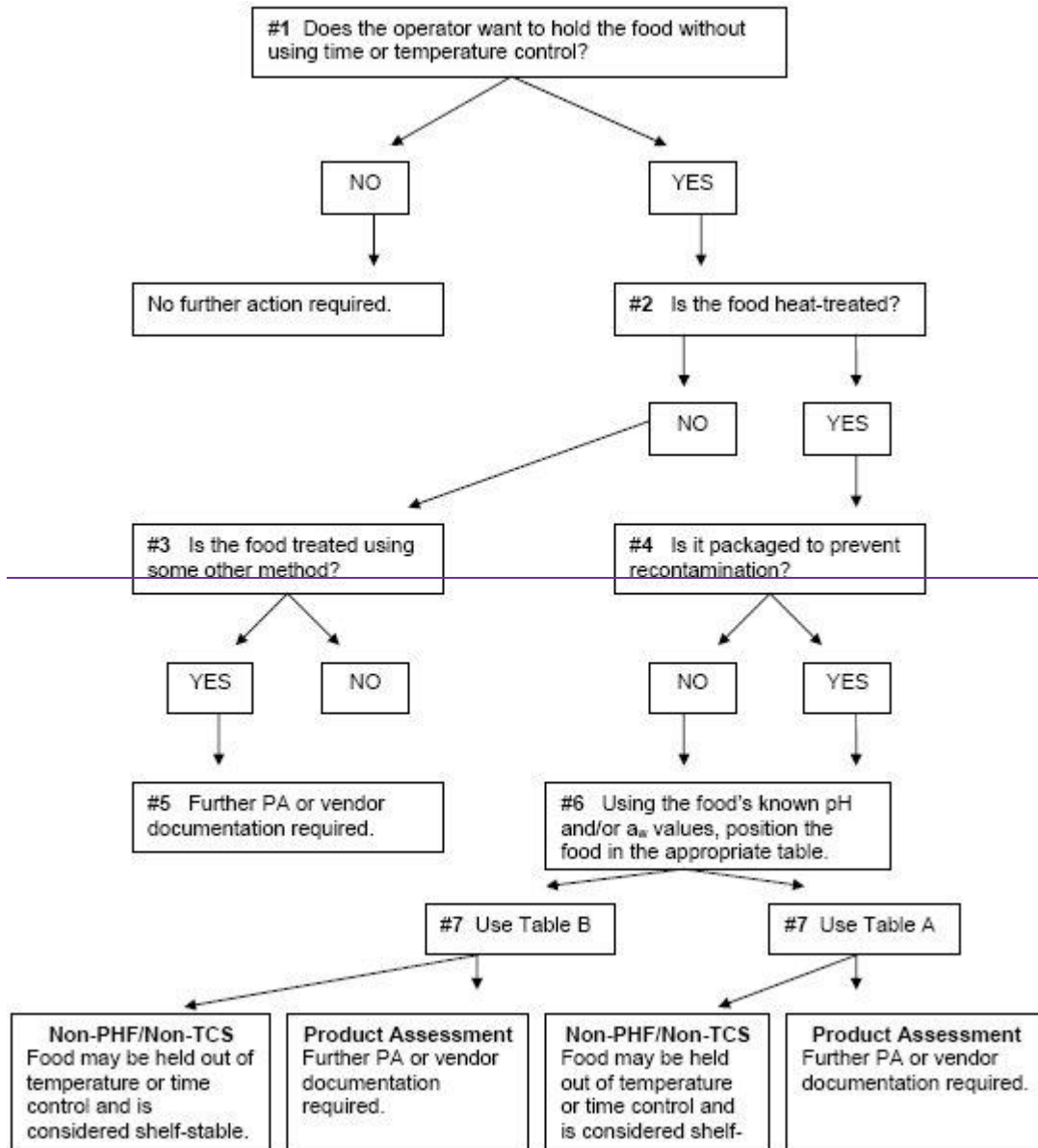
4742 **Instructions for using the following Decision Tree and Table A and Table B:**

- 4743 1. ~~Does the operator want to hold the food without using time or temperature control?~~
 - 4744 a. ~~No—Continue holding the food at $\leq 41^\circ\text{F}$ (5°C) or $\geq 135^\circ\text{F}$ (57°C) for safety and/or quality.~~
 - 4745 b. ~~Yes—Continue using the decision tree to identify which table to use to determine whether~~
 - 4746 ~~time/temperature control for safety (TCS) is required.~~
- 4747 2. ~~Is the food heat treated?~~
 - 4748 a. ~~No—The food is either raw, partially cooked (not cooked to the temperature specified in~~
 - 4749 ~~section 3-502 of the Rules and Regulations) or treated with some other method other than~~
 - 4750 ~~heat. Proceed to step #3.~~
 - 4751 b. ~~Yes—If the food is heat treated to the required temperature for that food as specified under~~
 - 4752 ~~section 3-502 of the Rules and Regulations, vegetative cells will be destroyed although~~
 - 4753 ~~spores will survive. Proceed to step #4.~~
- 4754 3. ~~Is the food treated using some other method?~~
 - 4755 a. ~~No—The food is raw or has only received a partial cook allowing vegetative cells and spores~~
 - 4756 ~~to survive. Proceed to step #6.~~
 - 4757 b. ~~Yes—If a method other than heat is used to destroy pathogens such as irradiation, high~~
 - 4758 ~~pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the~~

- 4759 effectiveness of the process needs to be validated by inoculation studies or other means.
4760 Proceed to step #5.
- 4761 4. ~~Is it packaged to prevent re-contamination?~~
- 4762 a. ~~No. Re-contamination of the product can occur after heat treatment because it is not
4763 packaged. Proceed to step #6.~~
- 4764 b. ~~Yes. If the food is packaged immediately after heat treatment to prevent re-contamination,
4765 higher ranges of pH and/or a_w can be tolerated because spore-forming bacteria are the only
4766 microbial hazard. Proceed to step #7.~~
- 4767 5. ~~Further product assessment or vendor documentation required.~~
- 4768 a. ~~The vendor of this product may be able to supply documentation that inoculation studies
4769 indicate the food can be safely held without time/temperature control for safety.~~
- 4770 b. ~~Food prepared or processed using new technologies may be held without time/temperature
4771 control provided the effectiveness of the use of such technologies is based on a validated
4772 inoculation study.~~
- 4773 6. ~~Using the food's known pH and/or a_w values, position the food in the appropriate table.~~
- 4774 a. ~~Choose the column under "pH values" that contains the pH value of the food in question.~~
- 4775 b. ~~Choose the row under " a_w values" that contains the a_w value of the food in question.~~
- 4776 c. ~~Note where the row and column intersect to identify whether the food is "non-PHF/non-TCS
4777 food" and therefore does not require time/temperature control, or whether further product
4778 assessment (PA) is required. Other factors such as redox potential, competitive
4779 microorganisms, salt content, or processing methods may allow the product to be held
4780 without time/temperature control but an inoculation study is required.~~
- 4781 7. ~~Use Table A for foods that are heat treated and packaged OR use Table B for foods that are not heat
4782 treated or heat treated but not packaged.~~
- 4783 8. ~~Determine if the item is non-PHF/non-TCS or needs further product assessment (PA).~~
- 4784

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4788

DECISION TREE #1 – USING pH, A_w , OR THE INTERACTION OF pH AND A_w TO DETERMINE IF A FOOD REQUIRES TIME/TEMPERATURE CONTROL FOR SAFETY



4789

4790

TABLE A AND TABLE B

TABLE A. INTERACTION OF PH AND A_w FOR CONTROL OF SPORES IN FOOD HEAT-TREATED TO DESTROY VEGETATIVE CELLS AND SUBSEQUENTLY PACKAGED			
A_w VALUES	<u>PH VALUES</u>		
	4.6 OR LESS	> 4.6 – 5.6	> 5.6
≤ 0.92	NON-PHF*/NON-TCS FOOD**	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD
$> 0.92 - .95$	NON-PHF/NON-TCS FOOD	NON-PHF/NON-TCS FOOD	PA***
≥ 0.95	NON-PHF/NON-TCS FOOD	PA	PA

4791

* PHF MEANS POTENTIALLY HAZARDOUS FOOD

4792

** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY

4793

FOOD

4794

*** PA MEANS PRODUCT ASSESSMENT REQUIRED

4795

~~**TABLE B. INTERACTION OF PH AND A_w FOR CONTROL OF VEGETATIVE CELLS AND SPORES IN FOOD NOT HEAT-TREATED OR HEAT-TREATED BUT NOT PACKAGED**~~

A_w VALUES	<u>PH VALUES</u>			
	<4.2	4.2-4.6	>4.6- 5.0	≥5.0
<0.88	NON-PHF*/ NON-TCS FOOD**	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD
0.88- 0.90	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	PA***
≥0.90- 0.92	NON-PHF/ NON-TCS FOOD	NON-PHF/ NON-TCS FOOD	PA	PA
>0.92	NON-PHF/ NON-TCS FOOD	PA	PA	PA

4796

4797 * PHF MEANS POTENTIALLY HAZARDOUS FOOD

4798 ** TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

4799 *** PA MEANS PRODUCT ASSESSMENT REQUIRED

4800

4801 The following is a limited list of specific food products that have been classified to be potentially
4802 hazardous:

- 4803 1. ~~Bacon~~ If it has not been fully cooked.
- 4804 2. ~~Balutes~~ Fertile eggs, generally chicken or duck eggs, which are incubated for a period of
4805 time shorter than is necessary for hatching. The developing embryo is incubated generally
4806 14 to 18 days and is considered a delicacy by various ethnic populations when eaten raw or
4807 cooked.
- 4808 3. ~~Beans~~ All types of cooked beans.
- 4809 4. ~~Whipped Butter~~ Hazardous because of the apparent reduced microbiological safety factor
4810 created by whipping.
- 4811 5. ~~Cheese~~ Soft unripened cheese. Ripened, low moisture hard cheese such as wheels, flats,
4812 blocks or longhorns of cheddar cheese produced from pasteurized milk, when waxed or

- 4813 packaged in "shrink" wrapping with the wax or packaging intact, can be safely shipped or
 4814 stored for a short period of time without refrigeration but it is not recommended. If wheels,
 4815 flats, blocks, longhorns, or any other forms of cheese have been damaged, cut and
 4816 repackaged for display and/or sale, thereby exposing interior surfaces to possible
 4817 contamination, the cut portions as well as the remaining cheese shall be held under
 4818 refrigeration.
- 4819 6. ~~Coffee Creaming Agents—All non dairy coffee creaming agents in liquid form, except~~
 4820 ~~aseptically processed ultra high temperature (UHT) liquid coffee creaming agents.~~
- 4821 7. ~~Cut Leafy Greens—Following 24 multi-state outbreaks between 1998 and 2008, cut leafy~~
 4822 ~~greens was added to the definition of potentially hazardous food requiring time-temperature~~
 4823 ~~control for safety (TCS). The term used in the definition includes a variety of cut lettuces and~~
 4824 ~~leafy greens. Raw agricultural commodities (RACs) that are not processed or cut on-site are~~
 4825 ~~excluded from the definition of cut leafy greens. Herbs such as cilantro or parsley are also~~
 4826 ~~not considered cut leafy greens. The pH, water activity, available moisture and nutrients of~~
 4827 ~~cut leafy greens supports the growth of foodborne pathogens and refrigeration at 41°F (5°C)~~
 4828 ~~or less inhibits growth and promotes general die-off in some pathogens such as *E. coli*~~
 4829 ~~O157:H7, *Salmonella*, *E. coli* O157:H7 and *Listeria monocytogenes*, once attached to the~~
 4830 ~~surface or internalized into cut surfaces of leafy greens, are only marginally affected by~~
 4831 ~~chemical sanitizers.~~
- 4832 8. ~~Cut Tomatoes—Historically, uncooked fruits and vegetables, such as cut tomatoes, have been~~
 4833 ~~considered non-PHF unless they were epidemiologically implicated in foodborne illness~~
 4834 ~~outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of~~
 4835 ~~temperature control. The US Food and Drug Administration (FDA) has reported that since~~
 4836 ~~1990, at least 12 multi-state foodborne illness outbreaks have been associated with different~~
 4837 ~~varieties of tomatoes and additionally, from 1998–2006, outbreaks associated with tomatoes~~
 4838 ~~made up 17% of the produce related outbreaks reported to FDA nationwide. *Salmonella* has~~
 4839 ~~been the pathogen of concern most often associated with tomato outbreaks.~~
- 4840 9. ~~Eggs—Cooked, cracked, fresh with outer shell removed, peeled hard-boiled eggs, and hard-~~
 4841 ~~boiled eggs with intact shells which have been hard-boiled and then cooled in liquid.~~
 4842 ~~Refrigeration of raw whole eggs in the shell is required.~~
- 4843 10. ~~Garlic—Garlic in oil products.~~
- 4844 11. ~~Mayonnaise or Other Acidified Salad Dressings—If the pH is above 4.6 and/or combined~~
 4845 ~~with other food products.~~
- 4846 12. ~~Onions—Cooked and dehydrated that have been reconstituted.~~
- 4847 13. ~~Pasta—All types that have been cooked.~~
- 4848 14. ~~Pastries—Meat, cheese and cream filled.~~
- 4849 15. ~~Pies—Meat, fish, poultry, natural cream, synthetic cream, custard, pumpkin and pies that are~~
 4850 ~~covered with toppings which will support microbial growth.~~
- 4851 16. ~~Potatoes—Baked, boiled or fried.~~
- 4852 17. ~~Rice—Boiled, steamed, fried, Spanish and cooked rice used in sushi.~~
- 4853 18. ~~Sour Cream—If the pH is above 4.6 and/or combined with other food products.~~
- 4854 19. ~~Soy Protein—Tofu and other moist soy protein products.~~
- 4855 20. ~~Seed Sprouts—All types.~~
- 4856 FOODS WHICH ARE NOT POTENTIALLY HAZARDOUS ARE:

- 4857 1. ~~Hard Boiled eggs with shells intact which have been air dried; and~~
- 4858 2. ~~Foods which have been adequately commercially processed and remain in their unopened~~
- 4859 ~~hermetically sealed container.~~

4860 ***APPENDIX B – Safe Materials Colorado Pure Food and Drug Law***

4861

4862 **Sections ~~25-5-402 (3) and (12)~~, C.R.S.**

4863

4864 (3) a. "Color additive" means a material which:

4865 (I.) — Is a dye, pigment, or other substance made by a process of synthesis or similar
4866 artifice or extracted, isolated, or otherwise derived, with or without intermediate or final
4867 change of identity, from a vegetable, animal, mineral, or other source; and

4868 (II.) — When added or applied to a food, drug, or cosmetic or to the human body or any part
4869 thereof; is capable (alone or through reaction with other substance) of imparting color
4870 thereto; except that such term does not include any material which is exempted under the
4871 federal act.

4872 b. — Nothing in this subsection (3) shall be construed to apply to any pesticide chemical, soil or
4873 plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or
4874 otherwise affecting, directly or indirectly, the growth or other natural physiological process or
4875 produce of the soil and thereby affecting its color, whether before or after harvest.

4876 (12) — "Food additive" means any substance, the intended use of which results or may be reasonably
4877 expected to result, directly or indirectly, in its becoming a component or otherwise affecting the
4878 characteristics of any food (including any substance intended for use in producing, manufacturing,
4879 packing, processing, preparing, treating, packaging, transporting, or holding such substance is not
4880 generally recognized among experts qualified by scientific training and experience to evaluate its
4881 safety as having been adequately shown through scientific procedures or, in the case of a substance
4882 used in a food prior to January 1, 1958, through either scientific procedures or experience based on
4883 common use in food) to be safe under the conditions of its intended use. The term does not include:

4884 a. — A pesticide chemical in or on a raw agricultural commodity;

4885 b. — A pesticide chemical to the extent that it is intended for use or is used in the production,
4886 storage, or transportation of any raw agricultural commodity;

4887 e. — A color additive; or

4888 d. — Any substance used in accordance with a sanction or approval granted prior to the enactment
4889 of the amendment to the federal act known as the "Food Additives Amendment of 1958," the
4890 Poultry Products Inspection Act" (21 U.S.C. 451-470), or the "Meat Inspection Act of March
4891 4, 1907," as amended and extended (21 U.S.C. 71-91)

~~**APPENDIX C – Worksheets for Calculating Minimum Hot Water Requirements**~~

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The following worksheet is provided to assist operators in calculating hot water usage and sizing of the water heater system required for the operation.

What is the distance between the water heating system(s) and the fixture that is farthest from the heating system?

Fixture: _____ Feet from water heating system: _____

Standard Tank Type Systems:

I. _____ Calculate Total Water Required By All Fixtures:

A. _____ Three compartment sink calculation of water usage:

1. _____ Measure dimensions, in inches, of each compartment, if compartments are not the same dimensions see note below.

Length = _____ Width = _____ Depth = _____

2. _____ Insert measurements into equation:

$$\left(\frac{\text{length} \times \text{width} \times \text{depth} \times 3 \times 0.375}{2.31} \right) = \text{GPH}$$

—length— width— depth— water usage

Note: If all the compartment sizes of the sink are not the same, then 3 is taken out of the equation, and the above calculation is done for each compartment. The volumes are added to obtain the total gallons per hour of hot water used in the sink.

Enter number into the attached “Table to Calculate Total Water Required By All Fixtures,” found on page C-4.

B. _____ Utensil soak sink

1. _____ Measure dimensions, in inches, of the sink

Length = _____ Width = _____ Depth = _____ GPH

4929
4930 2. _____ Insert measurements into equation:

4931
4932 $(\frac{\text{_____}}{\text{length}} \times \frac{\text{_____}}{\text{width}} \times \frac{\text{_____}}{\text{depth}} \times .375) \div 231 = \frac{\text{_____}}{\text{water usage}}$

4934 Enter number into the attached “Table to Calculate Total Water Required By All Fixtures,” found
4935 on page C-4.

4936
4937 C. _____ Dishmachine and conveyor pre-rinse water usage:

4938 1. _____ Use manufacturer’s rating in gallons per hour. Enter number into attached
4939 “Table to Calculate Total Water Required By All Fixtures,” found on page C-4.

4940
4941 2. _____ Clothes washer water usage:

- 4942 • _____ Use manufacturer’s rating: _____, or
4943 • _____ 32 GPH for 9-12 pound washer, or
4944 • _____ 42 GPH for 16 pound washer.

4945
4946 Enter number into the attached “Table to Calculate Total Water Required By All Fixtures,” found
4947 on page C-4.

4948
4949 D. _____ “Calculate Total Water Required By All Fixtures” and the number of fixtures in the
4950 operation to determine maximum hourly usage for each type of fixture in the operation.

4951
4952 Total water (GPH) required by all fixtures: _____ GPH.

4953
4954 H. _____ Calculate Maximum Hourly Hot Water Usage

4955 If gas water heater is used go to Step A; if electric, Step B.

4956 A. _____ Gas Water Heater: If a gas water heater is to be used, calculate the maximum
4957 hourly hot water usage for the facility by adjusting the total water required by all fixtures
4958 for altitude. The altitude adjustment is 4% per 1000 feet of elevation, or 20% at 5000
4959 feet.

4960
4961 Use the following equations to determine the maximum hourly hot water usage when a gas
4962 powered water heater is to be used:

4963
4964 $(0.04 \times \frac{\text{_____}}{\text{elevation of facility}} \div 1000) + 1 = \frac{\text{_____}}{\text{adjustment factor}}$

4966

4967
$$\frac{\text{_____}}{\text{_____}} \times \frac{\text{_____}}{\text{_____}} = \text{_____ GPH}$$

4968 ~~adjustment factor~~ ~~total water required~~ ~~maximum hourly~~

4969 ~~by all fixtures~~ ~~hot water usage~~

4970

4971 Example, if the total gallon per hour usage for an establishment at an elevation of 5000 feet is 100

4972 GPH, the adjustment factor is 1.2. Therefore, a water heater with 120 GPH recovery rate would

4973 be required.

4974

4975 Use this value in the equation to calculate the minimum BTU rating of the water heater.

4976

4977 B. ~~Electric Water Heater: If an electric water heater is to be used, the maximum~~

4978 ~~hourly usage for the operation is the same as the total water required by all fixtures. Use~~

4979 ~~this value in the equation to calculate the minimum Kilowatt (KW) rating of the water~~

4980 ~~heater.~~

4981

4982 C. ~~the value determined in Step A or B the minimum recovery rate of the water~~

4983 ~~heater which should be provided for the facility.~~

4984

4985 III. ~~Calculate the minimum BTU or Kilowatt rating of water heater:~~

4986 A. ~~For gas water heater, calculate the minimum BTU rating:~~

4987

4988 ~~$$\frac{(\text{max hourly usage as calculated above}) \times (100^{\circ}\text{F}^*) \times (8.33)}{\text{_____}} = \text{minimum BTU rating}$$~~

4989 ~~.80 or use manufacturer's thermal efficiency~~

4990

4991 B. ~~For electric water heater, calculate the minimum Kilowatt rating:~~

4992

4993 ~~$$\frac{(\text{max hourly usage as calculated above}) \times (100^{\circ}\text{F}^*) \times (8.33)}{\text{_____}} = \text{minimum KW rating}$$~~

4994 ~~3412~~

4995 ~~*If there is no high temperature dishwashing machine or other fixtures requiring input water~~

4996 ~~temperature of 140°F (100°F rise) or more, then 80°F rise can be used.~~

4997

4998 C. ~~Select water heater based upon BTU or Kilowatt rating.~~

4999

5000 Make: _____ ; Model #: _____

5001

5002 BTU or Kilowatt Rating: _____

5003 _____

5004 Recovery rate: _____ gallons per hour at 100°F rise at sea level.

5005

5006 D. ~~Heat reclaim systems:~~

5007

5008

Make: _____; Model #: _____

5009

5010

BTU Rating: _____

5011

5012

Recovery rate: _____ gallons per hour at 100°F rise at sea level.

5013

5014

5015 Table to Calculate Total Water Required For All Fixtures.

Plumbing Fixture	Water Usage (gallons per hour)	Number of Fixtures	Maximum Hourly Water Usage Per Type of Fixture (gallon per hour)
<i>example: dishwashing machine</i>	<i>50</i>	<i>1</i>	<i>50</i>
<i>example: handsink(s)</i>	<i>5</i>	<i>4</i>	<i>(5 x 4 =) 20</i>
3-compartment sink			
3-compartment sink (bar)			
Utensil soak sink			
Dishmachine			
Dishwashing machine conveyor pre-rinse			
Clothes washer			
Hand-operated pre-rinse sprayer*	32		
Hand-washing sinks (including restrooms)*	5		
Mop/utility sinks	7		
Garbage can washer	35		
Showers*	14		
Hose bib used for cleaning	35		
Total water (GPH) required by all fixtures:			

5016

*A hot water use reduction can be calculated for water saving devices used on hand-operated pre-rinse sprayers, hand washing sinks and showers by doing the following calculations.

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A. ~~Water savings device. Obtain manufacturer’s flow rate for each device. The manufacture’s flow rate must be less than what is listed below to be considered:~~

1. ~~Hand operated pre-rinse sprayers with flow rate less than 3.5 GPM standard flow rate.~~

Make: _____ ; Model #: _____

Manufacturer’s Flow Rating: _____ GPM

2. ~~Hand washing sink faucet or aerator with flow rate less than 2.2 GPM standard flow rate.~~

Make: _____ ; Model #: _____

Manufacturer’s Flow Rating: _____ GPM

3. ~~Shower head with flow rate less than 2.5 GPM standard flow rate.~~

Make: _____ ; Model #: _____

Manufacturer’s Flow Rating: _____ GPM

B. ~~Use the following equation to determine the reduced hourly hot water usage for each of the three types of fixtures:~~

~~(_____ x _____) : _____ = _____~~

_____	_____	_____	_____
manufacturer’s flow	water use value from	GPM standard flow	new water
use value rate	Table to Calculate Total	rate	to be entered into Table
_____	Water Required for All	_____	to Calculate Total Water
_____	Fixtures on page C-4	_____	Required for All Fixtures on
_____	_____	_____	page C-4)

~~Example calculation for a hand washing sink that has an aerator with a manufacturer’s flow rate of 0.5 gpm:~~

~~(_____ 0.5 GPM _____ x _____ 5 GPH _____) : _____ 2.2 GPM _____ = _____ 1.14 GPH _____~~

_____	_____	_____	_____
manufacturer’s flow	water use value from	GPM standard flow	new water
use value rate	table to Calculate Total	rate	to be entered into table
_____	Water Required for All	_____	to Calculate Total Water
_____	Fixtures on page C-4	_____	Required for All Fixtures on
_____	_____	_____	page C-4)

~~1.14 GPH would be entered into the “Table to Calculate Total Water Required for All Fixtures,” found on page Appendix C-4 in place of the 5 GPH for hand washing sinks.~~

5066

5067 Requirements for Dishwashing Machine Booster Heaters:5068 I. Dishwashing Machine

5069

5070 Manufacturer: _____

5071

5072 Model Number: _____

5073

5074 Final Sanitizing Rinse Cycle Gallons Per Hour Water Consumption: _____ GPH

5075

5076 H. Calculate the minimum BTU or Kilowatt rating of the booster heater:

5077

5078 A. For gas booster heater, calculate the minimum BTU rating:

5079

5080
$$\frac{(\text{Gallons Per Hour Water Consumption}) \times (40^{\circ}\text{F}) \times (8.33)}{\text{efficiency}} = \text{minimum BTU rating}$$

5081

.80 or use manufacturer's thermal efficiency

5082

5083 B. For electric water heater, calculate the minimum Kilowatt rating:

5084

5085
$$\frac{(\text{Gallons Per Hour Water Consumption}) \times (40^{\circ}\text{F}) \times (8.33)}{3412} = \text{minimum KW rating}$$

5086

5087 C. Select booster heater based upon BTU or Kilowatt rating. The booster heater must have recovery
5088 rate greater than the dishwashing machine's final rinse water consumption.

5089

5090 Make: _____ ; Model #: _____

5091

5092 BTU or Kilowatt Rating: _____

5093

5094 Recovery rate: _____ gallons per hour at 40°F rise at sea level.

5095 Tankless or Instantaneous Systems5096 I. Heater Specifications:

5097

5098 Manufacturer*: _____

5099

5100 Model Number: _____

5101

5102 Flow Rate in Gallons Per Minute (GPM) at 100°F rise** : _____ GPM

5103

5104 BTU Rating: _____ BTU***

5105

* Units must be designed for commercial use.

5106 ~~** If there are no high temperature dishwashing machine or other fixtures requiring input water~~
 5107 ~~temperature of 140°F (100°F rise) or more, then 80°F rise can be used.~~

5108 ~~*** Electric units will only be approved as a dedicated hot water supply to hand washing sinks.~~

5109 III. Calculate the total hot water demand flow rate in Gallons Per Minute (GPM) using this table.

PLUMBING FIXTURE	WATER USAGE (GALLONS PER MINUTE)	NUMBER OF FIXTURES	WATER DEMAND FLOW RATE IN GALLONS PER MINUTE
EXAMPLE: DISHWASHING MACHINE † HOBART AM-14	8.0	1	(8.0 × 1) = 8.0
EXAMPLE: HANDSINK(S)	0.5	4	(0.5 × 4) = 2.0
3-COMPARTMENT SINK*	2.0 FOR EACH FAUCET		
3-COMPARTMENT SINK (BAR)*	2.0 FOR EACH FAUCET		
UTENSIL SOAK SINK	1.0		
DISHWASHING MACHINE †			
DISHWASHING MACHINE CONVEYOR PRE-RINSE †			
CLOTHES WASHER	2.0		
HAND OPERATED PRE-RINSE SPRAYER †	2.0		
FOOD PREPARATION SINK(S)	1.0		
HAND WASHING SINKS (INCLUDING RESTROOMS)*	0.5		
MOP/UTILITY SINKS	2.0		
GARBAGE CAN WASHER	1.0		
SHOWERS †	1.0		
HOSE BIB USED FOR CLEANING	5.0		
TOTAL WATER DEMAND (GPM) REQUIRED:			

5110

5111 ~~*A flow rate reduction can be used for low flow water faucets installed on 3-compartment sinks, hand-operated pre-~~
 5112 ~~rinse sprayers, food preparation sinks, hand washing sinks and showers by entering the manufacturer's flow rate listed~~
 5113 ~~for the faucet or faucet's aerator.~~

5114 ~~†Use manufacturer's flow rate in GPM for specific make and model of dishwashing machine or shower head.~~

5115 ~~IV. Calculate the maximum flow rate for the establishment. The thermal efficiency of the water~~
 5116 ~~heating units must be adjusted for altitude. The altitude adjustment is 4% per 1000 feet of~~
 5117 ~~elevation, or 20% at 5000 feet.~~

5119 Use the following equations to determine the establishment's maximum flow rate in GPM:

5120
$$(0.04 \times \frac{\text{elevation of facility}}{1000} + 1) = \text{adjustment factor}$$

5123

5124
$$\frac{\text{adjustment factor}}{\text{calculated in III}} \times \frac{\text{total water demand for all fixtures}}{\text{calculated in III}} = \frac{\text{maximum GPM hot water usage}}{\text{calculated in III}}$$

5128 Use calculated maximum GPM hot water usage value in this equation to determine the minimum
 5129 number of heating units that will be required in IV below.

5131 ~~V. Determine the number of heating units that will be needed to meet the required flow rate.~~

5132 -

5133
$$\frac{\text{maximum demand (GPM) calculated in PART III}}{\text{manufacturer's flow rate in GPM @ 100°F}} = \frac{\text{number of heating units required*}}{\text{calculated in PART III}}$$

5137 ~~*Multiple units must be installed and plumbed to operate in a parallel configuration.~~

5138 VI. Storage Tank Sizing:

5140 If a dishwashing machine(s) is to be installed the instantaneous water heating system must
 5141 include a storage tank. The storage tank must be at least 25 gallons or at least 25% of the gallons
 5142 per hour (GPH) demand of the dishwashing machine(s). The larger value of the two is the
 5143 required storage tank size.

5144 Dishwashing Machine*

5146 Manufacturer: _____

5148 Model Number: _____

5150 Gallons Per Hour Water Consumption: _____ x 0.25 = _____
 5151 _____ storage tank capacity
 5152 _____ in gallons

5153 Calculated Storage Tank Capacity: _____ vs. 25 Gallons Storage Tank

5154

5155 Enter the larger of the two: _____ Required Storage Tank Capacity**

5156

5157 *High temperature, heat sanitizing dishwashing machines must be provided with a separate
5158 booster heater. Use of an instantaneous unit is not allowed for use as a booster heater.

5159 **The storage tank must be installed in the hot water supply line located between the heater
5160 unit(s) and the hot water distribution line. A recirculation line, equipped with a recirculation
5161 pump and aquastat, (water thermostat) must be installed at the storage tank to assure the water in
5162 the tank remains at the appropriate temperature (120-140°F). The recirculation line must be
5163 connected between the storage tank and the cold water supply line at the heater unit(s).

5164

APPENDIX D—Specific Usage Additives5165 ~~173.310—Boiler water additives.~~

5166

5167 ——— Boiler water additives may be safely used in the preparation of steam that will contact food, under
5168 the following conditions:5169 A. ——— The amount of additive is not in excess of that required for its functional purpose, and the
5170 amount of steam in contact with food does not exceed that required to produce the
5171 intended effect in or on the food.5172 B. ——— The compounds are prepared from substances identified in paragraphs (C) and (D) of this
5173 section, and are subject to the limitations, if any, prescribed:

5174 C. ——— List of substances:

Substances	Limitations
<p>Acrylamide-sodium acrylate resin.....</p> <p>Acrylic acid/2 acrylamido-2-methyl propane sulfonic acid copolymer having a minimum weight average molecular weight of 9,900 and a minimum number average molecular weight of 5,700 as determined by a method entitled "Determination of Weight Average and Number Average Molecular Weight of 60/40 AA/AMPS" (October 23, 1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies may be obtained from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.</p> <p>Ammonium alginate.</p> <p>Cobalt sulfate (as catalyst).</p> <p>1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4) and its sodium and potassium salts.</p> <p>Lignosulfonic acid.</p>	<p>Contains not more than 0.05 percent by weight of acrylamide monomer.</p> <p>Total not to exceed 20 parts per million (active) in boiler feedwater.</p>
<p>Monobutyl ethers of polyethylene-polypropylene glycol produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol.</p> <p>Poly(acrylic acid-co-hypophosphite), sodium salt (CAS Reg. No. 71050-62-9), produced from a 4:1 to a 16:1 mixture by weight of acrylic acid and sodium hypophosphite.</p> <p>Polyethylene glycol.....</p>	<p>Minimum mol. Wt. 1,500.</p> <p>Total not to exceed 1.5 parts per million in boiler feed water. Copolymer contains not more than 0.5 percent by weight of acrylic acid monomer (dry weight basis).</p> <p>As defined in 172.820 of this chapter.</p>

Substances	Limitations
<p>Polymaleic acid [CAS Reg. No. 26099-09-2], and/or its sodium salt. [CAS Reg. No. 30915-61-8 or CAS Reg. No. 70247-90-4].</p> <p>Polyoxypropylene glycol</p> <p>Potassium carbonate.</p> <p>Potassium tripolyphosphate.</p> <p>Sodium acetate.</p> <p>Sodium alginate.</p> <p>Sodium aluminate.</p> <p>Sodium carbonate.</p>	<p>Total not to exceed 1 part per million in boiler feed water (calculated as the acid).</p> <p>Minimum mol wt. 1,000.</p>
<p>Sodium carboxy-methylcellulose</p>	<p>Contains not less than 95 percent sodium carboxymethylcellulose on a dry weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2 percent by weight aqueous solution at 25°C; by method prescribed in the "Food Chemicals Codex," 3d Ed. (1981), pp. 280-282, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408</p>
<p>Sodium glucoheptonate</p> <p>Sodium hexametaphosphate.</p> <p>Sodium humate.</p> <p>Sodium hydroxide.</p> <p>Sodium lignosulfonate.</p> <p>Sodium metabisulfite.</p> <p>Sodium metasilicate.</p> <p>Sodium nitrate.</p> <p>Sodium phosphate (mono-, di-, tri-).</p> <p>Sodium polyacrylate.</p> <p>Sodium polymethacrylate.</p> <p>Sodium silicate.</p> <p>Sodium sulfate.</p> <p>Sodium sulfite (neutral or alkaline).</p> <p>Sodium tripolyphosphate.</p> <p>Tannin (including quebracho extract).</p> <p>Tetrasodium EDTA.</p> <p>Tetrasodium pyrophosphate.</p>	<p>Less than 1 part per million cyanide in the sodium glucoheptonate.</p>

5176 ~~D. Substances used alone or in combination with substances in paragraph (C) of this~~
 5177 ~~section:~~

Substances	Limitations
Cyclohexylamine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Diethylaminoethanol	Not to exceed 15 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Hydrazine	Zero in steam.
Morpholine	Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Octadecylamine	Not to exceed 3 parts per million in steam, and excluding use of such steam in contact with milk and milk products.
Trisodium nitrilotriacetate	Not to exceed 5 parts per million in boiler feedwater; not to be used where steam will be in contact with milk and milk products.

5178

5179 ~~E. To assure safe use of the additive, in addition to the other information required by the~~
 5180 ~~Act, the label or labeling shall bear:~~

5181 ~~1. The common or chemical name or names of the additive or additives.~~

5182 ~~2. Adequate directions for use to assure compliance with all the provisions of this~~
 5183 ~~section.~~

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APPENDIX E—LUBRICANTS

~~21 CFR Section 178.3570 (2009) Lubricants With Incidental Food Contact~~

~~Lubricants with incidental food contact may be safely used on machinery used for producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.~~

~~A. The lubricants are prepared from one or more of the following substances.~~

- ~~1. Substances generally recognized as safe for use in food.~~
- ~~2. Substances used in accordance with the provisions of a prior sanction or approval.~~
- ~~3. Substances identified in this paragraph (A)(3).~~

Substances	Limitations
Aluminum stearoyl benzoyl hydroxide	For use only as a thickening agent in mineral oil lubricants at a level not to exceed 10 pet by weight of the mineral oil.
BHA.	
BHT.	
α-Butyl-omega-hydroxypoly(oxyethylene) poly(oxypropylene) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9038-95-3.	Addition to food not to exceed 10 parts per million.
α-Butyl-omega-hydroxypoly(oxypropylene); minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-13-8.	Do.
Castor oil	Do.
Castor oil, dehydrated	Do.
Castor oil, partially dehydrated	Do.
Dialkyldimethylammonium aluminum silicate (CAS Reg. No. 68953-58-2), which may contain up to 7 percent by weight 1,6-hexanediol (CAS Reg. No. 629-11-8), where the alkyl groups are derived from hydrogenated tallow fatty acids (C₁₄-C₁₈) and where the aluminum silicate is derived from bentonite.	For use only as a wetting agent in mineral oil lubricants at a level not to exceed 15 percent by weight of the mineral oil.
Dimethylpolysiloxane (viscosity greater than 300 centistokes).	Addition to food not to exceed 1 part per million.

Substances	Limitations
Disodium decanedioate (CAS Reg. No. 17265-14-4).	For use as a corrosion inhibitor or rust preventative in mineral oil-bentonite lubricants at a level not to exceed 2 percent by weight of the grease.
<p>Disodium EDTA (CAS Reg. No. 139-33-3)</p> <p>Ethoxylated resin-phosphate ester mixture consisting of the following compounds:</p> <p>1.....Poly(methylene-p-tert-butylphenoxy) poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0-40 percent of the mixture). The resin is formed by condensation of 1 mole of p-tert-butylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide;</p> <p>2.....Poly(methylene-p-nonylphenoxy) poly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters (0-40 percent of the mixture). The resin is formed by condensation of 1 mole of p-nonylphenol with 2 to 4 moles of formaldehyde and subsequent ethoxylation with 4 to 12 moles of ethylene oxide; and</p> <p>3.....N-Tridecyl alcohol mixture of dihydrogen phosphate and monohydrogen phosphate esters (40 to 80 percent of the mixture; CAS Reg. No. 56831-62-0).</p> <p>Fatty acids derived from animal or vegetable sources, and the hydrogenated forms of such fatty acids.</p> <p>2-(8-Heptadecenyl)-4,5-dihydro-1H-imidazole-1-ethanol (CAS Reg. No. 95-38-5).</p> <p>Hexamethylenebis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).</p>	<p>For use only as a chelating agent and sequestant at a level not to exceed 0.06 percent by weight of lubricant at final use dilution.</p> <p>For use only as a surfactant to improve lubricity in lubricating fluids complying with this section at a level not to exceed 5 percent by weight of the lubricating fluid.</p> <p>For use at levels not to exceed 0.5 percent by weight of the lubricant.</p> <p>For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.</p>
<p>α-Hydro-ω-hydroxypoly(oxyethylene) poly(oxypropylene) produced by random condensation of mixtures of ethylene oxide and propylene oxide containing 25 to 75 percent by weight of ethylene oxide; minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-11-6.</p> <p>12-Hydroxystearic acid.</p>	Addition to food not to exceed 10 parts per million.

Substances	Limitations
Isopropyl oleate	For use only as an adjuvant (to improve lubricity) in mineral oil lubricants.
Magnesium ricinoleate	For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.
<p>Mineral oil</p> <p>N-Methyl-N-(1-oxo-9-octadecenyl)glycine (CAS Reg. No. 110-25-8).</p> <p>N-phenylbenzenamine, reaction products with 2,4,4-trimethylpentene (CAS Reg. No. 68411-46-1).</p> <p>Petrolatum</p> <p>Phenyl-α- and/or phenyl-β-naphthylamine</p> <p>Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C₁₁₋₁₄-alkylamines.</p> <p>Phosphoric acid, mono- and diisooctyl esters, reacted with tertalkyl and (C₁₂-C₁₄) primary amines (CAS Reg. No. 68187-67-7).</p> <p>Polyurea, having a nitrogen content of 9-14 percent based on the dry polyurea weight, produced by reacting tolylene diisocyanate with tall-oil fatty acid (C₁₆- and C₁₈-) amine and ethylene diamine in a 2:2:1 molar ratio.</p> <p>Polybutene (minimum average molecular weight 80,000)</p>	<p>Addition to food not to exceed 10 parts per million.</p> <p>For use as a corrosion inhibitor at levels not to exceed 0.5 percent by weight of the lubricant.</p> <p>For use only as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.</p> <p>Complying with 178.3700. Addition to food not to exceed 10 parts per million.</p> <p>For use only, singly or in combination, as antioxidant in mineral oil lubricants at a level not to exceed a total of 1 percent by weight of the mineral oil.</p> <p>For use only as an adjuvant at levels not to exceed 0.5 percent by weight of the lubricant.</p> <p>For use only as a corrosion inhibitor or rust preventative in lubricants at a level not to exceed 0.5 percent by weight of the lubricant.</p> <p>For use only as an adjuvant in mineral oil lubricants at a level not to exceed 10 percent by weight of the mineral oil.</p> <p>Addition to food not to exceed 10 parts per million</p>
<p>Polybutene, hydrogenated; complying with the identity prescribed under 178.3740.</p> <p>Polyethylene</p> <p>Polyisobutylene (average molecular weight 35,000-140,000 (Flory)).</p> <p>Sodium nitrite</p> <p>Tetrakis[methylene(3,5-di-tert-butyl-4-hydroxyhydro-cinnamate)]methane (CAS Reg. No. 6683-19-8).</p> <p>Thiodiethylenebis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 41484-35-9).</p>	<p>Do.</p> <p>Do.</p> <p>For use only as a thickening agent in mineral oil lubricants.</p> <p>For use only as a rust preventive in mineral oil lubricants at a level not to exceed 3 percent by weight of the mineral oil.</p> <p>For use only as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.</p> <p>For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.</p>

Substances	Limitations
Triphenyl phosphorothionate (CAS Reg. No. 597-82-0)	For use as an adjuvant in lubricants herein listed at a level not to exceed 0.5 percent by weight of the lubricant.
Tris(2,4 di tert butylphenyl)phosphite (CAS Reg No. 31570-04-4).	For use only as a stabilizer at levels not to exceed 0.5 percent by weight of the lubricant.
Thiodiethylenebis(3,5 di tert butyl 4 hydroxy hydro cinnamate)(CAS Reg. No. 41484-35-9).	For use as an antioxidant at levels not to exceed 0.5 percent by weight of the lubricant.
Zinc sulfide	For use at levels not to exceed 10 percent by weight of the lubricant.

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~~B. The lubricants are used on food processing equipment as a protective antirust film, as a release agent on gaskets or seals of tank closures, and as a lubricant for machine parts and equipment in locations in which there is exposure of the lubricated part to food. The amount used is the minimum required to accomplish the desired technical effect on the equipment, and the addition to food of any constituent identified in this section does not exceed the limitations prescribed.~~

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5205

~~C. Any substance employed in the production of the lubricants described in this section that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179.45 of this chapter conforms with any specification in such regulation.~~

5206

APPENDIX F - SANITIZERS

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5208

Refer to 40 CFR § 180.940, (2010) — Sanitizing solutions

- 5209 ***APPENDIX G – HACCP Guidelines***
- 5210 **1. Introduction to HACCP**
- 5211 **A. What is HACCP and how can it be used by operators and regulators of retail**
- 5212 **food and food service establishments?**
- 5213 Hazard Analysis and Critical control point (HACCP) is a systematic approach to
- 5214 identifying, evaluating, and controlling food safety hazards. Food safety hazards are
- 5215 biological, chemical, or physical agents that are reasonably likely to cause illness or
- 5216 injury in the absence of their control. Because a HACCP program is designed to ensure
- 5217 that hazards are prevented, eliminated, or reduced to an acceptable level before a food
- 5218 reaches the consumer, it embodies the preventive nature of "active managerial control."
- 5219 Active managerial control through the use of HACCP principles is achieved by
- 5220 identifying the food safety hazards attributed to products, determining the necessary steps
- 5221 that will control the identified hazards, and implementing on-going practices or
- 5222 procedures that will ensure safe food.
- 5223 Like many other quality assurance programs, HACCP provides a common-sense
- 5224 approach to identifying and controlling problems that are likely to exist in an operation.
- 5225 Consequently, many food safety management systems at the retail level already
- 5226 incorporate some, if not all, of the principles of HACCP. Combined with good basic
- 5227 sanitation, a solid employee training program, and other prerequisite programs, a food
- 5228 safety management system based on HACCP principles will prevent, eliminate, or reduce
- 5229 the occurrence of foodborne illness risk factors that lead to out-of-control hazards.
- 5230 HACCP represents an important tool in food protection that small independent businesses
- 5231 as well as national companies can use to achieve active managerial control of risk factors.
- 5232 The Food Code requires a comprehensive HACCP plan when conducting certain
- 5233 specialized processes at retail such as when a variance is granted or when a reduced
- 5234 oxygen packaging method is used. However, in general, the implementation of HACCP
- 5235 at the retail level is voluntary. FDA endorses the voluntary implementation of food safety
- 5236 management systems based on HACCP principles as an effective means for controlling
- 5237 the occurrence of foodborne illness risk factors that result in out-of-control hazards.
- 5238 While the operator is responsible for developing and implementing a system of controls
- 5239 to prevent foodborne illness risk factors, the role of the regulator is to assess whether the
- 5240 system the operator has in place is achieving control of foodborne illness risk factors.
- 5241 Using HACCP principles during inspections will enhance the effectiveness of routine
- 5242 inspections by incorporating a risk-based approach. This helps inspectors focus their
- 5243 inspection on evaluating the effectiveness of food safety management systems
- 5244 implemented by industry to control foodborne illness risk factors.
- 5245 For regulatory program managers, the use of risk-based inspection methodology based on
- 5246 HACCP principles is a viable and practical option for evaluating the degree of active
- 5247 managerial control operators have over the foodborne illness risk factors.
- 5248

5249 **B. ~~What are the Seven HACCP Principles?~~**

5250 In November 1992, the National Advisory Committee on Microbiological Criteria for
5251 Foods (NACMCF) defined seven widely accepted HACCP principles that explained the
5252 HACCP process in great detail. In 1997, NACMCF reconvened to review the 1992
5253 document and compare it to current HACCP guidance prepared by the CODEX
5254 Committee on Food Hygiene. Based on this review, NACMCF again endorsed HACCP
5255 and defined HACCP as a systematic approach to the identification, evaluation, and
5256 control of food safety. Based on a solid foundation of prerequisite programs to control
5257 basic operational and sanitation conditions, the following seven basic principles are used
5258 to accomplish this objective:

- 5259 1. ~~Principle 1: Conduct a hazard analysis~~
- 5260 2. ~~Principle 2: Determine the critical control points (CCPs)~~
- 5261 3. ~~Principle 3: Establish critical limits~~
- 5262 4. ~~Principle 4: Establish monitoring procedures~~
- 5263 5. ~~Principle 5: Establish corrective actions~~
- 5264 6. ~~Principle 6: Establish verification procedures~~
- 5265 7. ~~Principle 7: Establish record keeping and documentation procedures.~~

5266 This appendix will provide a brief overview of each of the seven principles of HACCP. A
5267 more comprehensive discussion of these principles is available from FDA by accessing
5268 the NACMCF guidance document⁴. Following the overview, a practical scheme for
5269 applying and implementing the HACCP principles in retail and food service
5270 establishments is presented.

5271 **C. ~~What are Prerequisite Programs?~~**

5272 In order for a HACCP system to be effective, a strong foundation of procedures that
5273 address the basic operational and sanitation conditions within an operation must first be
5274 developed and implemented. These procedures are collectively termed "prerequisite
5275 programs." When prerequisite programs are in place, more attention can be given to
5276 controlling hazards associated with the food and its preparation. Prerequisite programs
5277 may include such things as:

- 5278 ○ ~~Vendor certification programs~~
- 5279 ○ ~~Training programs~~
- 5280 ○ ~~Allergen management~~
- 5281 ○ ~~Buyer specifications~~
- 5282 ○ ~~Recipe/process instructions~~
- 5283 ○ ~~First In First Out (FIFO) procedures~~
- 5284 ○ ~~Other Standard Operating Procedures (SOPs).~~

5285 Basic prerequisite programs should be in place to:

5286 ○ Protect products from contamination by biological, chemical, and physical food
5287 safety hazards

5288 ○ Control bacterial growth that can result from temperature abuse

5289 ○ Maintain equipment.

5290 Additional information about prerequisite programs and the types of activities usually
5291 included in them can be found in the FDA's Retail HACCP manuals discussed later in
5292 this Appendix or by accessing the NACMCF guidance document on the FDA Web Page.

5293 **2. The HACCP Principles**

5294 **A. Principle #1: Conduct a Hazard Analysis**

5295 **1. What is a food safety hazard?**

5296 A hazard is a biological, chemical, or physical property that may cause a food to
5297 be unsafe for human consumption.

5298 **2. What are biological hazards?**

5299 Biological hazards include bacterial, viral, and parasitic microorganisms. See
5300 Table 1 in this Appendix for a listing of selected biological hazards. Bacterial
5301 pathogens comprise the majority of confirmed foodborne disease outbreaks and
5302 cases. Although cooking destroys the vegetative cells of foodborne bacteria to
5303 acceptable levels, spores of spore-forming bacteria such as *Bacillus cereus*,
5304 *Clostridium botulinum*, and *Clostridium perfringens* survive cooking and may
5305 germinate and grow if food is not properly cooled or held after cooking. The
5306 toxins produced by the vegetative cells of *Bacillus cereus*, *Clostridium*
5307 *botulinum*, and *Staphylococcus aureus* may not be destroyed to safe levels by
5308 reheating. Post-cook recontamination with vegetative cells of bacteria such as
5309 *Salmonellae* and *Campylobacter jejuni* is also a major concern for operators of
5310 retail and food service establishments.

5311 Viruses such as norovirus, hepatitis A, and rotavirus are directly related to
5312 contamination from human feces. Recent outbreaks have also shown that these
5313 viruses may be transmitted via droplets in the air. In limited cases, foodborne
5314 viruses may occur in raw commodities contaminated by human feces (e.g.,
5315 shellfish harvested from unapproved, polluted waters). In most cases, however,
5316 contamination of food by viruses is the result of cross-contamination by ill food
5317 employees or unclean equipment and utensils. Unlike bacteria, a virus cannot
5318 multiply outside of a living cell. Cooking as a control for viruses may be
5319 ineffective because many foodborne viruses seem to exhibit heat resistance
5320 exceeding cooking temperature requirements, under laboratory conditions.
5321 Obtaining food from approved sources, practicing no bare hand contact with
5322 ready-to-eat food as well as proper handwashing, and implementing an employee
5323 health policy to restrict or exclude ill employees are important control measures
5324 for viruses.

5325 Parasites are most often animal host specific, but can include humans in their life
 5326 cycles. Parasitic infections are commonly associated with undercooking meat
 5327 products or cross contamination of ready to eat food with raw animal foods,
 5328 untreated water, or contaminated equipment or utensils. Like viruses, parasites do
 5329 not grow in food, so control is focused on destroying the parasites and/or
 5330 preventing their introduction. Adequate cooking destroys parasites. In addition,
 5331 parasites in fish to be consumed raw or undercooked can also be destroyed by
 5332 effective freezing techniques. Parasitic contamination by ill employees can be
 5333 prevented by proper handwashing, no bare hand contact with ready to eat food,
 5334 and implementation of an employee health policy to restrict or exclude ill
 5335 employees.

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Appendix G, Table 1. Selected Biological Hazards Found at Retail, Associated Foods, and Control Measures

Hazard		Associated Foods	Control Measures
Bacteria	Bacillus cereus (intoxication caused by heat stable, preformed emetic toxin and infection by heat labile, diarrheal toxin)	Meat, poultry, starchy foods (rice, potatoes), puddings, soups, cooked vegetables	Cooking, cooling, cold holding, hot holding
	Campylobacter jejuni	Poultry, raw milk	Cooking, handwashing, prevention of cross contamination
	Clostridium botulinum	Vacuum packed foods, reduced oxygen packaged foods, under processed canned foods, garlic in oil mixtures, time/temperature abused baked potatoes/sautéed onions	Thermal processing (time + pressure), cooling, cold holding, hot holding, acidification and drying, etc.
	Clostridium perfringens	Cooked meat and poultry, Cooked meat and poultry products including casseroles, gravies	Cooling, cold holding, reheating, hot holding
	E. coli O157:H7 (other shiga toxin producing E. coli)	Raw ground beef, raw seed sprouts, raw milk, unpasteurized juice, foods contaminated by infected food workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing, prevention of cross contamination, pasteurization or treatment of juice

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	<i>Listeria monocytogenes</i>	Raw meat and poultry, fresh soft cheese, pâté, smoked seafood, deli meats, deli salads	Cooking, date marking, cold holding, handwashing, prevention of cross contamination
	<i>Salmonella</i> spp.	Meat and poultry, seafood, eggs, raw seed sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, use of pasteurized eggs, employee health policy, no bare hand contact with RTE foods, handwashing, pasteurization or treatment of juice
	<i>Shigella</i> spp.	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, no bare hand contact with RTE foods, employee health policy, handwashing
	<i>Staphylococcus aureus</i> (preformed heat stable toxin)	RTE PHF foods touched by bare hands after cooking and further time/temperature abused	Cooling, cold holding, hot holding, no bare hand contact with RTE food, handwashing
	<i>Vibrio</i> spp.	Seafood, shellfish	Cooking, approved source, prevention of cross contamination, cold holding
Parasites	<i>Anisakis simplex</i>	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, freezing
	<i>Taenia</i> spp.	Beef and pork	Cooking
	<i>Trichinella spiralis</i>	Pork, bear, and seal meat	Cooking

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Viruses	Hepatitis A and E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing
	Other Viruses (Rotavirus, Norovirus, Reovirus)	Any food contaminated by infected worker via fecal-oral route	No bare hand contact with RTE food, minimizing bare hand contact with foods not RTE, employee health policy, handwashing

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RTE = ready to eat

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PHF = potentially hazardous food (time/temperature control for safety food)

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3. ~~What are Chemical Hazards?~~

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Chemical hazards may be naturally occurring or may be added during the processing of food. High levels of toxic chemicals may cause acute cases of foodborne illness, while chronic illness may result from low levels.

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The Code of Federal Regulations⁵, Title 21 Food and Drugs, provides guidance on naturally occurring poisonous or deleterious substances, e.g., 21 CFR Parts 109 Unavoidable Contaminants in Food for Human Consumption and Food Packaging Material, and 184 Direct Food Substances Affirmed as Generally Recognized as Safe. The CFR also provide allowable limits for many of the chemicals added during processing, e.g., 21 CFR Part 172 Food Additives Permitted for Direct Addition to Food For Human Consumption.

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FDA's Compliance Policy Guidelines also provide information on naturally occurring chemicals. See Chapter 5 Foods, Colors and Cosmetics⁶. Examples include sections:

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- ~~540.600 Fish, Shellfish, Crustaceans, and Other Aquatic Animals—Fresh, Frozen or Processed—Methyl Mercury,~~

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- ~~555.400 Foods—Adulteration with Aflatoxin, and~~

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- ~~570.200 Aflatoxin in Brazil Nuts, .375 Peanuts and Peanut Products, and .500 Pistachio Nuts.~~

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Table 2 of this Appendix provides additional examples of chemical hazards, both naturally occurring and added.

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4. ~~Food Allergens As Food Safety Hazards~~

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Recent studies indicate that over 11 million Americans suffer from one or more food allergies. A food allergy is caused by a naturally occurring protein in a food or a food ingredient, which is referred to as an "allergen." For unknown reasons, certain individuals produce immunoglobulin E (IgE) antibodies specifically directed to food allergens. When these sensitive individuals ingest sufficient concentrations of foods containing these allergens, the allergenic proteins interact with IgE antibodies and elicit an abnormal immune response. A food allergic

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- 5372 response is commonly characterized by hives or other itchy rashes, nausea,
 5373 abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and
 5374 swelling of various parts of the body. In severe cases, anaphylactic shock and
 5375 death may result.
- 5376 Many foods, with or without identifiable allergens, have been reported to cause
 5377 food allergies. However, FDA believes there is scientific consensus that the
 5378 following foods can cause a serious allergic reaction in sensitive individuals;
 5379 these foods account for 90% or more of all food allergies:
- 5380 *—Milk
 - 5381 *—Egg
 - 5382 *—Fish (such as bass, flounder, or cod)
 - 5383 *—Crustacean shellfish (such as crab, lobster, or shrimp)
 - 5384 *—Tree nuts (such as almonds, pecans, or walnuts)
 - 5385 *—Wheat
 - 5386 *—Peanuts
 - 5387 *—Soybeans.
- 5388 Consumers with food allergies rely heavily on information contained on food
 5389 labels to avoid food allergens. Each year, FDA receives reports from consumers
 5390 who have experienced an adverse reaction following exposure to a food allergen.
 5391 Frequently, these reactions occur either because product labeling does not inform
 5392 the consumer of the presence of the allergenic ingredient in the food or because
 5393 of the cross-contact of a food with an allergenic substance not intended as an
 5394 ingredient of the food during processing and preparation.
- 5395 In August 2004, the Food Allergen Labeling and Consumer Protection Act
 5396 (Public Law 108-282, Title II) was enacted, which defines the term "major food
 5397 allergen." The definition of "major food allergen" adopted for use in the Food
 5398 Code (see paragraph 1-201.10(B)) is consistent with the definition in the new
 5399 law. The following requirements are included in the new law:
- 5400 *—For foods labeled on or after January 1, 2006, food manufacturers must
 5401 identify in plain language on the label of the food any major food allergen
 5402 used as an ingredient in the food, including a coloring, flavoring, or
 5403 incidental additive.
 - 5404 *—FDA is to conduct inspections to ensure that food facilities comply with
 5405 practices to reduce or eliminate cross-contact of a food with any major food
 5406 allergens that are not intentional ingredients of the food.
 - 5407 *—Within 18 months of the date of enactment of the new law (i.e., by February
 5408 2, 2006), FDA must submit a report to Congress that analyzes the results of
 5409 its food inspection findings and addresses a number of specific issues related
 5410 to the production, labeling, and recall of foods that contain an undeclared
 5411 major food allergen.

- 5412 ▪—Within 2 years of the date of enactment of the new law (i.e., by August 2,
- 5413 2006), FDA must issue a proposed rule, and within 4 years of the date of
- 5414 enactment of the new law (i.e., by August 2, 2008), FDA must issue a final
- 5415 rule to define and permit the use of the term "gluten free" on food labeling.

- 5416 ▪—FDA is to work in cooperation with the Conference for Food Protection
- 5417 (CFP) to pursue revision of the Food Code to provide guidelines for
- 5418 preparing allergen-free foods in food establishments.

Appendix G, Table 2. Common Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Chemical Hazards		Associated Foods	Control measures
Naturally Occurring:	Scombrototoxin	Primarily associated with tuna fish, mahi-mahi, blue fish, anchovies bonito, mackerel; Also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature abused prior to arrival in facility.
	Ciguatotoxin	Reef fin fish from extreme SE US, Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, and snappers	Ensure fin fish have not been caught: Purchase fish from approved sources. Fish should not be harvested from an area that is subject to an adverse advisory.
	Tetrodotoxin	Puffer fish (Fugu; Blowfish)	Do not consume these fish.
Mycotoxins	Aflatoxin	Corn and corn products, peanuts and peanut products, cottonseed, milk, and tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts. Other grains and nuts are susceptible but less prone to contamination.	Check condition at receiving; do not use moldy or decomposed food.
	Patulin	Apple juice products	Buyer Specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing.
	Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved source.
	Shellfish toxins	Paralytic shellfish poisoning	Molluscan shellfish from NE and NW coastal regions; mackerel,

	(PSP)	viscera of lobsters and Dungeness, tanner, and red rock crabs	from an approved source; and properly tagged and labeled.
	Diarrhetic shellfish poisoning (DSP)	Molluscan shellfish in Japan, western Europe, Chile, NZ, eastern Canada	
	Neurotoxin shellfish poisoning (NSP)	Molluscan shellfish from Gulf of Mexico	
	Amnesic shellfish poisoning (ASP)	Molluscan shellfish from NE and NW coasts of NA; viscera of Dungeness, tanner, red rock crabs and anchovies.	
	Pyrrolizidine alkaloids	Plants food containing these alkaloids. Most commonly found in members of the Boraginaceae, Compositae, and Leguminosae families.	Do not consume of food or medicinals contaminated with these alkaloids.
	Phytohaemagglutinin	Raw red kidney beans (Undercooked beans may be more toxic than raw beans)	Soak in water for at least 5 hours. Pour away the water. Boil briskly in fresh water, with occasional stirring, for at least 10 minutes.
Added Chemicals:	Environmental contaminants: Pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
	PCBs	Fish	Comply with fish advisories.
	Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.
	Toxic elements/compounds	Fish exposed to organic mercury: shark, tilefish,	Pregnant women/women of childbearing age/nursing mothers, and

Mercury	king mackerel and swordfish. Grains treated with mercury based fungicides	young children should not eat shark, swordfish, king mackerel or tilefish because they contain high levels of mercury. Do not use mercury containing fungicides on grains or animals.
Copper	High acid foods and beverages.	Do not store high acid foods in copper utensils; use backflow prevention device on beverage vending machines.
Lead	High acid foods and beverages.	Do not use vessels containing lead.
Preservatives and Food Additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite) Nitrites/nitrates Niacin	Fresh fruits and Vegetables Shrimp Lobster Wine Cured meats, fish, any food exposed to accidental contamination, spinach Meat and other foods to which sodium nicotinate is added	Sulfiting agents added to a product in a processing plant must be declared on labeling. Do not use on raw produce in food establishments. Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrites.
Flavor enhancers Monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints)	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.
Allergens	Foods containing or contacted by: <ul style="list-style-type: none"> ▪ Milk ▪ Egg ▪ Fish ▪ Crustacean shellfish ▪ Tree nuts 	Use a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients.

		<ul style="list-style-type: none"> ▪—Wheat ▪—Peanuts ▪—Soybeans 	
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5. —What are Physical Hazards?

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Illness and injury can result from foreign objects in food. These physical hazards can result from contamination or poor procedures at many points in the food chain from harvest to consumer, including those within the food establishment. As establishments develop their food safety management systems, Appendix G, Table 3 can be used to aid in the identification of sources of potential physical hazards to the food being prepared, served, or sold. Appendix G, Table 3 provides some examples of common physical hazards.

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Appendix G, Table 3. Main Materials of Concern as Physical Hazards and Common Sources^{a, b}		
Material	Injury Potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth Cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

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^a Adapted from Corlett (1991).

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^b Used with permission, "HACCP principles and Applications", Pierson and Corlett, Eds. 1992. Chapman & Hall, New York, NY.

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6. —What is the purpose of the hazard analysis principle?

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~~The purpose of hazard analysis is to develop a list of food safety hazards that are reasonably likely to cause illness or injury if not effectively controlled.~~

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7. ~~How is the hazard analysis conducted?~~

~~The process of conducting a hazard analysis involves two stages:~~

- ~~• Hazard Identification~~
- ~~• Hazard Evaluation~~

~~Hazard identification can be thought of as a brain storming session. This stage focuses on identifying the food safety hazards that might be present in the food given the food preparation process used, the handling of the food, the facility, and general characteristics of the food itself. During this stage, a review is made of the ingredients used in the product, the activities conducted at each step in the process, the equipment used, the final product, and its method of storage and distribution, as well as the intended use and consumers of the product. Based on this review, a list of potential biological, chemical, or physical hazards is made at each stage in the food preparation process.~~

~~In stage two, the hazard evaluation, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. The purpose of this stage is to determine which of the potential hazards listed in stage one of the hazard analysis warrant control in the HACCP plan. Severity is the seriousness of the consequences of exposure to the hazard. Considerations made when determining the severity of a hazard include understanding the impact of the medical condition caused by the illness, as well as the magnitude and duration of the illness or injury. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. Hazards that are not reasonably likely to occur are not considered in a HACCP plan. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage, and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled.~~

~~Upon completion of the hazard analysis, a list of significant hazards that must be considered in the HACCP plan is made, along with any measure(s) that can be used to control the hazards. These measures, called control measures, are actions or activities that can be used to prevent, eliminate, or reduce a hazard. Some control measures are not essential to food safety, while others are. Control measures essential to food safety like proper cooking, cooling, and refrigeration of ready-to-eat, potentially hazardous foods (time/temperature control for safety foods) are usually applied at critical control points (CCPs) in the HACCP plan (discussed later). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. Likewise, more than one hazard may be addressed by a specific control measure (e.g., proper cooking).~~

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B. Principle #2: Determine Critical Control Points (CCPs)

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1. What is the Critical Control Point (CCP)?

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A critical control point (CCP) means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk. Control can be applied at this point and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated, or reduced to acceptable levels. Common examples of CCPs include cooking, cooling, hot holding, and cold holding of ready-to-eat potentially hazardous foods (time/temperature control for safety foods). Due to vegetative and spore- and toxin-forming bacteria that are associated with raw animal foods, it is apparent that the proper execution of control measures at each of these operational steps is essential to prevent or eliminate food safety hazards or reduce them to acceptable levels.

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2. Are quality issues considered when determining CCPs?

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CCPs are only used to address issues with product safety. Actions taken on the part of the establishment such as first-in-first-out (FIFO) or refrigerating nonpotentially hazardous foods (time/temperature control for safety foods) are to ensure food quality rather than food safety and therefore should not be considered as CCPs unless they serve a dual purpose of ensuring food safety.

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3. Are the CCPs the same for everyone?

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Different facilities preparing similar food items may identify different hazards and the CCPs. This can be due to differences in each facility's layout, equipment, selection of ingredients, and processes employed. In mandatory HACCP systems, there may be rigid regulatory requirements regarding what must be designated a CCP. In voluntary HACCP systems, hazard control may be accomplished at CCPs or through prerequisite programs. For instance, one facility may decide that it can best manage the hazards associated with cooling through a standardized procedure in its prerequisite programs rather than at a CCP in its HACCP plan. One tool that can be used to assist each facility in the identification of CCPs unique to its operation is a CCP decision tree.

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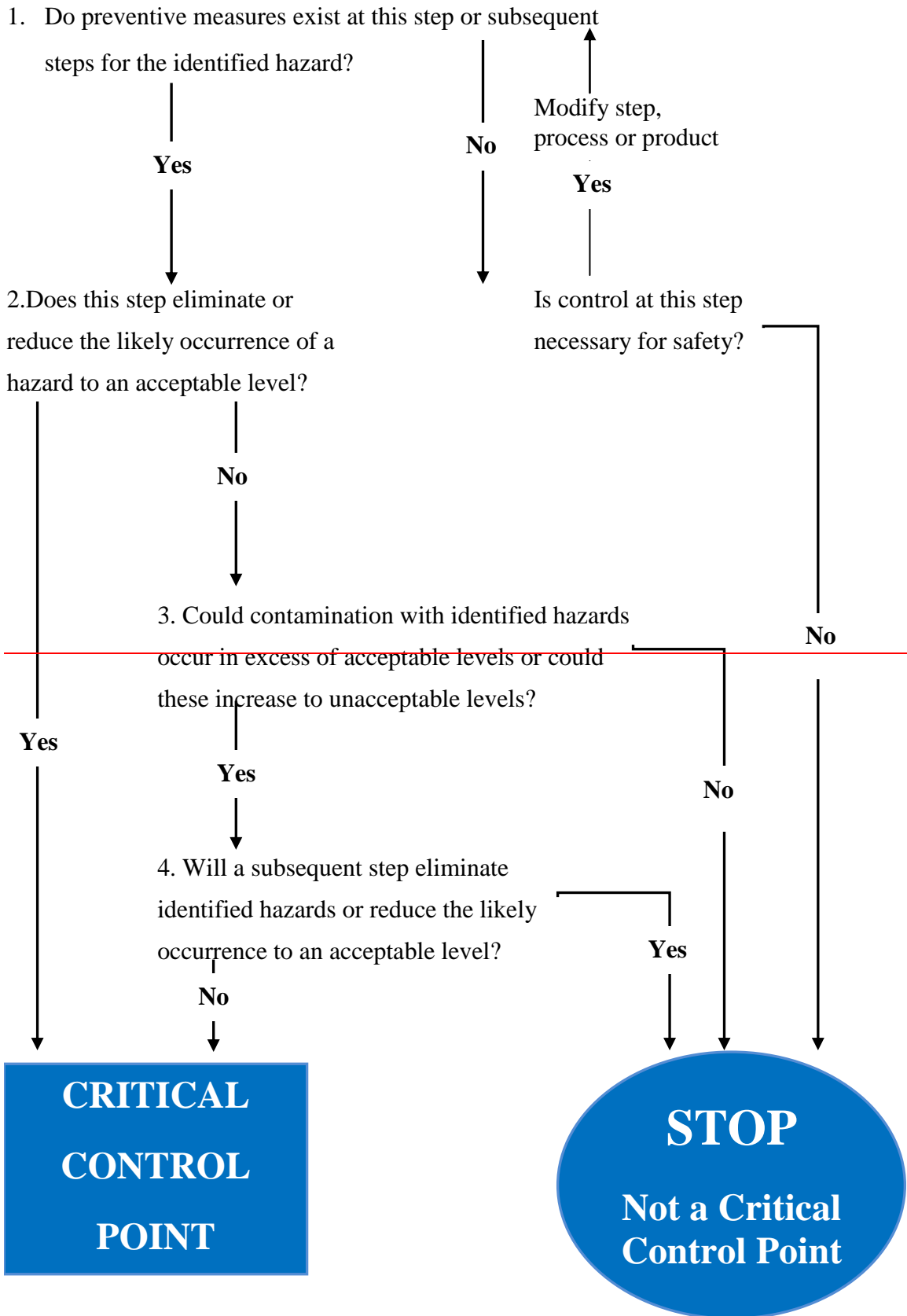
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5512 **C. ~~Principle #3: Establish Critical Limits~~**

5513 **1. ~~What is a critical limit and what is its purpose?~~**

5514 A critical limit is a prescribed parameter (e.g., minimum and/or maximum value)
5515 that must be met to ensure that food safety hazards are controlled at each CCP. A
5516 critical limit is used to distinguish between safe and unsafe operating conditions
5517 at a CCP. Each control measure at a CCP has one or more associated critical
5518 limits. Critical limits may be based upon factors like temperature, time, moisture
5519 level, water activity (a_w), or pH. They must be scientifically based and
5520 measurable.

5521 **2. ~~What are examples of critical limits?~~**

5522 Examples of critical limits are the time/temperature parameters for cooking
5523 chicken (165°F for 15 seconds). In this case, the critical limit designates the
5524 minimum criteria required to eliminate food safety hazards or reduce them to an
5525 acceptable level. The critical limit for the acidification of sushi rice, a pH of ≤ 4.6 ,
5526 sets the maximum limit for pH necessary to control the growth of spore and
5527 toxin forming bacteria. Critical limits may be derived from regulatory standards
5528 such as the rules and regulations, other applicable guidelines, performance
5529 standards, or experimental results.

5530 **D. ~~Principle #4: Establish Monitoring Procedures~~**

5531 **1. ~~What is the purpose of monitoring?~~**

5532 Monitoring is the act of observing and making measurements to help determine if
5533 critical limits are being met and maintained. It is used to determine whether the
5534 critical limits that have been established for each CCP are being met.

5535 **2. ~~What are examples of monitoring activities?~~**

5536 Examples of monitoring activities include visual observations and measurements
5537 of time, temperature, pH, and water activity. If cooking chicken is determined to
5538 be a CCP in an operation, then monitoring the internal temperature of a select
5539 number of chicken pieces immediately following the cook step would be an
5540 example of a monitoring activity. Alternatively, the temperature of an oven or
5541 fryer and the time required to reach an internal temperature of 165°F could also
5542 be monitored.

5543 **3. ~~How is monitoring conducted?~~**

5544 Typically, monitoring activities fall under two broad categories:

5545 * ~~measurements~~

5546 * ~~observations~~

5547 Measurements usually involve time and temperature but also include other
5548 parameters such as pH. If an operation identifies the acidification of sushi rice as

5549 a CCP and the critical limit as the final pH of the product being ≤ 4.6 , then the
5550 pH of the product would be measured to ensure that the critical limit is met.

5551 Observations involve visual inspections to monitor the presence or absence of a
5552 food safety activity. If date marking is identified as a CCP in a deli operation for
5553 controlling *Listeria monocytogenes* in ready-to-eat deli meats, then the
5554 monitoring activity could involve making visual inspections of the date marking
5555 system to monitor the sell, consume, or discard dates.

5556 **4. How often is monitoring conducted?**

5557 Monitoring can be performed on a continuous or intermittent basis. Continuous
5558 monitoring is always preferred when feasible as it provides the most complete
5559 information regarding the history of a product at a CCP. For example, the
5560 temperature and time for an institutional cook-chill operation can be recorded
5561 continuously on temperature recording charts.

5562 If intermittent monitoring is used, the frequency of monitoring should be
5563 conducted often enough to make sure that the critical limits are being met.

5564 **5. Who conducts monitoring?**

5565 Individuals directly associated with the operation (e.g., the person in charge of
5566 the establishment, chefs, and departmental supervisors) are often selected to
5567 monitor CCPs. They are usually in the best position to detect deviations and take
5568 corrective actions when necessary. These employees should be properly trained
5569 in the specific monitoring techniques and procedures used.

5570 **E. Principle #5: Establish Corrective Actions**

5571 **1. What are corrective actions?**

5572 Corrective actions are activities that are taken by a person whenever a critical
5573 limit is not met. Discarding food that may pose an unacceptable food safety risk
5574 to consumers is a corrective action. However, other corrective actions such as
5575 further cooking or reheating a product can be used provided food safety is not
5576 compromised. For example, a restaurant may be able to continue cooking
5577 hamburgers that have not reached an internal temperature of 155°F for 15
5578 seconds until the proper temperature is met. Clear instructions should be
5579 developed detailing who is responsible for performing the corrective actions, the
5580 procedures to be followed, and when.

5581 **F. Principle #6: Establish Verification Procedures**

5582 **1. What is verification?**

5583 Verification includes those activities, other than monitoring, that determine the
5584 validity of the HACCP plan and show that the system is operating according to
5585 the plan. Validation is a component of verification which focuses on collecting
5586 and evaluating scientific and technical information to determine if the HACCP
5587 system, when properly implemented, will effectively control the hazards. Clear
5588 instructions should be developed detailing who is responsible for conducting
5589 verification, the frequency of verification, and the procedures used.

5590 **2. ~~What is the frequency of verification activities? What are some~~**
 5591 **~~examples of verification activities?~~**

5592 Verification activities are conducted frequently, such as daily, weekly, monthly,
 5593 and include the following:

- 5594 ~~▪—observing the person doing the monitoring and determining whether~~
 5595 ~~monitoring is being done as planned~~
- 5596 ~~▪—reviewing the monitoring records to determine if they are completed~~
 5597 ~~accurately and consistently~~
- 5598 ~~▪—determining whether the records show that the frequency of monitoring~~
 5599 ~~stated in the plan is being followed~~
- 5600 ~~▪—ensuring that corrective action was taken when the person monitoring found~~
 5601 ~~and recorded that the critical limit was not met~~
- 5602 ~~▪—validating that the critical limits are achieving the desired results of~~
 5603 ~~controlling the identified hazard~~
- 5604 ~~▪—confirming that all equipment, including equipment used for monitoring, is~~
 5605 ~~operated, maintained, and calibrated properly.~~

5606 **G. ~~Principle #7: Establish Record Keeping Procedures~~**

5607 **1. ~~Why are records important?~~**

5608 Maintaining documentation of the activities in a food safety management system
 5609 can be vital to its success. Records provide documentation that appropriate
 5610 corrective actions were taken when critical limits were not met. In the event that
 5611 an establishment is implicated in a foodborne illness, documentation of activities
 5612 related to monitoring and corrective actions can provide proof that reasonable
 5613 care was exercised in the operation of the establishment. Documenting activities
 5614 provides a mechanism for verifying that the activities in the HACCP plan were
 5615 properly completed. In many cases, records can serve a dual purpose of ensuring
 5616 quality and food safety.

5617 **2. ~~What types of records are maintained as part of a food safety~~**
 5618 **~~management system?~~**

5619 There are at least 5 types of records that could be maintained to support a food
 5620 safety management system:

- 5621 ~~▪—records documenting the activities related to the prerequisite programs~~
- 5622 ~~▪—monitoring records~~
- 5623 ~~▪—corrective action records~~
- 5624 ~~▪—verification and validation records~~
- 5625 ~~▪—calibration records.~~

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5628 **3. The Process Approach – A Practical Application of HACCP at Retail to Achieve**
5629 **Active Managerial Control**

5630 **A. Why Focus on HACCP Principles at Retail and Food Service?**

5631 FDA recognizes that there are important differences between using HACCP principles in
5632 a food safety management system developed for food manufacturing plants and applying
5633 these same principles in food safety management system developed for use in retail and
5634 food service establishments.

5635 Since the 1980's, operators and regulators have been exploring the use of the HACCP
5636 principles in restaurants, grocery stores, institutional care facilities, and other retail food
5637 establishments. During this time, much has been learned about how these principles can
5638 be used in these varied operations, collectively referred to as retail food establishments.
5639 Most of this exploration has centered around the focal question of how to stay true to the
5640 NACMCF definitions of HACCP and still make the principles useful to an industry that
5641 encompasses the broadest range of conditions.

5642 Unlike industries such as canning, other food processing, and dairy plants, the retail
5643 industry is not easily defined by specific commodities or conditions. Consider the
5644 following characteristics that retail food establishments share that set them apart from
5645 most food processors:

- 5646 1. Employee and management turnover is exceptionally high in food
5647 establishments, especially for entry level positions. This means the many
5648 employees or managers have little experience and food safety training must be
5649 continuously provided.
- 5650 2. Many establishments are start-up businesses operating without benefit of a large
5651 corporate support structure and having a relatively low profit margin and perhaps
5652 less capital to work with than other segments of the food industry.
- 5653 3. There is an almost endless number of production techniques, products, menu
5654 items, and ingredients used which are not easily adapted to a simple, standardized
5655 approach. Changes occur frequently and little preparation time is available.

5656 FDA fully recognizes the diversity of retail and food service establishments and their
5657 varying in-house resources to implement HACCP. That recognition is combined with an
5658 understanding that the success of such implementation is dependent upon establishing
5659 realistic and useful food safety strategies that are customized to the operation.

5660 **B. What is the Process Approach?**

5661 When conducting the hazard analysis, food manufacturers usually use food commodities
5662 as an organizational tool and follow the flow of each product. This is a very useful
5663 approach for producers or processors since they are usually handling one product at a
5664 time. By contrast, in retail and food service operations, foods of all types are worked
5665 together to produce the final product. This makes a different approach to the hazard
5666 analysis necessary. Conducting the hazard analysis by using the food preparation
5667 processes common to a specific operation is often more efficient and useful for retail and
5668 food service operators. This is called the "process approach" to HACCP.

5669 The process approach can best be described as dividing the many food flows in an
 5670 establishment into broad categories based on activities or stages in the preparation of the
 5671 food, then analyzing the hazards, and placing managerial controls on each grouping.

5672 ~~C. What are the three food preparation processes most often used in retail and~~
 5673 ~~food service establishments and how are they determined?~~

5674 The flow of food in a retail or food service establishment is the path that food follows
 5675 from receiving through service or sale to the consumer. Several activities or stages make
 5676 up the flow of food and are called operational steps. Examples of operational steps
 5677 include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling,
 5678 packaging, serving, and selling. The terminology used for operational steps may differ
 5679 between food service and retail food store operations.

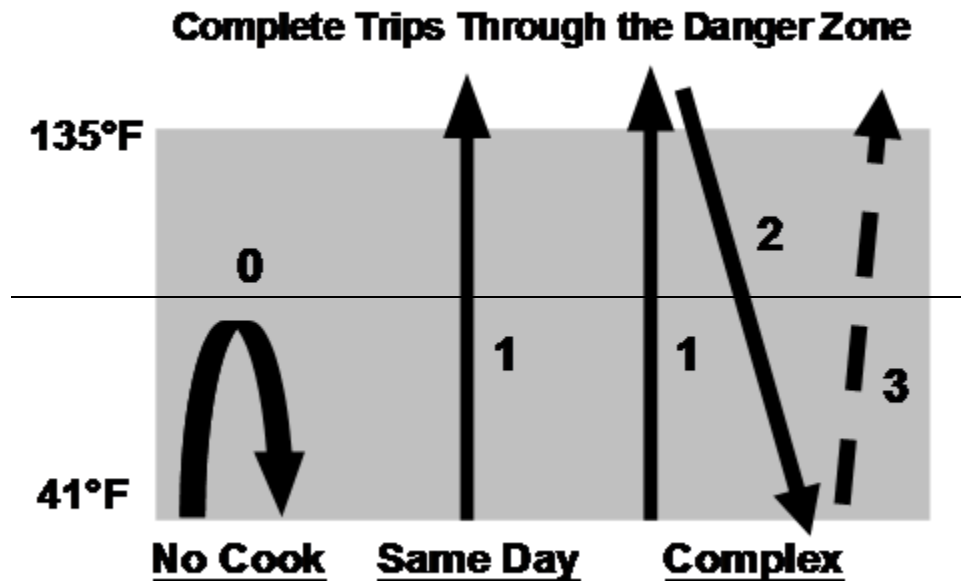
5680 Most food items produced in a retail or food service establishment can be categorized
 5681 into one of three preparation processes based on the number of times the food passes
 5682 through the temperature danger zone between 41°F and 135°F:

5683 ~~○ Process 1: Food Preparation with No Cook Step~~
 5684 ~~Example flow: Receive – Store – Prepare – Hold – Serve~~
 5685 ~~(other food flows are included in this process, but there is no cook step to destroy~~
 5686 ~~pathogens)~~

5687 ~~○ Process 2: Preparation for Same Day Service~~
 5688 ~~Example flow: Receive – Store – Prepare – Cook – Hold – Serve~~
 5689 ~~(other food flows are included in this process, but there is only one trip through the~~
 5690 ~~temperature danger zone)~~

5691 ~~○ Process 3: Complex Food Preparation~~
 5692 ~~Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve~~
 5693 ~~(other food flows are included in this process, but there are always two or more complete~~
 5694 ~~trips through the temperature danger zone)~~

5695 A summary of the three food preparation processes in terms of number of times through
 5696 the temperature danger zone can be depicted in a Danger Zone diagram. Although foods
 5697 produced using process 1 may enter the danger zone, they do not pass all the way through
 5698 it. Foods that go through the danger zone only once are classified as Same Day Service,
 5699 while foods that go through more than once are classified as Complex food preparation.



5700

5701 The three food preparation processes conducted in retail and food service establishments
 5702 are not intended to be all-inclusive. For instance, quick service facilities may have "cook
 5703 and serve" processes specific to their operation. These processes are likely to be different
 5704 from the "Same Day Service" preparation processes in full service restaurants since many
 5705 of their foods are generally cooked and hot held before service. In addition, in retail food
 5706 stores, operational steps such as packaging and assembly may be included in all of the
 5707 food preparation processes before the product is sold to the consumer. It is also very
 5708 common for a retail or food service operator to use multiple food preparation processes to
 5709 create a single menu item.

5710 **D. How is a hazard analysis conducted in process HACCP?**

5711 In the process approach to HACCP, conducting a hazard analysis on individual food
 5712 items is time and labor intensive and is generally unnecessary. Identifying and controlling
 5713 the hazards in each food preparation process achieves the same control of risk factors as
 5714 preparing a HACCP plan for each individual product.

5715 Example: An establishment has dozens of food items (including baked chicken and baked
 5716 meatloaf) in the "Preparation for Same Day Service" category. Each of the food items
 5717 may have unique hazards, but regardless of the individual hazards, control via proper
 5718 cooking and holding will generally ensure the safety of all of the foods in this category.
 5719 An illustration of this concept follows:

5720 1. Even though they have unique hazards, baked chicken and meatloaf are items
 5721 frequently grouped in the "Same Day Service" category (Process 2).

5722 2. Salmonella spp. and Campylobacter, as well as spore formers, such as Bacillus cereus
 5723 and Clostridium perfringens, are significant biological hazards in chicken.

- 5724 3. Significant biological hazards in meatloaf include Salmonella spp., E. coli
5725 O157:H7, Bacillus cereus, and Clostridium perfringens.
- 5726 4. Despite their different hazards, the control measure used to kill pathogens in both
5727 these products is cooking to the proper temperature.
- 5728 5. Additionally, if the products are held after cooking, then proper hot holding or
5729 time control is also required to prevent the outgrowth of spore formers that are
5730 not destroyed by cooking.

5731 As with product-specific HACCP, critical limits for cooking remain specific to each food
5732 item in the process. In the scenario described above, the cooking step for chicken requires
5733 a final internal temperature of 165°F for 15 seconds to control the pathogen load for
5734 Salmonella spp. Meatloaf, on the other hand, is a ground beef product and requires a final
5735 internal temperature of 155°F for 15 seconds to control the pathogen load for both
5736 Salmonella spp. and E. coli O157:H7. Some operational steps such as refrigerated storage
5737 or hot holding have critical limits that apply to all foods.

5738 Appendix G, Table 4 further illustrates this concept. Note that the only unique control
5739 measure applies to the critical limit of the cooking step for each of the products. Other
5740 food safety hazards and control measures may exist that are not depicted here:

Appendix G, Table 4: Examples of Hazards and Control Measures for Same Day Service Items

Process 2: Preparation for Same Day Service		
Example Products	Baked Meatloaf	Baked Chicken
Example Biological Hazards	Salmonella spp.	Salmonella spp.
	E. coli O157:H7	Campylobacter
	Clostridium perfringens	Clostridium perfringens
	Bacillus cereus	Bacillus cereus
	Various fecal-oral route pathogens	Various fecal-oral route pathogens
Example Control Measures	Refrigeration at 41°F or below	Refrigeration at 41°F or below
	Cooking at 155°F for 15 seconds	Cooking at 165°F for 15 seconds
	Hot Holding at 135°F or above OR Time Control	Hot Holding at 135°F or above OR Time Control
	Good personal hygiene (No bare hand contact with RTE* food, proper handwashing, exclusion/restriction of ill employees)	Good personal hygiene (No bare hand contact with RTE* food, proper handwashing, exclusion/restriction of ill employees)

5741 *RTE = ready to eat food

5742 **E. — How is the process approach helpful to industry in determining the measures**
 5743 **that must be implemented to actively manage the foodborne illness risk**
 5744 **factors that result in out-of-control hazards?**

5745 ~~Even though variations in foods and in the three food preparation process flows used to~~
 5746 ~~prepare them are common, the control measures will generally be the same based on the~~
 5747 ~~number of times the food goes through the temperature danger zone. Several of the most~~
 5748 ~~common control measures associated with each food preparation process are discussed in~~
 5749 ~~this Appendix. Retail or food service establishments should use these simple control~~
 5750 ~~measures as the core of their food safety management systems; however, there may be~~
 5751 ~~other risk factors unique to an operation or process that are not listed here. Each operation~~
 5752 ~~should be evaluated independently.~~

5753 ~~In developing a voluntary food safety management system, active managerial control of~~
 5754 ~~risk factors common to each process can be achieved by implementing control measures~~
 5755 ~~at certain operational steps designated as critical control points (CCPs) or by~~
 5756 ~~implementing prerequisite programs. This is explained in more detail in the Operator's~~
 5757 ~~Manual discussed in Part 5 of this Appendix.~~

5758 **F. — Facility-wide Considerations**

5759 In order to have active managerial control over personal hygiene and cross
 5760 contamination, certain control measures must be implemented in all phases of the
 5761 operation. All of the following control measures should be implemented regardless of the
 5762 food preparation process used:

5763 ○ ~~No bare hand contact with ready to eat foods (or use of a pre approved, alternative~~
 5764 ~~procedure) to help prevent the transfer of viruses, bacteria, or parasites from hands to~~
 5765 ~~food~~

5766 ○ ~~Proper handwashing to help prevent the transfer of viruses, bacteria, or parasites from~~
 5767 ~~hands to food~~

5768 ○ ~~Restriction or exclusion of ill employees to help prevent the transfer of viruses,~~
 5769 ~~bacteria, or parasites from hands to food~~

5770 ○ ~~Prevention of cross contamination of ready to eat food or clean and sanitized food-~~
 5771 ~~contact surfaces with soiled cutting boards, utensils, aprons, etc., or raw animal foods.~~

5772 **G. — Food Preparation Process 1 — Food Preparation with No Cook Step**

5773 Example Flow: RECEIVE → STORE → PREPARE → HOLD → SERVE

5774 Several food flows are represented by this particular process. Many of these food flows
 5775 are common to both retail food stores and food service facilities, while others only apply
 5776 to retail operations. Raw, ready to eat food like sashimi, raw oysters, and salads are
 5777 grouped in this category. Components of these foods are received raw and will not be
 5778 cooked before consumption.

5779 Foods cooked at the processing level but that undergo no further cooking at the retail
 5780 level before being consumed are also represented in this category. Examples of these
 5781 kinds of foods are deli meats, cheeses, and other pasteurized dairy products (such as
 5782 yogurt). In addition, foods that are received and sold raw but are to be cooked by the

5783 consumer after purchase, e.g., hamburger meat, chicken, and steaks, are also included in
5784 this category.

5785 All the foods in this category lack a cook step while at the retail or food service facility;
5786 thus, there are no complete trips through the danger zone. Purchase specifications can be
5787 required by the retail or food service establishment to ensure that foods are received as
5788 safe as possible. Without a kill step to destroy pathogens, preventing further
5789 contamination by ensuring that employees follow good hygienic practices is an important
5790 control measure.

5791 Cross-contamination must be prevented by properly storing ready-to-eat food away from
5792 raw animal foods and soiled equipment and utensils. Foodborne illness may result from
5793 ready-to-eat food being held at unsafe temperatures for long periods of time due to the
5794 outgrowth of bacteria.

5795 In addition to the facility-wide considerations, a food safety management system
5796 involving this food preparation process should focus on ensuring active managerial
5797 control over the following:

5798 ○ Cold holding or using time alone to control bacterial growth and toxin production

5799 ○ Food source (e.g., shellfish due to concerns with viruses, natural toxins, and *Vibrio*
5800 and for certain marine finfish intended for raw consumption due to concerns with
5801 ciguatera toxin)

5802 ○ Receiving temperatures (e.g., certain species of marine finfish due to concerns with
5803 secombrototoxin)

5804 ○ Date marking of ready-to-eat PHF (TCS food) held for more than 24 hours to control
5805 the growth of psychrophiles such as *Listeria monocytogenes*

5806 ○ Freezing certain species of fish intended for raw consumption due to parasite
5807 concerns

5808 ○ Cooling from ambient temperature to prevent the outgrowth of spore-forming or
5809 toxin-forming bacteria.

5810 **H. Food preparation Process 2 – Preparation for Same Day Service**

5811 Example Flow: RECEIVE → STORE → PREPARE → COOK → HOLD → SERVE

5812 In this food preparation process, food passes through the danger zone only once in the
5813 retail or food service facility before it is served or sold to the consumer. Food is usually
5814 cooked and held hot until served, e.g., fried chicken, but can also be cooked and served
5815 immediately. In addition to the facility-wide considerations, a food safety management
5816 system involving this food preparation process should focus on ensuring active
5817 managerial control over the following:

5818 ○ **Cooking** to destroy bacteria and parasites

5819 ○ **Hot holding or using time alone** to prevent the outgrowth of spore-forming bacteria.

5820 Approved food source, proper receiving temperatures, and proper cold holding before
 5821 cooking would also be important if dealing with certain marine finfish due to concerns
 5822 with ciguatera toxin and scombrototoxin.

5823 ~~I. Food Preparation Process 3 – Complex Food Preparation~~

5824 Example Flow: RECEIVE → STORE → PREPARE → COOK → COOL → REHEAT
 5825 HOT HOLD → SERVE

5826 Foods prepared in large volumes or in advance for next day service usually follow an
 5827 extended process flow. These foods pass through the temperature danger zone more than
 5828 one time; thus, the potential for the growth of spore forming or toxigenic bacteria is
 5829 greater in this process. Failure to adequately control food product temperatures is one of
 5830 the most frequently encountered risk factors contributing to foodborne illness. Food
 5831 handlers should minimize the time foods are at unsafe temperatures.

5832 In addition to the facility wide considerations, a food safety management system
 5833 involving this food preparation process should focus on ensuring active managerial
 5834 control over the following:

- 5835 ○ ~~Cooking~~ to destroy bacteria and parasites
- 5836 ○ ~~Cooling~~ to prevent the outgrowth of spore forming or toxin forming bacteria
- 5837 ○ ~~Hot and cold holding or using time alone~~ to control bacterial growth and toxin
 5838 formation
- 5839 ○ ~~Date marking~~ of ready to eat PHF (TCS food) held for more than 24 hours to control the
 5840 growth of psychrophiles such as *Listeria monocytogenes*
- 5841 ○ ~~Reheating~~ for hot holding, if applicable.

5842 Approved food source, proper receiving temperatures, and proper cold holding before
 5843 cooking would also be important if dealing with certain marine finfish due to concerns
 5844 with ciguatera toxin and scombrototoxin.

5845 ~~4. FDA Retail HACCP Manuals~~

5846 ~~A. What guidance has been developed by FDA to assist operators of retail and food
 5847 service establishments in achieving active managerial control of foodborne illness
 5848 risk factors?~~

5849 FDA, in partnership with Federal, State, and local regulators, industry, academia, and
 5850 consumers, has written a guidance document entitled, "Managing Food Safety: A Manual
 5851 for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail
 5852 Establishments".⁷ "Commonly referred to as the "Operator's Manual," this document is
 5853 designed to assist operators with developing or enhancing food safety management
 5854 systems based on the process approach to HACCP. The manual presents a step-by-step
 5855 procedure for writing and voluntarily implementing a food safety management system
 5856 based on the principles of HACCP. The desired outcome is an operator who employs a
 5857 preventive rather than a reactive strategy to food safety.

5858 The Operator's Manual embodies FDA's current thinking on the application of HACCP
 5859 principles at retail. It advocates the voluntary use of HACCP principles using the process
 5860 approach as a practical and effective means of reducing the occurrence of foodborne

5861 illness risk factors leading to out-of-control hazards. The Operator's Manual is strictly for
 5862 the voluntary implementation of HACCP principles at retail and should not be used to
 5863 develop HACCP plans that are required through Federal, State, or local regulations,
 5864 ordinances, or laws.

5865 **B. ~~What guidance has been developed by FDA to assist regulators of retail and~~**
 5866 **~~food service establishments in assessing industry's active managerial control~~**
 5867 **~~of foodborne illness risk factors?~~**

5868 FDA has written a document for regulators of retail and food service establishments
 5869 entitled, "Managing Food Safety: A Regulator's Manual for Applying HACCP Principles
 5870 to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food
 5871 Safety Management Systems." Commonly referred to as the "Regulator's Manual," this
 5872 document was written to provide a risk-based inspectional "roadmap" for evaluating the
 5873 degree of active managerial control an operator has over foodborne illness risk factors.

5874 In addition, the manual advocates the use of voluntary intervention strategies, including
 5875 the development of food safety management systems or risk control plans to bring about
 5876 a long-term behavior change that will result in a reduction in the occurrence of risk
 5877 factors. In cases where an operator may want their inspector to provide them with
 5878 feedback on their voluntarily implemented food safety management system, the manual
 5879 provides regulators with information on how to validate and verify an existing system.

5880 Annex 5 of the Food Code outlines the basis for conducting successful risk-based
 5881 inspections and is provided to assist industry in achieving active managerial control of
 5882 foodborne illness risk factors as outlined in the draft Recommended National Retail Food
 5883 Regulatory Program Standards and the Regulator's Manual.

5884 **5. ~~Advantages of the HACCP Principles~~**

5885 **A. ~~What advantages does using HACCP principles offer operators of retail and food~~**
 5886 **~~service establishments?~~**

5887 Rather than relying solely on periodic feedback from inspections by regulatory agencies,
 5888 an establishment operator who implements a food safety management system based on
 5889 HACCP principles emphasizes continuous problem-solving and prevention. Additionally,
 5890 HACCP enhances and encourages communication between industry and regulators.

5891 A food safety management system based on HACCP principles offers many other
 5892 advantages to industry. One advantage is that such a system may provide a method for
 5893 achieving active managerial control of multiple risk factors associated with an entire
 5894 operation. Other advantages include:

- 5895 ○ ~~Reduction in product loss~~
- 5896 ○ ~~Increase in product quality~~
- 5897 ○ ~~Better inventory control~~
- 5898 ○ ~~Consistency in product preparation~~
- 5899 ○ ~~Increase in profit~~
- 5900 ○ ~~Increased employee awareness and participation in food safety.~~

5901 **B. ~~What advantage does using HACCP principles offer regulators of retail and food~~**
5902 **~~service establishments?~~**

5903 ~~Traditional inspections are relatively resource-intensive, inefficient, and reactive rather~~
5904 ~~than preventive in nature. Using traditional inspection techniques allows for a satisfactory~~
5905 ~~"snapshot" assessment of the requirements of the code at the time of the inspection.~~
5906 ~~Unfortunately, unless an inspector asks questions and inquires about the activities and~~
5907 ~~procedures being utilized by the establishment even at times when the inspector is not~~
5908 ~~there, there is no way to know if an operator is achieving active _____~~

5909 ~~With the limited time often available for conducting inspections, regulators must focus~~
5910 ~~their attention on those areas that clearly have the greatest impact on food safety—~~
5911 ~~foodborne illness risk factors. By knowing that there are only a few control measures that~~
5912 ~~are essential to food safety and focusing on these during the inspection, an inspector can~~
5913 ~~assess the operator's active managerial control of the foodborne illness risk factors.~~

5914 ~~Regulators can provide invaluable feedback to an operator through their routine~~
5915 ~~inspections. This is especially useful when utilizing a risk-based approach. By~~
5916 ~~incorporating HACCP principles into routine inspections, an inspector can provide an~~
5917 ~~operator with the constructive input needed to establish the control system necessary to~~
5918 ~~bring the foodborne illness risk factors back under continuous control.~~

5919 **6. ~~Summary~~**

5920 ~~In order to make a positive impact on foodborne illness, retail and food service operators must~~
5921 ~~achieve active managerial control of the risk factors contributing to foodborne illness. Combined~~
5922 ~~with basic sanitation, employee training, and other prerequisite programs, the principles of~~
5923 ~~HACCP provide an effective system for achieving this objective.~~

5924 ~~The goal in applying HACCP principles in retail and food service is to have the operator take~~
5925 ~~purposeful actions to ensure safe food. The process approach simplifies HACCP principles for~~
5926 ~~use in retail and food service. This practical and effective method of hazard control embodies the~~
5927 ~~concept of active managerial control by providing an on-going system of simple control measures~~
5928 ~~that will reduce the occurrence of risk factors that lead to out-of-control hazards.~~

5929 ~~The role of retail and food service regulatory professionals is to conduct risk-based inspections~~
5930 ~~using HACCP principles to assess the degree of control industry has over the foodborne illness~~
5931 ~~risk factors. Regulators can assist industry in achieving active managerial control of risk factors~~
5932 ~~by using a risk-based inspection approach to identify strengths and weaknesses and suggesting~~
5933 ~~possible solutions and improvements.~~

5934

5935

5936 **7. Acknowledgements**

5937 Much of this Appendix is adapted from the National Advisory Committee on Microbiological
5938 Criteria for Foods, Hazard Analysis and Critical Control Point Principles and Guidelines, adopted
5939 August 14, 1997.

5940 The physical hazards table (Table 3) was provided courtesy of "Overview of Biological,
5941 Chemical, and Physical Hazards" in "HACCP Principles and Applications," Merle Pierson and
5942 Donald A. Corlett, Jr. (Eds.), 1992. p. 8-28. Chapman and Hall, New York.

5943 Based on a recommendation from the Retail HACCP Committee of the Conference for Food
5944 Protection, the two HACCP Manuals have been endorsed by the Conference.

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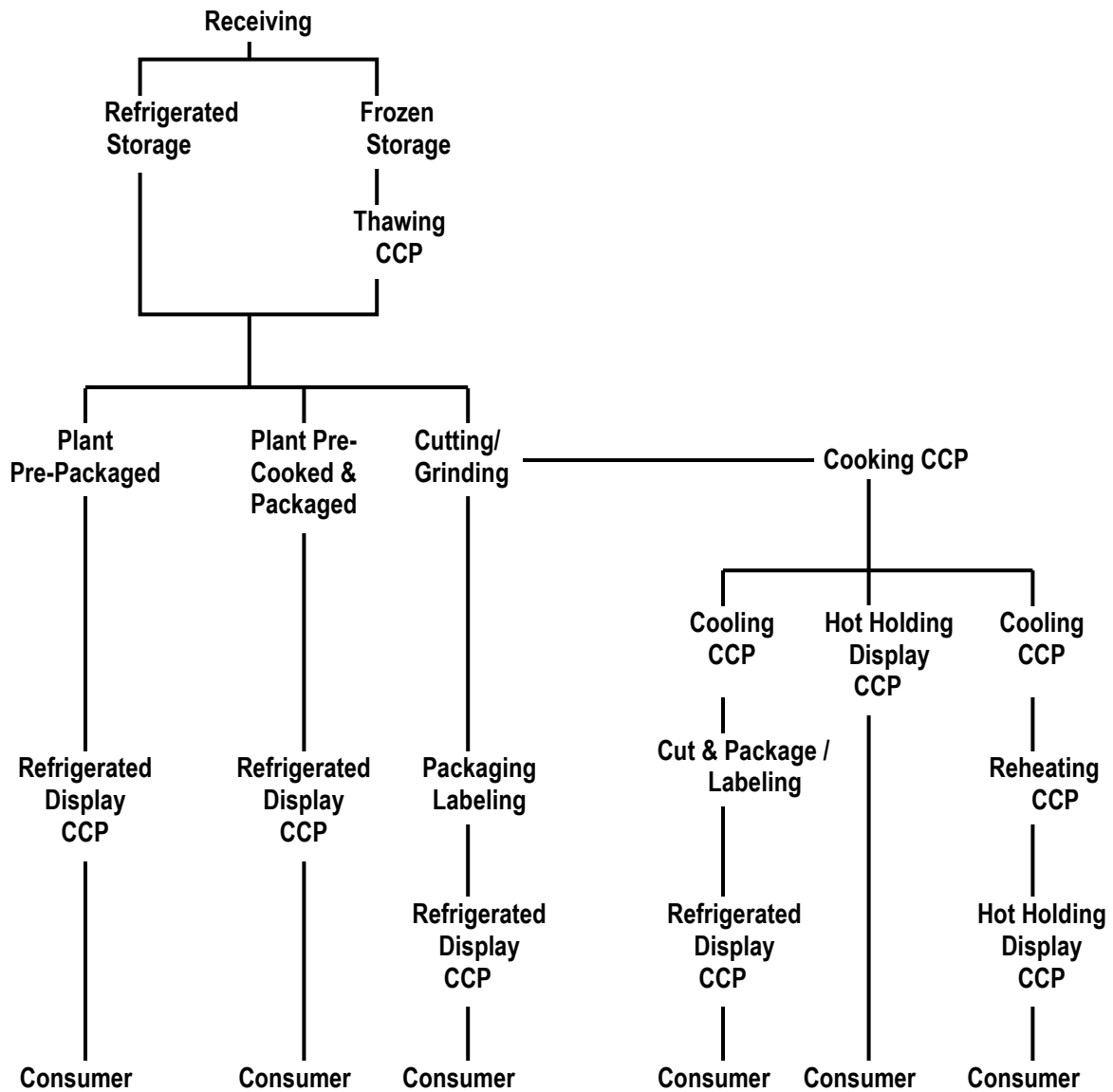
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6007 ~~Fishery Products.~~
- 6008 ~~Fish and Fishery Products Hazards and Controls Guide, Third Edition, June 2001. Food~~
6009 ~~and Drug Administration, Washington, D.C. May be purchased from:~~
- 6010 ~~National Technical Information Service,~~
6011 ~~U.S. Department of Commerce,~~
6012 ~~703 487 4650.~~
- 6013 ~~The Fish and Fishery Products Hazards and Controls Guide¹⁰. Single copies may be~~
6014 ~~obtained as long as supplies last from FDA district offices and from:~~
- 6015 ~~U.S. Food and Drug Administration~~
6016 ~~Office of Seafood~~
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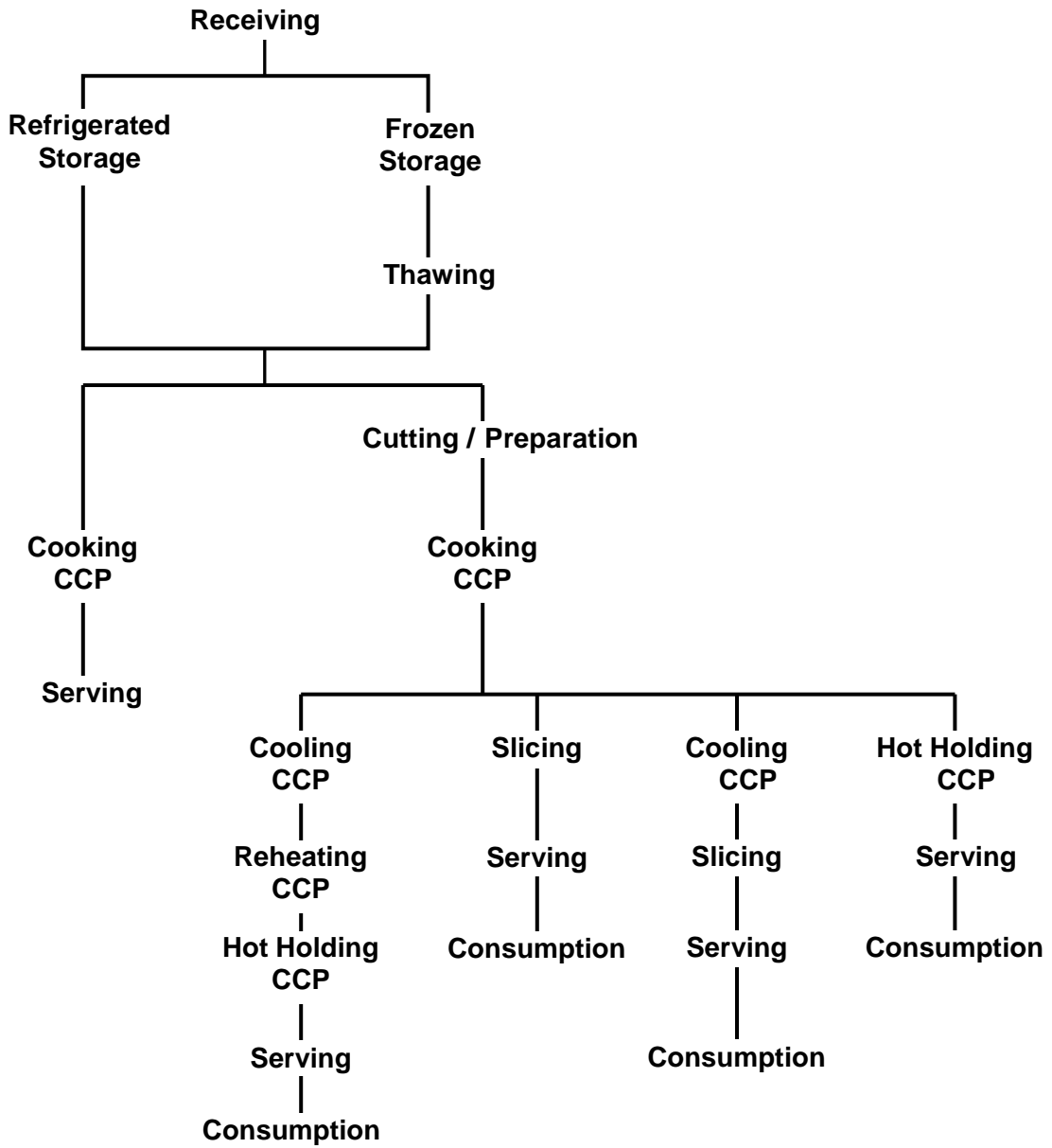
Two Typical Flow Diagrams

Flow Chart 1



6027

Flow Chart 2



6028 ***Appendix H – RETAIL FOOD STORE SANITATION ACT***

6029 ~~25-4-1301. Legislative declaration. The general assembly hereby declares that the sanitary protection of~~
6030 ~~bulk foods and the sanitary maintenance of equipment used to display and dispense bulk foods are matters~~
6031 ~~of statewide concern and are affected with a public interest and that the provisions of this part 13 are~~
6032 ~~enacted in the exercise of the police powers of this state for the purpose of protecting the health, peace,~~
6033 ~~safety, and general welfare of the people of this state.~~

6034 ~~25-4-1302. Definitions. As used in this part 13, unless the context otherwise requires:~~

6035 ~~(1) “Bulk foods” means unpackaged or unwrapped foods, either processed or unprocessed, in aggregate~~
6036 ~~containers from which quantities desired by the consumer are withdrawn. “Bulk foods” does not include~~
6037 ~~fresh fruits, fresh vegetables, nuts in the shell, salad bar, bulk pet foods, potentially hazardous foods, and~~
6038 ~~bulk nonfood items.~~

6039 ~~(2) “Department” means the department of health.~~

6040 ~~(3) “Display area” means a location including physical facilities and equipment, where bulk foods are~~
6041 ~~offered for customer self service.~~

6042 ~~(4) “Potentially hazardous foods” includes any food that consists in whole or in part, of milk or milk~~
6043 ~~products, eggs, meat, poultry, fish, shellfish, edible crustacea, or other food products or ingredients,~~
6044 ~~including synthetic ingredients, in a form capable of supporting rapid and progressive growth of~~
6045 ~~infectious or toxigenic microorganisms. This term does not include refrigerated, clean, whole, uncracked,~~
6046 ~~odor-free shell eggs.~~

6047 ~~(5) “Product module” means a food contact container (multiuse or single service) designed for customer~~
6048 ~~self service of bulk foods by either direct or indirect means.~~

6049 ~~(6) “Servicing area” means a designated location equipped for cleaning, sanitizing drying, or refilling~~
6050 ~~product modules or for preparing bulk foods.~~

6051 ~~25-4-1303. Labeling – product modules – take home containers. (1) product modules shall be labeled with~~
6052 ~~either:~~

6053 ~~(a) The manufacturer's or processor's bulk food container labeling plainly in view; or~~

6054 ~~(b) A counter card, a counter sign, or any other appropriate device bearing prominently and conspicuously~~
6055 ~~the common name of the product, a list of ingredients in their proper order of predominance, and a~~
6056 ~~declaration of artificial color or flavor and chemical preservatives if contained in the product.~~

6057 ~~(2) any unpack aged bulk food need not comply with the labeling requirements of this section if the~~
6058 ~~unpackaged bulk food is manufactured on the premises of a store or manufactured by the same store at the~~
6059 ~~different location and if the manufactured bulk food is offered for retail sale on the store's premises and if~~
6060 ~~there are no state requirements.~~

6061 ~~(3) Labels or marking pens shall be available to customers to identify their take home containers with the~~
6062 ~~common name of the product unless the product is readily identifiable on sight.~~

6063 ~~25-4-1304. Bulk food protection. (1) Bulk foods and product modules shall be protected from~~
6064 ~~contamination during , display, customer self service, refilling, and storage.~~

- 6065 ~~(2) Containers of bulk pet foods and bulk nonfood items shall be separated from product modules by a~~
6066 ~~barrier or open space.~~
- 6067 ~~(3) Bulk foods returned to stores by customers shall not be offered for resale.~~
- 6068 ~~(4) Only containers provided by stores in their display areas shall be filled with bulk foods; except that~~
6069 ~~any customer may fill or refill his own containers with vended or dispensed water; however, the risk that~~
6070 ~~the customer's own container is unsafe, unpure, contaminated, or in a non-sterile condition when it is~~
6071 ~~filled or refilled by the customer, shall be borne solely by the customer, and, except for warranties, no~~
6072 ~~liability shall attach thereto to the manufacturer, seller, or dispenser of such container.~~
- 6073 ~~25-4-1305. Bulk food display. (1) Bulk foods shall be dispensed only from product modules which are~~
6074 ~~protected by close fitting, individual covers. If any product module is to be opened by customers, the~~
6075 ~~cover shall be self-closing and shall remain close when not in use.~~
- 6076 ~~(2) Customer access to bulk foods in product modules shall be limited and controlled to avoid the~~
6077 ~~introduction of contaminants. All product modules shall have an access height of thirty inches or more~~
6078 ~~above the floor and a depth of eighteen inches or less.~~
- 6079 ~~(3) Potentially hazardous foods shall not be made available for customer self-service.~~
- 6080 ~~25-4-1306. Dispensing utensils. (1) Manual handling of bulk foods by customers during dispensing shall~~
6081 ~~be discouraged. Mechanical dispensing devices shall be used, including gravity dispensers, pumps,~~
6082 ~~extruders, and augers. Manual dispensing utensils shall also be used, including tongs, scoops, ladles, and~~
6083 ~~spatulas.~~
- 6084 ~~(2) If the dispensing devices and utensils listed in subsection (1) of this section do not discourage manual~~
6085 ~~customer handling of bulk foods, such bulk foods must be wrapped or sacked prior to display.~~
- 6086 ~~(3) Manual dispensing utensils shall be protected against becoming contaminated and serving as vehicles~~
6087 ~~for introducing contamination into bulk foods. A tether of easily cleanable material shall be attached to~~
6088 ~~such a utensil and shall be of such length that the utensil cannot contact the floor. A sleeve or protective~~
6089 ~~housing attached or adjacent to the display unit shall be available for storing a utensil when not in use.~~
- 6090 ~~(4) Ladles and spatulas shall be stored in bulk foods with handles extending to the outside of product~~
6091 ~~modules. Handles shall not prevent lids from being self-closing.~~
- 6092 ~~25-4-1307. Materials. Product modules and utensils shall be constructed of safe materials and shall be~~
6093 ~~corrosion resistant, nonabsorbent, smooth, easily cleanable, and durable under conditions of normal use.~~
6094 ~~Wood shall not be used as a food-contact surface.~~
- 6095 ~~25-4-1308. Food contact surfaces. Product modules, lids, dispensing units, and utensils shall be designed~~
6096 ~~and fabricated to meet the requirements for food-contact surfaces, as provided in section 25-4-1307.~~
- 6097 ~~25-4-1309. Non food contact surfaces. Surfaces of product module display units, tethers, and display~~
6098 ~~equipment which are not intended for food contact but which are exposed to splash, food debris, or other~~
6099 ~~soiling shall be designed and fabricated to be smooth, cleanable, durable under conditions of normal use,~~
6100 ~~and free of unnecessary ledges, projections, and crevices. The materials for non-food contact surfaces~~
6101 ~~shall be nonabsorbent or made nonabsorbent by being finished and sealed with a cleanable coating.~~
- 6102 ~~25-4-1310. Accessibility. Individual product modules shall be designed to be easily removable from a~~
6103 ~~display unit for servicing unless the product modules are so designed and fabricated that they can be~~

6104 effectively cleaned and sanitized when necessary through a manual in place cleaning procedure that will
6105 not contaminate or otherwise adversely affect bulk foods or equipment in any adjoining display areas.

6106 ~~25-4-1311. Equipment sanitization. (1) Tongs, scoops, ladles, spatulas, and other appropriate utensils and~~
6107 ~~tethers used by customers shall be cleaned and sanitized at least daily or at more frequent intervals based~~
6108 ~~on the type of bulk food and the amount of food particle accumulation or soiling.~~

6109 ~~(2) When soiled, product modules, lids, and other equipment shall be cleaned and sanitized prior to~~
6110 ~~restocking or at intervals of a schedule based on the type of bulk food and the amount of food particle~~
6111 ~~accumulation.~~

6112 ~~(3) Food contact surfaces shall be cleaned and sanitized immediately if contamination is observed or~~
6113 ~~suspected.~~

6114 ~~(4) Facilities and equipment shall be available, either in a servicing area or in place, to provide for the~~
6115 ~~proper cleaning and sanitizing of all food contact surfaces, including product modules, lids, and~~
6116 ~~dispensing utensils.~~

6117 ~~(5) Take home containers, including but not limited to bags, cups, and lids, which are provided in a~~
6118 ~~display area for customer use shall be stored and dispensed in a sanitary manner.~~

6119 ~~25-4-1312. Violation - Penalty. Any retail food store owner violating any of the provisions of this part 13~~
6120 ~~is guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not more than five~~
6121 ~~hundred dollars, or by imprisonment in the county jail for not more than ninety days, or by both such fine~~
6122 ~~and imprisonment. It is the duty of the district attorneys of the several districts of this state to prosecute~~
6123 ~~for violations of this part 13 as for other crimes and misdemeanors.~~

6124 ~~25-4-1313. Rules and regulations. The department has the power to promulgate rules and regulations for~~
6125 ~~the implementation of this part 13.~~

6126 ~~25-4-1314. Limitation. The provisions of this part 13 shall be expressly limited to retail food store outlets.~~

APPENDIX I - Equipment Investigation Report

6127
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6129 ~~Section 4-101 of the Colorado Retail Food Establishment Rules and Regulation specify all equipment,~~
6130 ~~utensils and single service articles shall be fabricated with safe materials; be of commercial design, that is~~
6131 ~~certified or classified by an American National Standards Institute (ANSI) accredited certification~~
6132 ~~program, such as the National Sanitation Foundation (NSF), Underwriters Laboratories (UL) sanitation~~
6133 ~~standards, Environmental Testing Laboratories, Inc. (ETL) sanitation standards, Baking Industry~~
6134 ~~Sanitation Standards Committee (BISSC), or other comparable design criteria as approved by the~~
6135 ~~Department during a standardized equipment review.~~

6136 ~~If a retail food establishment intends to have any equipment, utensils and single service articles approved~~
6137 ~~by the Department, the approval will be based upon submission of the following information to be~~
6138 ~~provided to the local public health agency and/or the Colorado Department of Public Health and~~
6139 ~~Environment for evaluation.~~

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**COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
4300 CHERRY CREEK DRIVE SOUTH
DENVER, CO 80246-1530**

EQUIPMENT INVESTIGATION REPORT	
1. LOCATION (STATE AND COUNTY) _____	
2. RECOMMENDATION <input type="checkbox"/> ACCEPT <input type="checkbox"/> REJECT	
3. PREPARED BY NAME _____ TITLE _____ AGENCY _____ SIGNATURE _____ DATE _____	
4. NAME/TITLE/ORGANIZATION REQUESTING INVESTIGATION _____	5. DATE OF REQUEST _____
6. NAME AND ADDRESS OF MANUFACTURER _____	7. DATE OF INVESTIGATION _____
8. NAME AND TITLE OF CONTACT _____	
EQUIPMENT INFORMATION	
9. TRADE NAME _____	10. MODEL NUMBER _____
11. DESCRIPTION OF EQUIPMENT (CHECK APPROPRIATE LINE AND DESCRIBE) <input type="checkbox"/> PROTOTYPE <input type="checkbox"/> PRODUCTION <input type="checkbox"/> IN USE <input type="checkbox"/> OTHER	
12. SPECIFIC USE OF EQUIPMENT _____	
13. FOOD CONTACT SURFACE MATERIAL TYPE (CHECK APPROPRIATE LINE AND DESCRIBE) <input type="checkbox"/> METAL <input type="checkbox"/> PAINT	

<input type="checkbox"/> RUBBER _____ <input type="checkbox"/> PLASTIC _____
14. _____ PLEASE ATTACH A SPECIFICATION SHEET OR A BLUE PRINT DRAWING OF EQUIPMENT
15. _____ RESULTS OF INVESTIGATION
16. _____ ACTION TAKEN

17. COMMENTS

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6146

6147

6148

~~Summary of Changes to the Colorado Retail Food Establishment Rules and Regulations~~

6149

6150

6151 *This summary provides a synopsis of the textual changes from the 2007 Colorado Retail Food*6152 *Establishment Rules and Regulations to the 2013 edition. The primary intent of this record is to*6153 *capture the nature of the changes rather than to identify every word or editing change. This*6154 *record should not be relied upon as an absolute comparison that identifies each and every*6155 *change. Section numbers listed refer to the section as it appears in the 2013 edition.*

6156

6157 **Chapter 1— Purpose and Definitions**

6158

6159 **This section was revised for clarity and consistency with the FDA Model Food Code.**

6160 1-201 ————— Added language to clarify that this regulation is intended to be the standard

6161 for the department and its authorized agents and employees, to be applied

6162 uniformly by all parties.

6163 1-201(1) ————— Added definition of “Accredited Program”

6164 1-201(3) ————— Added definition of “Allergens”

6165 1-201(6) ————— Added definition of “Asymptomatic”

6166 1-201(7) ————— Added definition of “Aw”

6167 1-201(8) ————— Added definition of “Balut”

6168 1-201(10) ————— Added definition of “Catering Operation”

6169 1-201(11) ————— Added definition of “Certified Food Protection Manager”

6170 1-201(12) ————— Added definition of “CFR”

6171 1-201(14) ————— Amended definition of “Commercial Design” to specify that it is certified or

6172 classified by an American National Standards Institute (ANSI) accredited

6173 certification program

6174 1-201(15) ————— Added definition of “Commingle”

6175 1-201(17) ————— Amended definition of “Commissary” to include language that specifies it

6176 needs to be approved by the Department and serve as a base of operation for

6177 temporary, pushcart, or mobile food operations.

6178 1-201(18) ————— Added definition of “Conditional Employee”

6179 1-201(19) ————— Amended definition of “Contamination” to include language that is consistent

6180 with USDA's definition

- 6181 1-201(20) — Added definition of “Confirmed Disease Outbreak”
- 6182 1-201(21) — Amended definition of “Corrosion Resistant Materials” to be more clear and
6183 concise
- 6184 1-201(24) — Added definition of “Critical Limit”
- 6185 1-201(25) — Added definition of “Cross Connection”
- 6186 1-201(26) — Added definition of “Cross Contamination”
- 6187 1-201(27) — Added definition of “Cut Leafy Greens”
- 6188 1-201(29) — Added definition of “Drinking Water” to be more in line with terms used by
6189 Water Quality Control Division
- 6190 1-201(32) — Added definition of “Egg”
- 6191 1-201(33) — Added definition of “Egg Product”
- 6192 1-201(34) — Revised definition of “employee” to be consistent with the Model Food Code
- 6193 1-201(35) — Added definition of “Enterohemorrhagic Escherichia Coli”
- 6194 1-201(36) — Added definition of “EPA”
- 6195 1-201(38) — Added definition of “Exclude”
- 6196 1-201(40) — Amended definition of “Fish” to include finfish
- 6197 1-201(43) — Added definition of “Foodborne Illness Risk Factor”
- 6198 1-201(44) — Added definition of “Food Employee”
- 6199 1-201(45) — Added definition of “Food Preparation”
- 6200 1-201(47) — Added definition of “Game Animal”
- 6201 1-201(50) — Added definition of “Handwashing Sink”
- 6202 1-201(52) — Added definition of “Health Practitioner”
- 6203 1-201(57) — Added definition of “Injected”
- 6204 1-201(58) — Added definition of “Inspection”
- 6205 1-201(59) — Added definition of “Juice”
- 6206 1-201(62) — Amended definition of “License” to include the term licensee
- 6207 1-201(63) — Amended definition of “Licensee” to clarify a licensee is responsible for the
6208 lawful operation of a retail food establishment
- 6209 1-201(65) — Added definition of “Major Food Allergen”

- 6210 1-201(67) — Added definition of “Mechanically Tenderized”
- 6211 1-201(69) — Amended “Mobile Retail Food Establishment” to include that it is a wheeled
6212 vehicle or trailer that is readily moveable and intended to physically report to
6213 and operate out of a commissary each day.
- 6214 1-201(71) — Added definition of “New Retail Food Establishment”
- 6215 1-201(73) — Added definition of “Non-Continuous Cooking”
- 6216 1-201(74) — Added definition of “Non-Critical Item”
- 6217 1-201(82) — Amended definition of “Potentially Hazardous Food” to clarify the term time
6218 and temperature controlled for safety, and added several matrixes to explain
6219 time and temperature controlled for safety in accordance with the Model
6220 Food Code.
- 6221 1-201(85) — Revised definition of “primal meat cuts” in accordance with the Model Food
6222 Code
- 6223 1-201(88) — Added definition of “Ratite”
- 6224 1-201(91) — Added definition of “Reduced Oxygen Packaging” in accordance with the
6225 Model Food Code.
- 6226 1-201(92) — Added definition of “Refuse”
- 6227 1-201(93) — Added definition of “Re-service”
- 6228 1-201(94) — Added definition of “Restrict”
- 6229 1-201(96) — Added definition of “Risk”
- 6230 1-201(100) — Added definition of “Sealed”
- 6231 1-201(101) — Added definition of “Self-Contained Mobile Retail Food Establishment”
- 6232 1-201(102) — Added definition of “Service Animal” in accordance with ADA.
- 6233 1-201(103) — Added definition of “Sewage”
- 6234 1-201(105) — Added definition of “Shiga Toxin-Producing Escherichia Coli”
- 6235 1-201(108) — Added definition of “Single Use Articles”
- 6236 1-201(109) — Added definition of “Slacking”
- 6237 1-201(112) — Added definition of “Temperature Measuring Device”
- 6238 1-201(113) — Added definition of “Temporary Event”
- 6239 1-201(115) — Added definition of “USDA”
- 6240 1-201(117) — Added definition of “Variance”

6241	1-201(120)	Added definition of "Whole Muscle, Intact Beef"
6242	Chapter 2 – Management and Personnel	
6243	2-102	Amended section describing how a person in charge can demonstrate
6244		knowledge by adding a information on HACCP plans; the relationship
6245		between potentially hazardous foods and maintaining time and temperature
6246		controlled for safety; sick employee policy; and major food allergens in
6247		accordance with the Model Food Code.
6248	2-103	Amended section to clarify employee and conditional employees obligation
6249		to report illness and infection to the person in charge; and added language to
6250		clarify a consumer warning on consuming raw or partially cooked ready to
6251		eat foods in accordance with the Model Food Code.
6252	2-201	This section was amended to be consistent with the Model Food Code and
6253		the Colorado Disease Control Manual, it requires persons in charge, food
6254		and/or conditional employees to report specific symptom and illnesses.
6255	2-202	This section was amended to be consistent with the Model Food Code and
6256		the Colorado Disease Control Manual; it requires food employees be
6257		excluded or restricted from specific activities when exhibiting specific
6258		symptoms and/or illness.
6259	2-203	This section was amended to be consistent with the Model Food Code and
6260		the Colorado Disease Control Manual, it provides guidelines for removing,
6261		adjusting, or retaining the exclusion or restriction of a food employee.
6262	2-401	Added language to clarify that food employees shall keep their hands and
6263		exposed portions of their arms clean.
6264	2-402	Added language to address the requirement for food employees with
6265		surrogate prosthetic hands or arms to clean such devices in accordance with
6266		the Model Food Code.
6267	2-403	Amended section describing to clarify when an employee shall wash hands.
6268		Added language "after returning to food preparation, food storage, equipment
6269		storage and warewashing areas from using the restroom."
6270	2-406	Language was stricken which excluded employees such as counter staff who
6271		only serve beverages and wrapped or packaged foods, or hosts and wait staff
6272		who present a minimal risk of contaminating exposed foods and equipment
6273		from fingernail care and the ability to wear artificial nails and nail polish.
6274		Food employee is now defined to mean "an individual working with
6275		unpacked food, food equipment or utensils, or food contact surfaces"
6276		therefore the stricken language was redundant. This change is consistent with
6277		the Model Food Code.

6278	2-408	Amended section to clarify food employees shall only wear a single plain
6279		band, such as a wedding band, while preparing food in accordance with the
6280		Model Food Code.
6281		
6282		Chapter 3 – Food
6283	3-101	Added language “food shall not contain unsafe or unapproved food or color
6284		additives per 21 CFR 170-186” to be consistent with the Model Food Code.
6285	3-201	Added language to section requiring molluscan shellfish be obtained from
6286		approved sources as listed on the National Shellfish Sanitation Program
6287		Guide in accordance with the Model Food Code.
6288	3-201(B)	Added language on the condition molluscan shellfish shall be received in
6289		accordance with the Model Food Code.
6290	3-202(C)	Added language excluding molluscan shellfish that has been caught
6291		recreationally from being sold in retail food establishments in accordance
6292		with the Model Food Code.
6293	3-202(E)	Added section regarding how molluscan shellfish shall be received and
6294		labeled in accordance with the Model Food Code.
6295	3-103	Amended this section to be more in line with the Model Food Code verbiage
6296	3-202	Added this section to clarify package integrity in accordance with the Model
6297		Food Code.
6298	3-302	Amended to include reference to “A Guide to Can Defects and Basic
6299		Components of Double Seam Containers”, November 2011, published by the
6300		Association of Food and Drug Officials.
6301	3-305(C)(1-5)	Added this section to be consistent with the Colorado Raw Milk Rule.
6302	3-306(A)(1-6)	Added section to clarify stipulations to selling wild harvested mushrooms
6303		and the qualifications for a mushroom expert in accordance with the Model
6304		Food Code.
6305	3-307	Expanded this section on meat, poultry, game animals and exotic species to
6306		be consistent with the Model Food Code.
6307	3-308	Expanded this section to address condition of egg cartons, labeling of eggs
6308		and pooling of eggs.
6309	3-309	Changed “potable” to “drinking” to be consistent with Water Quality Control
6310		Division's rules and regulations. Removed previous language on “dispensing”
6311		of ice and moved it to 3-409(B).
6312	3-312	Added section on requirements of whole muscle intact beef intended for
6313		consumption in accordance with the Model Food Code.

6314 6315	3-401	Amended to clarify that a confirmed foodborne illness serves as grounds for the suspension or revocation of a bare hand contact policy.
6316 6317	3-402	Added section on requirements of gloves use and clarified slash resistant glove use in accordance with the Model Food Code.
6318 6319	3-403	Added section to clarify tasting utensil use in accordance with the Model Food Code.
6320 6321	3-406	Added section to clarify segregation of packaged and un-packaged food storage in accordance with the Model Food Code.
6322 6323	3-407	Amended section to include language on pasteurized eggs that is consistent with the Model Food Code.
6324 6325	3-408	Amended section on washing fruits and vegetables to be consistent with the Model Food Code.
6326	3-409(B)	Moved section from 3-309 to clarify acceptable storage of ice dispensing utensils.
6327 6328	3-412(C)	Added section to clarify that personal beverage cups can be refilled by employees in accordance with the Model Food Code.
6329 6330	3-417(B)	Added section noting that self-service buffets temperatures shall be monitored by trained staff in accordance with the Model Food Code.
6331 6332	3-501(D)	Added section indicating that food that is labeled frozen and shipped frozen shall be received frozen in accordance with the Model Food Code.
6333 6334	3-501(E)	Added section clarifying that food shall be received free of evidence of previous temperature abuse in accordance with the Model Food Code.
6335 6336	3-502(B)	Added language to include corned beef, lamb and cured roasts in cooking temperatures in accordance with the Model Food Code.
6337 6338	3-502(B)(1)	Added chart from the Model Food Code on the proper cooking temperature based on the type of oven that is used and the size of the roast.
6339 6340	3-502(B)(2)	Added chart from the Model Food Code on the time/temperature requirements for whole muscle intact beef.
6341 6342 6343	3-502(C)	Added section to include language that undercooked whole muscle intact beef cannot be sold to a highly susceptible population and the surface temperature is at least 145°F in accordance with the Model Food Code.
6344 6345	3-502(E)	Added section stating that eggs that are not prepared to consumer order shall be cooked to 155F in accordance with the Model Food Code.
6346 6347	3-502(H)	Amended section to include mechanically tenderized or injected beef in accordance with the Model Food Code.

6348	3-502(K)	Added section to require a consumer advisory on all animal products that are
6349		consumed raw, undercooked or partially cooked in accordance with the
6350		Model Food Code.
6351	3-503(A)	Added section to address non-continuous cooking of raw animal foods in
6352		accordance with the Model Food Code.
6353	3-505	Added section to clarify re-heating temperatures for cooked and refrigerated foods.
6354	3-601	Amended section on thawing to be consistent with the Model Food Code.
6355	3-602	Added section to clarify temperature requirements of “slacked” food
6356	3-605	Amended section on time as a public health control to make verbiage more
6357		consistent with the Model Food Code.
6358	3-606	Added section on specialized processing methods to be consistent with the
6359		Model Food Code.
6360	3-607	Amended and expanded section on reduced oxygen packaging to be more
6361		consistent with the Model Food Code.
6362	3-508 & 608	Added section on date marking and disposition of ready-to-eat food that do
6363		not meet the date marking requirements, then moved it to section 3-702 to
6364		apply only to facilities serving only highly susceptible populations.
6365	3-608	Added requirements for breeding mixtures used with raw animal products.
6366	3-702(A)	Amended section to require date marking in facilities that serve highly
6367		susceptible populations. The requirements are consistent with the Model
6368		Food Code, though they only apply in these settings.
6369	3-702(B)	Added the requirement that reduced oxygen packaging HACCP plans be pre-
6370		approved for facilities serving highly susceptible populations.
6371	3-702(D)	Added section to address the disposition of food that was not consumed by
6372		patients in accordance with the Model Food Code.
6373	3-801	Added section requiring a consumer advisory warning consumers of the risk
6374		of consuming raw and undercooked animal products to be consistent with the
6375		Model Food Code.
6376		
6377		
6378	Chapter 4 — Warewashing, Equipment, Utensils and Linens	
6379	4-102(A)	Added language to clarify that facilities that only sell pre-packaged food are
6380		not required to meet the minimum requirements of these regulations.
6381	4-202(D)	Amended language regarding enamelware to read “shall not be used for
6382		storage or preparation of acidic foods (e.g. vinegar, tomato-based sauces,
6383		juices, etc.)”.

6384	4-202(F)	Amended section on use of linen as a food contact surface for clarity.
6385	4-202(H)	Specified that pewter containing in excess of 0.05% lead cannot be used as a
6386		food contact surface, in accordance with the Model Food Code.
6387	4-202(L)	Section regarding newspaper, cloth, cardboard, etc. was stricken and
6388		incorporated into section (M)
6389	4-203(E)	Added section to clarify acceptable material as liners for shelves, drawers or
6390		drainboards.
6391	4-211	Added section regarding molluscan shellfish tanks to be consistent with
6392		Model Food Code.
6393	4-212(B-C)	Revised section regarding ventilation hood systems to be consistent with
6394		Model Food Code.
6395	4-301(A)(8-9)	Added sections to clarify that items used in a retail food establishment cannot
6396		be stored in a private home or under open stairwells to be more consistent
6397		with the Model Food Code.
6398	4-401	Revised section on temperature measuring devices for clarity and to be more
6399		consistent with the Model Food Code.
6400	4-402(A-B)	Section regarding chemical testing devices was revised and now includes a
6401		requirement for testing devices to measure the strength of chemicals used to
6402		wash fruits and vegetables.
6403	4-402(C)	Added requirement for temperature testing devices for high temperature dish
6404		machines to be consistent with the Model Food Code.
6405	4-403	Added clarification that utensil washing sinks be installed in new or
6406		remodeled establishments for utensil washing to be consistent with the Model
6407		Food Code.
6408	4-403(E)(6)	Section regarding drain boards has been revised and moved to section 4-405
6409		for clarity.
6410	4-403(G)	Clarified section regarding ware washing in a three compartment sink.
6411	4-403(I)(7-8)	Added language clarifying the use of alternate chemical sanitizes.
6412	4-404	Removed section that is now covered in section 4-102(A).
6413	4-404(K)	Added section to clarify that utensils shall not be rinsed prior air drying.
6414	4-405	Added section to clarify drainboard requirements.
6415	4-407(D)	Added section to clarify cleaning of in-use pans and equipment shall be done
6416		at least every 24 hours.

- 6417 4-407(D) — Added section to clarify that buffet style pans shall be cleaned at least every
6418 24 hours in accordance with the Model Food Code.
- 6419 4-603 — Clarified section regarding preset tableware.
6420
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- 6422 **Chapter 5 — Water, Plumbing and Waste**
- 6423 5-101(A)(1)(a-e) — Added sections to be consistent with Drinking Water Regulations.
- 6424 5-105 — Added section to specify the requirements for an alternative water supply in
6425 cases of emergency.
- 6426 5-201 — Clarified the role of the department and local public works with regards to
6427 plumbing violations.
- 6428 5-202 — Reworded section to be consistent with the Drinking Water Regulations.
- 6429 5-205(A-B) — Added section to clarify acceptable locations to install a food waste grinder.
- 6430 5-208(C) — Replaced “lavatory facility faucet” with “handwashing sink water
6431 temperatures” and increased the temperature requirement from 90°F to 100°F
6432 in accordance with the Model Food Code.
- 6433 5-208(D) — Revised section to allow shared handwashing supplies for adjacent hands
6434 sinks in accordance with the Model Food Code.
- 6435 5-208(E) — Revised section to state that common towels cannot be used to dry hands.
- 6436 5-208(F) — Added section to clarify that unused handtowels shall be protected from
6437 contamination.
- 6438 5-208(G) — Added section to requiring a waste receptacle for disposal towels in
6439 accordance with the Model Food Code.
- 6440 5-208(H) — Added section requiring that handwashing supply dispensers be kept clean
6441 and in good repair.
- 6442 5-208(I) — Added section to address commonly seen automatic handwashing facilities in
6443 accordance with the Model Food Code.
- 6444 5-208(J) — Added section to clarify the installation requirements for handwashing sinks
6445 in new or extensively remodeled establishments.
- 6446 5-209(G) — Added section to clarify toilet rooms shall be enclosed and provided with a
6447 self-closing door, unless located outside of the establishment.
- 6448 5-209(I) — Added section to clarify requirement for the installation and emptying of
6449 female sanitary trash can receptacles.
- 6450 5-210(D) — Added section requiring dump sinks in new and remodeled establishments.

6451 5-301(C) — Clarified section to include drain plugs in waste handling units.

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Chapter 6—Physical Facilities

- 6459 ~~6-202(C) — Added language clarifying acceptable surfaces in areas limited beverage~~
6460 ~~service and the heating of pre-prepared foods.~~
- 6461 ~~6-401(D) — Moved and expanded section clarifying how often mop water shall be~~
6462 ~~changed to prevent recontamination of cleaned surfaces.~~
- 6463 ~~6-402 — Added language stating that wet mops shall be allowed to air dry without risk~~
6464 ~~of re-contamination in accordance with the Model Food Code.~~
- 6465 ~~6-503 — Added section regarding dressing rooms and lockers to maintain consistency~~
6466 ~~with the Model Food Code.~~

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Chapter 7—Poisonous or Toxic Materials

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No significant changes

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Chapter 8—Insect, Rodent and Animal Control

- 6475 ~~8-102 — Clarified section on the control of pests to be consistent with the Model Food~~
6476 ~~Code.~~

- 6477 ~~8-106 — Added section to address service and other animals in retail food~~
6478 ~~establishments. Language is consistent with the Model Food Code and the~~
6479 ~~ADA.~~

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Chapter 9—Mobile Retail Food Establishments and Pushearts

6483 ~~This section was revised based on the recommendations of a stakeholder working group~~
6484 ~~comprised mostly of Local Public Health Agency Representatives.~~

- 6485 ~~9-101(B) — Added section to require all mobile unit equipment be installed and/or~~
6486 ~~mounted and to require all foods be prepared, assembled and served from~~
6487 ~~within the mobile unit.~~

- 6488 ~~9-101(C) — Added section to limit food preparation and storage on pushearts.~~

- 6489 ~~9-102 — Added language to exempt mobile retail food establishments and pushearts~~
6490 ~~with limited food preparation from water or sewage system requirements.~~

- 6491 ~~9-104(C) — Added section to provide additional clarification on water system~~
6492 ~~requirements for mobile retail food establishments.~~

- 6493 9-104 (D) — Added section to provide additional information on water tank supply
6494 capacity for pushcarts.
- 6495 9-104 (E) — Added section to provide additional information on water pressure
6496 requirements for mobile retail food establishments and pushcarts.
- 6497 9-104 (F) — Added section to provide additional information on hot water requirements
6498 for mobile retail food establishments and pushcarts. Water temperature for
6499 handwashing has been increased from 90F to 100F to be consistent with
6500 section 5-208(C) as well as the Model Food Code.
- 6501 9-104(I) — Clarified requirement for using food grade hoses for transferring drinking water.
- 6502 9-104 (J) — Added reference to 25-1.5-2, C.R.S., *COLORADO PRIMARY DRINKING WATER*
6503 *REGULATIONS* with regard to water system disinfection and flushing if the unit
6504 is not used daily.
- 6505 9-104(K) — Section was removed because it is redundant with the term "drinking water".
6506
- 6507 9-105 (A) — Added language to clarify the requirement for a water retention tank for
6508 mobile retail food establishments and pushcarts.
- 6509 9-106 (F) — Changed the requirement of providing 90°F water to handsinks on mobile
6510 retail food establishments and pushcarts to 100°F to be consistent with
6511 sections 5-208(C), 9-104 (F) and the Model Food Code.
- 6512 9-107 (A) — Added language to the section to have requirements in place for a written
6513 commissary agreement.
- 6514 9-107(B) — Section was revised for clarity.
- 6515 9-107 (D) — Provided clarification to the section to include what parameters must be met
6516 for a self-contained mobile retail food establishment to not have to report to a
6517 commissary.
- 6518 9-107 (E) — Added language which prohibits a mobile retail food establishment from
6519 acting as a commissary for another retail food establishment.
- 6520 9-108 (B) — Added section to require screening for openable windows and doors, except
6521 for service windows, in mobile retail food establishments and pushcarts.
- 6522 9-108 (C) — Added section to require employee restroom availability for mobile retail
6523 food establishments and pushcarts.
- 6524 9-108 (D) — Added section to provide clarification on temperature holding equipment for
6525 mobile retail food establishments and pushcarts.
- 6526 9-108 (E) — Added section to require an adequate number of clean utensils during
6527 operating hours of a mobile retail food establishment and/or a pushcart.

6528 9-108 (F) ——— Added section to require protection from contamination at customer self
 6529 service areas.

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6532 ~~Chapter 10 Temporary Retail Food Establishments~~

6533 ~~This section was revised based on the recommendations of a stakeholder working group~~
 6534 ~~comprised mostly of Local Public Health Agency Representatives.~~

6535 10-101 ——— Added language to require completion and submission of a temporary event
 6536 vendor application. Ambiguous language was stricken which allowed the
 6537 Department to impose additional requirements to protect against health
 6538 hazards. Added language requiring mobile retail food establishments and
 6539 pushcarts to operate in accordance with Chapter 9 of these Rules and
 6540 Regulations.

6541 10-102 ——— Clarified section to include requirements for food preparation at the
 6542 temporary event site location and at the temporary retail food establishments.
 6543 ort to a co Clarified section to include equipment installation and use at
 6544 temporary events.

6545 10-103 ——— Added section to include commissary requirements for a temporary retail
 6546 food establishment.

6547 10-104 ——— Added section to include the minimum equipment required at an event site
 6548 for a temporary retail food establishment.

6549 10-105 ——— Altered language regarding ice to be consistent with the Model Food Code.

6550 10-106 ——— Added language requiring temporary food establishments to provide only
 6551 single-service articles for use by the consumer.

6552 10-108 ——— Added language to clarify that the storage of food or beverage in undrained
 6553 ice is prohibited.

6554 10-109 ——— Added language to clarify that waste water shall not be discharged onto the
 6555 ground or into a storm drainage system.

6556 10-110 ——— Added language to provide more detail on the requirements of handwashing
 6557 on site at a temporary event. Language was stricken which required floors,
 6558 walls and ceilings be made of approved materials.

6559 10-111 ——— Added section to require screening or other provisions to prevent the
 6560 entrance of pests and debris. Language was stricken which required floors,
 6561 walls and ceilings be made of approved materials.

6562 10-112 ——— Added section to clarify requirements for the temporary event grounds.

6563 10-113 ——— Added language to require overhead protection at a temporary food
 6564 establishment.

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6569	Chapter 11 – Compliance Procedures	
6570	11-102 (D)	Added language to clarify when existing retail food establishments must
6571		obtain a new retail food establishment license.
6572	11-102(A)	Restrictive language was removed to allow risk-based inspection frequencies.
6573	11-201 (B)	Added language clarifying the inspection frequency for low risk category
6574		establishments.
6575	11-203	Added language to clarify the requirement to clearly document observed
6576		violations or conditions and removed requirement for next day delivery of
6577		the inspection form to allow time for electronic delivery in remote locations.
6578	11-204(A)	Clarified what constitutes an imminent health hazard and added "severe and
6579		active pest infestation". Imminent health hazards require immediate closure.
6580	11-204(B)	Amended section to allow 30 days following the receipt of an inspection to
6581		request an administrative hearing to appeal the inspection findings.
6582	11-205	Revised the retail food establishment inspection form to match the revisions
6583		to these Rules and Regulations.
6584	11-403	Added section to clarify the required contents of a HACCP plan in
6585		accordance with the Model Food Code.
6586	11-601 (E)	Added language to require documentation associated with variances be made
6587		available on site.
6588		
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6590	Appendices	
6591	Appendix A	This section was revised to provide guidance and clarification on the new
6592		definition of potentially hazardous food.
6593	Appendix C	This section was stricken. The plan review application will be available
6594		online rather than being included as an appendix in these Rules and
6595		Regulations.
6596	Appendix D	This section was stricken. The worksheet for calculating minimum hot water
6597		requirements will be available online rather than being included as an
6598		appendix in these Rules and Regulations.
6599	Appendix H	This section was revised to be consistent with the Model Food Code.
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Public Health Reasons/Administrative Guidelines

- 6602
6603 **CHAPTER 1 – PURPOSE AND DEFINITIONS**
6604 **CHAPTER 2 – MANAGEMENT AND PERSONNEL**
6605 **CHAPTER 3 – FOOD**
6606 **CHAPTER 4 – WAREWASHING, EQUIPMENT, UTENSILS, AND LINENS**
6607 **CHAPTER 5 – WATER, PLUMBING, AND WASTE**
6608 **CHAPTER 6 – PHYSICAL FACILITIES**
6609 **CHAPTER 7 – POISONOUS OR TOXIC MATERIALS**
6610 **CHAPTER 8 – INSECT, RODENT AND ANIMAL CONTROL**
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Chapter 1 – Purpose and Definitions

- 6613
6614 **Applicability and Terms Defined**
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6616 **1-201**
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6618 **Accredited Program**
6619 Food protection manager CERTIFICATION occurs when INDIVIDUALS demonstrate through a
6620 certification program that they have met specified food safety knowledge standards.
6621 Food protection certification program ACCREDITATION occurs when CERTIFICATION
6622 ORGANIZATIONS demonstrate through an accreditation program that they have met specified program
6623 standards.
6624 Accreditation is a conformity assessment process through which organizations that certify individuals
6625 may voluntarily seek independent evaluation and listing by an accrediting agency based upon the
6626 certifying organizations meeting program accreditation standards. Such accreditation standards typically
6627 relate to such factors as the certifying organization's structure, mission, policies, procedures, and the
6628 defensibility of its examination processes. These standards are intended to affirm or enhance the quality
6629 and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness
6630 to candidates for certification and others, and thereby increase public health protection.
6631 Program accreditation standards known to be relevant to food protection manager certification programs
6632 include those contained in the STANDARDS FOR ACCREDITATION OF FOOD PROTECTION
6633 MANAGER CERTIFICATION PROGRAMS available from the Conference for Food Protection, 2792
6634 Miramar Lane, Lincoln, CA 95648 and found at [Standards for Accreditation of Food Protection Manager
6635 Certification Programs](#)⁸
6636 Allowing food protection managers to demonstrate their required food safety knowledge "through passing
6637 a test that is part of an accredited program" is predicated on the fact that their credentials have been issued

6638 by certifying organizations that have demonstrated conformance with rigorous and nationally recognized
6639 program standards.

6640 **Egg**

6641 The definition of egg includes avian species' shell eggs known to be commercially marketed in the United
6642 States. Also included are the eggs of quail and ratites such as ostrich.

6643 Not included are baluts. Baluts are considered a delicacy among Philippine and Vietnamese populations.
6644 They are derived from fertile eggs; typically duck eggs, subjected to incubation temperatures for a period
6645 of time less than necessary for the embryo to hatch resulting in a partially formed embryo within the shell.
6646 Under the Egg Products Inspection Act (EPIA), an egg is typically considered adulterated if it has been
6647 subjected to incubation. However, in 9 CFR 590.5, baluts are specifically exempted from inspection as
6648 eggs under the EPIA.

6649 In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 42.5°C
6650 (108.5°F) in incubators with a relatively high humidity. (Complete development and hatching would take
6651 place in 28 days.) Under these conditions, the potential for growth of transovarian *Salmonella* organisms
6652 such as *S. Enteritidis* within the shell, and the potential for an increase in pathogenic microflora on the
6653 shell itself, are increased. Where chicken eggs are used in preparing baluts, the incubation period may
6654 only be 14 days at an incubation temperature of 37°C (99°F). A balut is a potentially hazardous food
6655 (time/temperature control for safety food) subject to time/temperature management including proper
6656 cooking and hot and cold holding. Baluts are typically boiled and packed in salt before sale or service.

6657 Also, not included in this definition are the eggs of reptile species such as alligators and turtles. Alligator
6658 eggs are available for sale in some parts of the southern United States. In restaurants, the menu item
6659 "Alligator Eggs" is sometimes made of alligator egg, but other times is simply a fanciful name for a menu
6660 item that may include seafood items such as shrimp, but contains no alligator egg.

6661 Sea turtle eggs have been consumed in Asian and Latin American Countries. However, turtle eggs are not
6662 mentioned in the definitions section because sea turtles (Loggerhead, East Pacific Green, Leatherback,
6663 Hawksbill, Kemp's Ridley, and Olive Ridley) are protected by The Endangered Species Act of 1973 and
6664 therefore may not be sold or consumed. This Act, with respect to turtle eggs, is enforced by the United
6665 States Department of Interior, U.S. Fish and Wildlife Service, Washington, DC.

6666 **Potentially Hazardous Food (Time/Temperature Control for Safety Food)**

6667 Potentially hazardous food (PHF/TCS food) is defined in terms of whether or not it requires
6668 time/temperature control for safety to limit pathogen growth or toxin formation. The term does not
6669 include foods that do not support growth but may contain a pathogenic microorganism or chemical or
6670 physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive
6671 growth of all foodborne pathogens is considered whether slow or rapid.

6672 The definition of PHF/TCS food takes into consideration pH, a_w , pH and a_w interaction, heat treatment,
6673 and packaging for a relatively simple determination of whether the food requires time/temperature control
6674 for safety. If the food is heat treated to eliminate vegetative cells, it needs to be addressed differently than
6675 a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat
6676 treatment to destroy vegetative cells and subsequently packaged to prevent re-contamination, higher
6677 ranges of pH and/or a_w can be tolerated because remaining spore-forming bacteria are the only microbial
6678 hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the
6679 package, they must be protected from contamination in an area with limited access and packaged before
6680 temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the a_w
6681 value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and

6682 ~~a_w may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves~~
6683 ~~several inhibitory factors being used together to control or eliminate pathogen growth, when they would~~
6684 ~~otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or a_w~~
6685 ~~values are unable to control or eliminate bacterial pathogens which may be present, growth may occur~~
6686 ~~and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where~~
6687 ~~intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids~~
6688 ~~and nutrients after cutting.~~

6689 ~~In determining if time/temperature control is required, combination products present their own challenge.~~
6690 ~~A combination product is one in which there are two or more distinct food components and an interface~~
6691 ~~between the two components may have a different property than either of the individual components. A~~
6692 ~~determination must be made about whether the food has distinct components such as pie with meringue~~
6693 ~~topping, focaccia bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform~~
6694 ~~consistency such as gravies, puddings, or sauces. In these products, the pH at the interface is important in~~
6695 ~~determining if the item is a PHF/TCS food.~~

6696 ~~A well designed inoculation study or other published scientific research should be used to determine~~
6697 ~~whether a food can be held without time/temperature control when:~~

6698 ~~• process technologies other than heat are applied to destroy foodborne pathogens (e.g., irradiation,~~
6699 ~~high pressure processing, pulsed light, ozonation);~~

6700 ~~• combination products are prepared; or~~

6701 ~~• other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential, salt~~
6702 ~~content, antimicrobials) are used to control or eliminate pathogen growth.~~

6703 ~~Before using Tables A and B of the definition for "potentially hazardous food (time/temperature control~~
6704 ~~for safety food)" in determining whether a food requires time/temperature control for safety (TCS),~~
6705 ~~answers to the following questions should be considered:~~

6706 ~~• Is the intent to hold the food without using time or temperature control?~~

6707 ~~○ If the answer is No, no further action is required. The decision tree later in this Annex is~~
6708 ~~not needed to determine if the item is a PHF/TCS food.~~

6709 ~~• Is the food raw, or is the food heat treated?~~

6710 ~~• Does the food already require time/temperature control for safety?~~

6711 ~~• Does a product history with sound scientific rationale exist indicating a safe history of use?~~

6712 ~~• Is the food processed and packaged so that it no longer requires TCS such as ultra high~~
6713 ~~temperature (UHT) creamers or shelf stable canned goods?~~

6714 ~~• What is the pH and a_w of the food in question using an independent laboratory and Association of~~
6715 ~~Official Analytical Chemists (AOAC) methods of analysis?~~

6716 ~~A food designated as product assessment required (PA), in either table should be considered PHF/TCS~~
6717 ~~Food until further study proves otherwise. The PA means that based on the food's pH and a_w and whether~~
6718 ~~it was raw or heat treated or packaged, it has to be considered PHF until inoculation studies or some other~~
6719 ~~acceptable evidence shows that the food is a PHF/TCS food or not.~~

6720 The Regulation definition designates certain raw plant foods as PHF/TCS food because they have been
6721 shown to support the growth of foodborne pathogens in the absence of temperature control and to lack
6722 intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these
6723 designations are supported by Tables A and B. For example:

6724 For cut cantaloupe (pH 6.2–7.1, $a_w > 0.99$, not heat treated), fresh sprouts (pH > 6.5 , $a_w > 0.99$, not heat
6725 treated), and cut tomatoes (pH 4.23–5.04, $a_w > 0.99$, not heat treated), Table B indicates that they are
6726 considered PHF/TCS Foods unless a product assessment shows otherwise. Maintaining these products
6727 under the temperature control requirements prescribed in this Regulation for PHF/TCS food will limit the
6728 growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

6729 If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than
6730 flavor enhancement, a standardized recipe validated by lab testing for pH and a_w would be requested to
6731 verify compliance with the conditions of the food storage.

6732 More information can be found in the Institute of Food Technologists (IFT) Report, "[Evaluation and](#)
6733 [Definition of Potentially Hazardous Foods](#)⁹".

6734 **Instructions for using the following Decision Tree and Table A and Table B:**

6735 1. Does the operator want to hold the food without using time or temperature control?

6736 a. No—Continue holding the food at $\leq 5^\circ\text{C}$ (41°F) or $\geq 57^\circ\text{C}$ (135°F) for safety and/or
6737 quality.

6738 b. Yes—Continue using the decision tree to identify which table to use to determine whether
6739 time/temperature control for safety (TCS) is required.

6740 2. Is the food heat treated?

6741 a. No—The food is either raw, partially cooked or treated with some other method other
6742 than heat. Proceed to step #3.

6743 b. Yes—If the food is heat treated to the required temperature for that food vegetative cells
6744 will be destroyed although spores will survive. Proceed to step #4.

6745 3. Is the food treated using some other method?

6746 a. No—The food is raw or has only received a partial cook allowing vegetative cells and
6747 spores to survive. Proceed to step #6.

6748 b. Yes—If a method other than heat is used to destroy pathogens such as irradiation, high
6749 pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the
6750 effectiveness of the process needs to be validated by inoculation studies or other means.
6751 Proceed to step #5.

6752

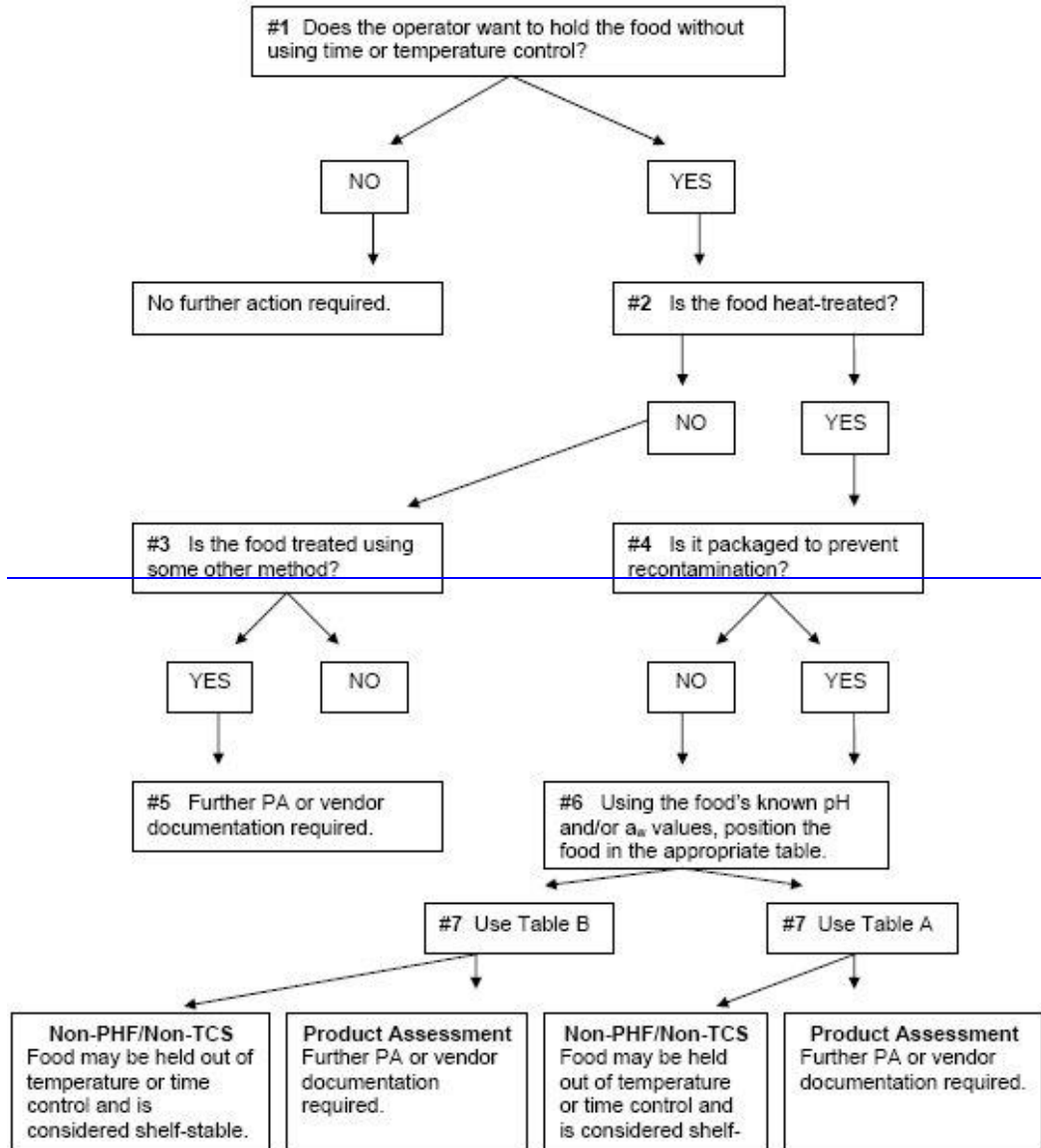
- 6753
- 6754 4. ~~Is it packaged to prevent re-contamination?~~
- 6755 a. ~~No—Re-contamination of the product can occur after heat treatment because it is not~~
6756 ~~packaged. Proceed to step #6.~~
- 6757 b. ~~Yes—If the food is packaged immediately after heat treatment to prevent re-~~
6758 ~~contamination, higher ranges of pH and/or a_w can be tolerated because spore-forming~~
6759 ~~bacteria are the only microbial hazard. Proceed to step #7.~~
- 6760 5. ~~Further product assessment or vendor documentation required.~~
- 6761 a. ~~The vendor of this product may be able to supply documentation that inoculation studies~~
6762 ~~indicate the food can be safely held without time/temperature control for safety.~~
- 6763 b. ~~Food prepared or processed using new technologies may be held without~~
6764 ~~time/temperature control provided the effectiveness of the use of such technologies is~~
6765 ~~based on a validated inoculation study.~~
- 6766 6. ~~Using the food's known pH and/or a_w values, position the food in the appropriate table.~~
- 6767 a. ~~Choose the column under "pH values" that contains the pH value of the food in question.~~
- 6768 b. ~~Choose the row under " a_w values" that contains the a_w value of the food in question.~~
- 6769 c. ~~Note where the row and column intersect to identify whether the food is "non-PHF/non-~~
6770 ~~TCS food" and therefore does not require time/temperature control, or whether further~~
6771 ~~product assessment (PA) is required. Other factors such as redox potential, competitive~~
6772 ~~microorganisms, salt content, or processing methods may allow the product to be held~~
6773 ~~without time/temperature control but an inoculation study is required.~~
- 6774 7. ~~Use **Table A** for foods that are heat treated and packaged **OR** use **Table B** for foods that are not~~
6775 ~~heat treated or heat treated but not packaged.~~
- 6776 8. ~~Determine if the item is non-PHF/non-TCS or needs further product assessment (PA).~~
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Decision Tree #1—Using pH, a_w , or the Interaction of pH and a_w to Determine if a Food Requires Time/Temperature Control for Safety



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Potentially Hazardous Foods Table A and Table B

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged			
a_w values	<u>pH values</u>		
	4.6 or less	> 4.6 – 5.6	≥ 5.6
≤ 0.92	non-PHF*/non-TCS FOOD**	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD
> 0.92 – .95	non-PHF/non-TCS FOOD	non-PHF/non-TCS FOOD	PA***
≥ 0.95	non-PHF/non-TCS FOOD	PA	PA

* PHF means Potentially Hazardous Food

** TCS food means Time/Temperature Control for Safety food

*** PA means Product Assessment required

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Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged				
a_w values	<u>pH values</u>			
	< 4.2	4.2 – 4.6	> 4.6 – 5.0	≥ 5.0
< 0.88	non-PHF*/non-TCS food**	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food
0.88 – 0.90	non-PHF/non-TCS food	non-PHF/non-TCS food	non-PHF/non-TCS food	PA***
≥ 0.90 – 0.92	non-PHF/non-TCS food	non-PHF/non-TCS food	PA	PA
≥ 0.92	non-PHF/non-TCS food	PA	PA	PA

- 6793 * PHF means Potentially Hazardous Food
6794 ** TCS food means Time/Temperature Control for Safety food
6795 *** PA means Product Assessment required

Chapter 2 — Management and Personnel

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6797 *2-1 — Supervision*

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6799 **2-101 — Responsibilities**

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6801 Designation of a person in charge during all hours of operations ensures the continuous presence of
6802 someone who is responsible for monitoring and managing all retail food establishment operations and
6803 who is authorized to take actions to ensure that the Regulation's objectives are fulfilled. During the day-
6804 to-day operation of a retail food establishment, a person who is immediately available and knowledgeable
6805 in both operational and Regulation requirements is needed to respond to questions and concerns and to
6806 resolve problems.

6807

6808 **2-102 — Demonstration**

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6810 The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard
6811 Analysis and Critical Control Point (HACCP) principles, and Regulation requirements is prepared to
6812 recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with
6813 Regulation requirements, and to take appropriate preventive and corrective actions.

6814

6815 There are many ways in which the person in charge can demonstrate competency. Many aspects of the
6816 retail food operation itself will reflect the competency of that person. A dialogue with the person in
6817 charge during the inspection process will also reveal whether or not that person is enabled by a clear
6818 understanding of the Regulation and its public health principles to follow sound food safety practices and
6819 to produce foods that are safe, wholesome, unadulterated, and accurately represented.

6820

6821 The Regulation does not require reporting of uninfected cuts or reporting of covered, protected infected
6822 cuts/lesions/boils since it requires no bare hand contact with ready-to-eat food.

6823

6824 **Status of "Universal Acceptance" of Food Protection Manager Certification**

6825 The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks
6826 and other economic, staffing, cultural and behavioral challenges make it imperative that food protection
6827 managers know and control the risk factors that impact the safety of the food they sell or serve. Food
6828 protection managers have an important role in formulating policies, verifying food employees carry out
6829 these policies, and communicating with these same employees to give information about recommended
6830 practices to reduce the risk of foodborne illness. A Centers for Disease Control and Prevention
6831 Environmental Health Specialist Network (EHS-Net) study suggests that the presence of a certified food
6832 protection manager reduces the risk for a foodborne outbreak for an establishment and was a
6833 distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had
6834 not.

6835 FDA's Retail Food Risk Factor Studies suggest that the presence of a certified manager has a positive
6836 correlation with more effective control of certain risk factors, such as poor personal hygiene, in different
6837 facility types.

6838 There are a number of state and local agencies that currently mandate food protection manager
6839 certification. For state and local agencies whose regulations do not mandate food protection manager
6840 certification to establish criteria for assessing the food safety knowledge of food protection managers.

6841 Factors to consider when establishing such criteria include:

- 6842 • the size and scope of the operation;
- 6843 • the hours of operation;
- 6844 • the types of foods sold or served;
- 6845 • the extent to which food is prepared on site;
- 6846 • the number of staff;
- 6847 • type of population served, e.g. highly susceptible or not; and
- 6848 • the number of meals served.

6849 **2-103 Person in Charge**

6850
6851 A primary responsibility of the person in charge is to ensure compliance with Regulation requirements.
6852 Any individual present in areas of a retail food establishment where food and food-contact items are
6853 exposed presents a potential contamination risk. By controlling who is allowed in those areas and when
6854 visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery,
6855 maintenance and service personnel, and pest control operators, comply with the Regulation requirements,
6856 the person in charge establishes an important barrier to food contamination.

6857
6858 Tours of food preparation areas serve educational and promotional purposes; however, the timing of such
6859 visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the
6860 disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for
6861 contamination are reduced.

6862 When food and other purchased goods are delivered and placed into designated locations within the food
6863 establishment during non-operating hours, the Person in Charge must make sure food employees inspect
6864 such product and verify that it is from the appropriate supplier, is in the desired condition, and was
6865 delivered to a proper storage location. Distributors deliver and place food and other goods in refrigeration
6866 units, freezers, and dry storage areas for confirmation of receipt and inspection by employees immediately
6867 upon arrival to the food establishment. Distributors contracted by the food establishment are often given
6868 a key to allow access into the establishment outside of normal working hours. Upon delivery, all must be
6869 appropriately stored in a safe and secure manner within the food establishment. For example, potentially
6870 hazardous foods (time/temperature control for safety foods) must be stored within refrigeration units and
6871 held at temperatures of 5°C (41°F) or below. Likewise, if the food product is frozen, it must be placed
6872 into the freezer.

6873 To minimize the potential for access to the food establishment and the food by an unauthorized person,
6874 precautions should be applied overall to the food establishment and especially when access to the facility
6875 is made under key access deliveries. [Additional information on food defense](#)⁴⁰.

6876 Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S.
6877 population, or twelve million Americans. Restaurant and retail food service managers need to be aware
6878 of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; to know the
6879 eight major food allergens; to understand food allergen ingredient identities and labeling; and to avoid

6880 cross-contact during food preparation and service. The 2008 Conference of Food Protection (CFP) passed
6881 Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of
6882 the Person in Charge. Accordingly, the Person in Charge's duties were amended to assure the food safety
6883 training of employees includes food allergy awareness in order for them to safely perform duties related
6884 to food allergies.

6885 The Person in Charge (PIC) has an important role in making sure employees properly report certain
6886 information about their health status as it relates to diseases that are transmitted by food. In an effort to
6887 reinforce dialogue between food employees and the PIC, there must be a way to verify that food
6888 employees and conditional employees are informed of their responsibility to report such information.
6889 Examples of ways to verify that employees have been appropriately informed include:

6890 • Implementation of an employee health policy that includes a system of employee notification
6891 using a combination of training, signs, pocket cards or other means to convey all the required
6892 information;

6893 • Other methods that satisfactorily demonstrate that all food employees and conditional employees
6894 are informed of their responsibility to report to the PIC information about their health and
6895 activities as it relates to diseases that are transmissible through food, as specified under Section 2-
6896 201.

6897 Ultimately, responsibility for food safety at the retail level lies with retail and food service operators and
6898 their ability to develop and maintain effective food safety management systems. There are many tools
6899 that industry can use to develop an effective system to achieve active managerial control of foodborne
6900 illness risk factors. An important tool in controlling risk factors inherent in a food establishment is the
6901 development and implementation of written procedures or plans.

6902 **2-2 — Employee Health**

6903 **2-201 — Restrictions Regarding Ill or Otherwise Infected Employees**

6904 A wide range of communicable diseases and infections may be transmitted by infected food employees to
6905 consumers through food or food utensils. Proper management of a retail food establishment operation
6906 begins with employing healthy people and instituting a system of identifying employees who present a
6907 risk of transmitting foodborne pathogens to food or to other employees. In order to protect the health of
6908 both consumers and employees, information concerning the health status of applicants and retail food
6909 employees must be disclosed to the person in charge.
6910
6911

6912 Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and
6913 inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of
6914 employment. In order for the permit holder and the person in charge to be in compliance with this
6915 particular aspect of the Regulation and the ADA, a conditional job offer must be made before making
6916 inquiries about the applicant's health status.
6917

6918 Furthermore, an applicant to whom an employment offer is conditionally made or a retail food employee
6919 who meets the Regulation conditions that require restriction from certain duties or exclusion must be
6920 accommodated to the extent provided under the ADA. That is, if there is an accommodation that will not
6921 pose an undue hardship and that will prevent the transmission of the disease(s) of concern through food,
6922 such accommodation, e.g., reassignment to duties that fulfill the intent of restriction or exclusion, must be
6923 made. It should be noted that the information provided here about the ADA is intended to alert employers
6924 to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA
6925

6926 and its implications, consult the references listed in the References Annex that relate to this section of the
6927 Regulation or contact the U. S. Equal Employment Opportunity Commission.

6928
6929 The information required from applicants and retail food employees is designed to identify employees
6930 who may be suffering from a disease, which can be transmitted through food. It is the responsibility of the
6931 permit holder to convey to applicants and employees the importance of notifying the person in charge of
6932 changes in their health status. Once notified, the person in charge can take action to prevent the likelihood
6933 of the transmission of foodborne illness.

6934
6935 Applicants, to whom a conditional offer of employment is extended, and retail food employees are
6936 required to report specific high risk conditions, medical symptoms, and previous illnesses. The symptoms
6937 listed may be indicative of a disease that is transmitted through the food supply by infected retail food
6938 employees.

6939
6940 As required by the ADA, the Centers for Disease Control and Prevention (CDC) published in the Federal
6941 Register on September 27, 2000, (Volume 65, Number 188) a list of infectious and communicable
6942 diseases that are transmitted through food. CDC updates the list annually. The list is divided into two
6943 parts: pathogens often transmitted and pathogens occasionally transmitted by infected persons who handle
6944 food.

6945
6946 The Lists below summarize the CDC list by comparing the common symptoms of each pathogen.
6947 Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. CDC has no
6948 evidence that the HIV virus is transmissible via food. Therefore, a retail food employee positive for the
6949 HIV virus is not of concern unless suffering secondary illness listed below. The Lists below include all
6950 Shiga toxin producing *E. coli* likely to occur in foods in the United States.

6951

6952

LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Persons.					
	D	F	V	J	S
1. Caliciviruses (Noroviruses)	✓	✓	✓	-	-
2. Hepatitis A virus	-	✓	-	✓	-
3. Salmonella Typhi	-	✓	-	-	-
4. Shigella species	✓	✓	✓	-	-
5. Staphylococcus aureus	✓	-	✓	-	-
6. Streptococcus pyogenes	-	✓	-	-	✓
LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons					
	D	F	V	J	S
1. Campylobacter jejuni	✓	✓	✓	-	-
2. Cryptosporidium parvum	✓	-	-	-	-
3. Entamoeba histolytica	✓	✓	-	-	-
4. Enterohemorrhagic Escherichia coli	✓	-	-	-	-
5. Enterotoxigenic Escherichia coli	✓	-	✓	-	-
6. Giardia lamblia	✓	-	-	-	-
7. Non-typhoidal Salmonella	✓	✓	✓	-	-
8. Taenia solium	-	-	-	-	-
9. Vibrio cholerae 01	✓	-	✓	-	-
10. Yersinia enterocolitica	✓	✓	✓	-	-

6953

6954

KEY: D = Diarrhea V = Vomiting S = Sore throat with fever F = Fever J = Jaundice

6955

The definition of Shiga toxin-producing *Escherichia coli* (STEC) covers all STEC identified in clinical laboratories by O157 and H7 serological tests, or by Shiga toxin tests.

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The definition includes all STEC, including those that are not specifically implicated in hemorrhagic colitis (i.e., bloody diarrhea). Only a subset of STEC (>100 STEC strains cause the vast majority of human STEC diarrhea) are traditionally classified as "enterohemorrhagic", and those serotypes that are considered "enterohemorrhagic", including *E. coli* O157:H7, do not actually cause a hemorrhagic form of colitis in a substantial percentage of cases. Virtually all O157:H7 strains produce Shiga toxin, so are pathogens. Many O157:NM or O157:H- also produce Shiga toxin, but some don't, so testing for shiga toxin is needed to be sure that they are STEC.

The symptoms listed in the Regulation cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected retail food employees.

6968 An employee suffering from any of the symptoms listed presents an increased risk of transmitting
6969 foodborne illness.

6970

6971 The high risk conditions that require reporting are designed to be used with the symptoms listed to
6972 identify employees who may be suffering from an illness due to the following pathogens: *Salmonella*
6973 *Typhi*, *Shigella* spp., Shiga toxin producing *Escherichia coli*, and hepatitis A virus. The specific
6974 conditions requiring reporting were identified by CDC as significant contributing factors to the incidence
6975 of foodborne illness.

6976

6977 The 4 organisms listed have been designated by CDC as having high infectivity. This designation is based
6978 on the number of confirmed cases reported that involved retail food employees infected with one of these
6979 organisms and the severity of the medical consequences to those who become ill.

6980

6981 The following information, taken from Control of Communicable Diseases Manual, is provided regarding
6982 the period of communicability for the four pathogens of concern and the application of that information to
6983 employees likely to be shedding certain pathogens:

6984

6985 **Salmonella Typhi**—As long as the bacilli appear in the excreta, usually from the first week throughout
6986 the convalescence; variable thereafter (commonly 1–2 weeks for paratyphoid). About 10% of untreated
6987 typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%–5% become
6988 permanent carriers; considerable fewer persons affected with paratyphoid organisms may become
6989 permanent gallbladder carriers.

6990

6991 **Shigella spp.**—During acute infection and until the infectious agent is no longer present in feces, usually
6992 within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may
6993 persist for months or longer. Appropriate antimicrobial treatment usually reduces duration of carriage to a
6994 few days.

6995

6996 **Shiga toxin**—producing serotypes of *Escherichia coli*, including *E. coli* O157:H7—The duration of
6997 excretion of the pathogen, which is typically for a week or less in adults but 3 weeks in one third of
6998 children. Prolonged carriage is uncommon.

6999

7000 **Hepatitis A**—Evidence indicates maximum infectivity during the latter half of the incubation period,
7001 continuing for a few days after onset of jaundice, although prolonged viral excretion (up to 6 months) has
7002 been documented in infants born prematurely.—The infectious agent is found in feces, reaching peak
7003 levels the week or two before onset of symptoms, and diminishing rapidly after liver dysfunction or
7004 symptoms appear, which is concurrent with the appearance of circulating antibodies to HAV.

7005

7006 Lesions containing pus that may occur on a retail food employee's hands, as opposed to such wounds on
7007 other parts of the body, represent a direct threat for introducing *Staphylococcus aureus* into food.
7008 Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms
7009 are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is
7010 allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with
7011 food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other
7012 parts of the body need to be covered; but, an impermeable bandage is not considered necessary for food
7013 safety purposes. Retail food employees should be aware that hands and fingers that contact pustular
7014 lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for
7015 introducing *Staphylococcus aureus* into food.

7016

7017 If an employee has an infected cut and bandages it, plus puts on a glove, the employee does not have to
7018 report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is
7019 required.

7020
7021 A reporting requirement is an important component of any food safety program. A retail food employee
7022 who suffers from any of the illnesses or medical symptoms or meets any of the high-risk conditions in
7023 this Regulation may transmit disease through the food being prepared. The person in charge must first be
7024 aware that an employee or prospective employee is suffering from a disease or symptom listed in the
7025 Regulation before steps can be taken to reduce the chance of foodborne illness.

7026
7027 Some of the symptoms that must be reported may be observed by the person in charge. However, retail
7028 food employees and applicants share a responsibility for preventing foodborne illness and are obligated to
7029 inform the person in charge if they are suffering from any of the symptoms, high-risk conditions, or
7030 medical diagnoses listed in the Regulation and retail food employees must comply with restrictions or
7031 exclusions imposed upon them.

7032

7033 **2-202—Exclusions and Restrictions**

7034

7035 Restriction or exclusion of retail food employees suffering from a disease or medical symptom listed in
7036 the Regulation is necessary due to the increased risk that the food being prepared will be contaminated
7037 with a pathogenic organism transmissible through food. A person suffering from any of the symptoms or
7038 medical conditions listed may be suffering from a disease transmissible through food.

7039

7040 Because of the high infectivity (ability to invade and multiply) and virulence (ability to produce severe
7041 disease) of *Salmonella Typhi*, *Shigella* spp., Shiga toxin-producing *Escherichia coli*, and hepatitis A
7042 virus, a retail food employee diagnosed with an active case of illness caused by any of these four
7043 pathogens must be excluded from retail food establishments. The exclusion is based on the severe medical
7044 consequences to individuals infected with these organisms, i.e., hospitalization and even death.

7045

7046 Restrictions and exclusions vary according to the population served because highly susceptible
7047 populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy
7048 individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious
7049 medical consequences in immunocompromised individuals. This point is reinforced by statistics
7050 pertaining to deaths associated with foodborne illness caused by *Salmonella Enteritidis*. Over 70% of the
7051 deaths attributed to this organism occurred among individuals who for one reason or another were
7052 immunocompromised. This is why the restrictions and exclusions listed in the Regulation are especially
7053 stringent for retail food employees serving highly susceptible populations.

7054

7055 The Regulation does not require restriction of a retail food employee with an unprotected, uninfected cut,
7056 or a retail food employee with a covered, protected infected cut/lesion/boil since it requires no bare hand
7057 contact with ready-to-eat food.

7058

7059 Periodic testing of retail food employees for the presence of diseases transmissible through food is not
7060 cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active
7061 symptoms and high-risk conditions listed. A high-risk condition alone does not trigger restriction or
7062 exclusion. The employee must also suffer from one of the symptoms listed.

7063

7064 The use of high-risk conditions alone as the sole basis for restricting or excluding retail food employees is
7065 difficult to justify. The high-risk conditions that must be reported apply only to the 4 organisms listed. Of
7066 the 4 organisms listed, hepatitis A presents a different twist to this rationale. Retail food employees who

7067 meet a high risk condition involving hepatitis A may shed the virus before becoming symptomatic. In
7068 fact, the infected employee could be shedding hepatitis A virus for up to a week before experiencing
7069 symptoms of the infection. However, even in light of this fact, blanket exclusion or restriction of a retail
7070 food employee solely because of a high risk condition involving hepatitis A is not justified.

7071
7072 The following summarize the rationale for not restricting or excluding an asymptomatic retail food
7073 employee simply because the employee meets a high risk condition involving hepatitis A:

7074
7075 1. — Because hepatitis A virus infection can occur without clinical illness (i.e., without
7076 symptoms), or because a person may shed hepatitis A virus in the stool for up to a week
7077 before becoming symptomatic, it is possible that a person unknowingly may have been
7078 exposed to an asymptomatic hepatitis A virus shedder or to an infected person who is in the
7079 incubation stage. No restriction/exclusion routinely occurs under these — presumably much
7080 more common — circumstances.

7081 2. — Even though the asymptomatic retail food employee may be infected with hepatitis A virus
7082 and may in fact be shedding virus in the stool, foodborne transmission of hepatitis A virus is
7083 unlikely if the employee practices good personal hygiene, such as washing hands after going
7084 to the bathroom.

7085 3. — Exclusions from work for prolonged periods of time may involve economic hardship for the
7086 retail food employee excluded.

7087
7088 Based on the information presented, exclusion or restriction solely on a high risk condition would be
7089 potentially controversial and of questionable merit.

7090
7091 Because of the high infectivity of hepatitis A, the person in charge or regulatory authority should handle
7092 employees and applicants who meet a high risk condition involving hepatitis A on a case-by-case basis.
7093 With this approach in mind, the following criteria are offered as a guide. First, the following information
7094 should be collected and analyzed:

7095
7096 1. — Clarify the type of contact the individual had with another person diagnosed with hepatitis A
7097 virus infection. Keep in mind that the closer the contact (i.e., living in the same household as
7098 the infected person), the more likely it is that a susceptible person may become infected.

7099 2. — What job does the retail food employee perform at the retail food establishment, e.g., is the
7100 employee involved in food preparation?

7101 3. — When did the employee begin work at the establishment?

7102 4. — What level of personal hygiene does the individual exhibit? For example, does the individual
7103 adhere to the handwashing requirements specified in the Regulation?

7104 5. — Has the individual suffered from hepatitis A in the past? If the answer to this question is yes,
7105 was blood testing done? If the individual did have hepatitis A in the past, the individual is
7106 immune from re-infection.

7107 6. — In terms of the current high risk condition, has the individual received immune globin (IG)?
7108 When?

7109
7110

- 7111
7112 ~~In addition, upon being notified of the high risk condition, the person in charge should immediately:~~
7113
7114 1. ~~Discuss the traditional modes of transmission of hepatitis A virus infection with the retail~~
7115 ~~food employee involved.~~
- 7116 2. ~~Advise the retail food employee to observe good hygienic practices both at home and at~~
7117 ~~work. This includes a discussion of proper handwashing, as described in the Regulation, after~~
7118 ~~going to the bathroom, changing diapers, or handling stool-soiled material.~~
- 7119 3. ~~Review the symptoms listed in the Regulation that are caused by hepatitis A infection.~~
- 7120 4. ~~Remind the employee of the employee's responsibility as specified in the Regulation to~~
7121 ~~inform the person in charge immediately upon the onset of any of the symptoms listed in the~~
7122 ~~Regulation.~~
- 7123 5. ~~In light of the high infectivity of hepatitis A, ensure that the employee stops work~~
7124 ~~immediately if any of the symptoms described in the Regulation develop and reports to the~~
7125 ~~person in charge.~~

7126
7127 ~~If after consideration of all the information gathered, the person in charge feels that the employee in~~
7128 ~~question is likely to develop hepatitis A, restriction or exclusion of the individual's activities should be~~
7129 ~~considered.~~

7130
7131 ~~A restricted retail food employee may work in an area of the retail food establishment where there is~~
7132 ~~wrapped food, wrapped single-service or single-use articles, or soiled food equipment or utensils.~~
7133 ~~Examples of activities that a restricted person might do include working at the cash register, seating~~
7134 ~~patrons, bussing tables, stocking canned or other packaged foods, or working in a non-food cleaning or~~
7135 ~~maintenance capacity consistent with the criteria in the definition of the term "restricted." A retail food~~
7136 ~~employee who is restricted from working in one retail food establishment may not work in an unrestricted~~
7137 ~~capacity in another retail food establishment, but could work unrestricted in another retail store that is not~~
7138 ~~a retail food establishment. A restricted retail food employee may enter a retail food establishment as a~~
7139 ~~consumer or the same as any other member of the general public.~~

7140
7141 ~~An excluded individual may not work as a retail food employee on the premises of any retail food~~
7142 ~~establishment. In a facility that has different departments, such as a department store, school, or health~~
7143 ~~care facility, the regulatory authority, in concert with other infection control authorities, may consider~~
7144 ~~allowing an excluded retail food employee to work in an area or department that is separate and~~
7145 ~~segregated from the food preparation, service, and storage areas, and the food equipment and utensil~~
7146 ~~areas, such as the soiled linen/laundry area or exterior maintenance. An excluded person may enter the~~
7147 ~~retail food establishment as a customer or the same as any member of the general public.~~

7148 7149 **2-203—Removal of Exclusions**

7150
7151 ~~Chapter 2 provisions related to employee health are structured to recognize certain characteristics of each~~
7152 ~~of the four infectious agents, the risk of illness presented by asymptomatic shedders, the increased risk to~~
7153 ~~highly susceptible populations, and the need to provide extra protection to those high-risk populations.~~
7154

7155 Asymptomatic shedders are retail food employees who do not exhibit the symptoms of foodborne illness
7156 but who are identified through laboratory analysis of their stools to have any one of the three bacterial
7157 pathogens identified in Chapter 2 in their gastrointestinal system.

7158

7159 The duties that an asymptomatic shedder performs in a retail food establishment are restricted if the
7160 establishment serves a general population or, if a highly susceptible population is involved, the shedder is
7161 excluded. Several considerations factor into the need to preclude asymptomatic shedders from retail food
7162 establishment functions that may result in the transmission of foodborne disease.

7163 •——— Outbreaks of foodborne illness involving *Salmonella Typhi* have been traced to
7164 asymptomatic retail food employees who have transmitted the pathogen to food, causing
7165 illness.

7166 •——— There is some epidemiological evidence of transmission of food via retail food
7167 employees infected with *Shigella* spp.

7168 •——— Healthy consumers are at risk due to a low infectious dose of *Shigella* spp.

7169 •——— Despite lacking epidemiological evidence of transmission of food via retail food
7170 employees infected with Shiga toxin producing *Escherichia coli*, the documented ease of
7171 transmitting it from person to person in a day care setting, suggests a low infectious dose and
7172 the potential for the organism to be transmitted through food.

7173 •——— The severity and consequences of one of the illnesses, Hemolytic Uremic Syndrome
7174 (HUS), associated with Shiga toxin producing *Escherichia coli* warrant the institution of
7175 disease interventions.

7176 •——— Restriction in a retail food establishment that does not serve a highly susceptible
7177 population affords protection for the general population and the immune-suppressed subset of
7178 the general population.

7179

7180 The risk that a communicable disease will be transmitted by retail food employees who are asymptomatic
7181 shedders varies depending upon the hygienic habits of the worker, the food itself and how it is prepared,
7182 the susceptibility of the population served, and the infectivity of the organism.

7183

7184 To minimize the risk in all retail food establishments of the transmission of foodborne disease by an
7185 asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the
7186 three bacterial pathogens are either restricted or excluded, depending on the population served. Requiring
7187 restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion
7188 and is consistent with APHA published recommendations in the "Control of Communicable Diseases in
7189 Man."

7190

7191 The Regulation requires medical clearance, based on criteria designed to detect the shedder state, before a
7192 person who had a recent illness from, or is identified as a shedder of any of the three bacterial infectious
7193 agents is allowed to resume the duties from which that person was restricted or, in the case of an
7194 establishment that serves a highly susceptible population, before the person may return to work.

7195

7196 With respect to a retail food employee in an establishment that serves an immunocompromised
7197 population, more stringent provisions should be addressed. Specifically, exclusion may be required in 3
7198 situations in which it is not required for retail food employees in other retail food establishments.

7199

7200 Those 3 situations involve an employee who:

- 7201
7202 1. ~~Meets a high risk condition and has a symptom of acute gastrointestinal illness~~
- 7203 2. ~~Is diagnosed as an asymptomatic shedder of *S. Typhi*, *Shigella* spp. or Shiga toxin producing~~
7204 ~~*Escherichia coli*; or~~
- 7205 3. ~~Had a recent illness caused by *S. Typhi*, *Shigella* spp., or Shiga toxin producing *Escherichia*~~
7206 ~~*coli*. The exclusion is in effect until a physician licensed to practice medicine or, if allowed~~
7207 ~~by law, a nurse practitioner or physician assistant, provides the medical clearance, indicating~~
7208 ~~that the infectious agent is not detected.~~

7209

7210 ~~**2-204 Discharges from the Eyes, Nose, and Mouth**~~

7211

7212 ~~Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by retail food~~
7213 ~~employees can directly contaminate exposed food, equipment, utensils, linens, and single service and~~
7214 ~~single use articles. When these poor hygienic practices cannot be controlled, the employee must be~~
7215 ~~assigned to duties that minimize the potential for contaminating food and surrounding surfaces and~~
7216 ~~objects.~~

7217

7218 ~~**2-3 Authorized Personnel**~~

7219

7220 ~~**2-4 Personal Cleanliness**~~

7221

7222 ~~**2-401**~~

7223

7224 ~~**2-402 and 2-403 Cleaning Procedure and When to Wash**~~

7225

7226 ~~The hands are particularly important in transmitting foodborne pathogens. Retail food employees with~~
7227 ~~dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity, which~~
7228 ~~may contaminate the hands, must be followed by thorough handwashing in accordance with the~~
7229 ~~procedures outlined in the Regulation.~~

7230

7231 ~~Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are~~
7232 ~~transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth,~~
7233 ~~throat, and nose of many employees. The hands of employees can be contaminated by touching their nose~~
7234 ~~or other body parts.~~

7235

7236 ~~Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to~~
7237 ~~ready to eat food as well as other pathogens that can be transmitted via cross-contamination from raw~~
7238 ~~foods to ready to eat foods. Many employees fail to wash their hands as often as necessary and even those~~
7239 ~~who do may use flawed technique.~~

7240

7241 ~~In the case of a retail food worker with one hand or a hand-like prosthesis, the EEOC has agreed that this~~
7242 ~~requirement for thorough handwashing can be met through reasonable accommodation in accordance with~~
7243 ~~the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable~~
7244 ~~the retail food worker with one hand to adequately generate the necessary friction to achieve the intent of~~
7245 ~~this requirement without sacrificing public health concerns.~~

7246

7247 The greatest concentration of microbes exists around and under the fingernails of the hands. The area
7248 under the fingernails, known as the "subungal space", has by far the largest concentration of microbes on
7249 the hand and this is also the most difficult area of the hand to decontaminate.

7250
7251 There are two different types of microbes on the hands, transient and resident microbes. Transient
7252 microbes consist of contaminating pathogens which are loosely attached to the skin surface, do not
7253 survive nor multiply, and a moderate number of organisms can be removed with adequate handwashing.
7254 Resident microbes consist of a relatively stable population that survive and multiply on the skin, and are
7255 not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential
7256 contamination in retail food service.

7257
7258 All aspects of proper handwashing are important in reducing microbial transients on the hands. However,
7259 friction and water have been found to play the most important role. This is why the amount of time spent
7260 scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running
7261 water to remove the transient pathogens that may be present. It is the abrasive action obtained by
7262 vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

7263
7264 Research has shown a minimum 10–15 second scrub is necessary to remove transient pathogens from the
7265 hands, and when an antimicrobial soap is used, a minimum of 15 seconds is required.

7266
7267 Every stage in handwashing is equally important and has an additive effect in transient microbial
7268 reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When
7269 done properly, each stage of handwashing further decreases the transient microbial load on the hands.

7270
7271 Handwashing done properly can result in a 2–3 logarithmic reduction in transient bacteria and a 2-log
7272 reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens,
7273 (i.e. $> 10^4$ microbes, as found on hands contaminated with bodily wastes and infected bodily fluids)
7274 handwashing may be ineffective in completely decontaminating the hands. Therefore, a further
7275 intervention such as a barrier between hands and ready-to-eat food is necessary.

7276
7277 The hands may become contaminated when the retail food employee engages in specific activities. The
7278 increased risk of contamination requires handwashing immediately after the activities listed. The specific
7279 examples listed in this Regulation section are not intended to be all inclusive. Employees must wash their
7280 hands after any activity, which may result in contamination of the hands.

7281 7282 **2-404—Hand Antiseptics**

7283
7284 This provision is intended to ensure that an antimicrobial product applied to the hands is both, 1) safe and
7285 effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will
7286 come into direct contact with food. The prohibition against bare hand contact contained in Section 3-401
7287 applies only to an exposed ready-to-eat food.

7288 7289 As a Drug Product

7290
7291 There are three means by which a hand sanitizer is considered to be safe and effective when applied to
7292 human skin:

- 7293
7294 1. A hand sanitizer may be approved by FDA under a new drug application based on data
7295 showing safety and effectiveness and may be listed in the publication **Approved Drug**
7296 **Products with Therapeutic Equivalence Evaluations**. Also known as the "Orange Book,"
7297 this document provides "product specific" listings rather than listings by compound. It is

7298 published annually with monthly supplements. These publications are available on the
7299 Internet via the FDA Web Site and Center for Drug Evaluation and Research Home Page,
7300 from the Superintendent of Documents/Government Printing Office, and from the National
7301 Technical Information Service. However, as of the end of 1998, no hand sanitizers are listed
7302 in this publication since no new drug applications have been submitted and approved for
7303 these products.

7304 2. A hand sanitizer active ingredient may be identified by FDA in the monograph for OTC
7305 (over the counter) Health Care Antiseptic Drug Products under the antiseptic handwash
7306 category. Since hand sanitizing products are intended and labeled for topical antimicrobial
7307 use by retail food employees in the prevention of disease in humans, these products are
7308 "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand sanitizers
7309 and dips must be manufactured by an establishment that is duly registered with the FDA as a
7310 drug manufacturer; their manufacturing, processing, packaging, and labeling must be
7311 performed in conformance with drug Good Manufacturing Practices (GMP's); and the
7312 product must be listed with FDA as a drug product.

7313
7314 Products having the same formulation, labeling, and dosage form as those that existed in the marketplace
7315 on or before December 4, 1975 or that are authorized by USDA are being evaluated under the OTC (over-
7316 the counter) Drug Review by FDA's Center for Drug Evaluation and Research. Otherwise, the far more
7317 extensive FDA review process for a new drug application (NDA) is required before marketing.
7318

7319 However, as of the end of 1998, no hand sanitizers have been shown to be acceptable through this process
7320 since the monograph has not been finalized. FDA's Center for Drug Evaluation and Research is not
7321 presently objecting to the use of "instant hand sanitizers" based on ethyl alcohol or isopropyl alcohol, or
7322 certain chlorine "hand sanitizing dips" since these compounds are included in the OTC Drug Review. The
7323 ultimate status of these products will not be known until the final monograph publishes.
7324

7325 Acceptable antimicrobial ingredients for hand sanitizers will be identified in a future final monograph
7326 issued under the OTC Drug Review for OTC Antiseptic Handwashes. Information about whether a
7327 specific product has been accepted and included in the proposed monograph may be obtained from the
7328 manufacturer. You may also refer to *Federal Register* (59) No. 116, June 17, 1994, Tentative Final
7329 Monograph (TFM) for Health Care Antiseptic Drug Products; Proposed Rule. This TFM describes the
7330 inclusion of hand sanitizers in this Review, on page 31440 under Comment 28 of Part II.
7331

7332 Questions regarding acceptability of a hand sanitizer with respect to OTC compliance may be directed to
7333 the OTC Compliance Team, HFD-312, Division of Labeling and Nonprescription Drug Compliance,
7334 Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Place, Rockville, MD
7335 20855-2737. Specific product label/promotional information and the formulation are required for
7336 determining a product's regulatory status.
7337

7338 As a Food Additive

7339
7340 To be regulated under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the
7341 components of a hand care product must *reasonably* be expected to become a component of food based
7342 upon the product's intended use.
7343

7344 Where the components of a product are reasonably expected to become a component of food based upon
7345 the product's intended use, there are three means by which they are considered by FDA to be safe:
7346

7347 1. A substance may be exempted from the requirement of being listed in the federal food
7348 additive regulations as specified in 21 CFR 170.39 Threshold of regulation for substances
7349 used in food contact articles. A review by FDA's Center for Food Safety and Applied
7350 Nutrition is required for such an exemption to be issued. The Center's Indirect Additives
7351 Team has exempted ethyl alcohol and isopropyl alcohol from the requirement of being listed
7352 in the federal food additive regulations. Therefore, there is no food additive prohibition
7353 against using these substances as components of an instant hand sanitizer.

7354 2. A substance may be regulated for the intended use as a food additive as specified in 21 CFR
7355 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, and listed there
7356 under with conditions of safe use. However, as of 1998, no petitions have been received for
7357 the review and approval of substances for use as hand sanitizers, and therefore none are
7358 listed.

7359 3. A substance may be "generally recognized as safe (GRAS)" for the intended use in contact
7360 with food within the meaning of the Federal Food, Drug, and Cosmetic Act § 201(s).
7361 Substances affirmed by FDA to be GRAS are listed in one of the following: 21 CFR 182
7362 Substances Generally Recognized as Safe, 21 CFR 184 Direct Food Substances Affirmed as
7363 Generally Recognized as Safe, or 21 CFR 186 Indirect Food Substances Affirmed as
7364 Generally Recognized as Safe. The law also provides for independent GRAS determinations.

7365
7366 The Indirect Additives Team does not certify or provide approvals for specific products. However, if the
7367 use of a product meets the regulations of 21 CFR 170.39 Threshold of regulation for substances used in
7368 food contact articles, FDA may provide a letter to a firm stating that the use of this product is exempt
7369 from the requirement of a food additive listing regulation. However, the product must be the subject of a
7370 new drug application or under FDA's OTC Drug Review to be legally marketed.

7371
7372 Questions regarding the regulatory status of hand sanitizer components as food additives may be directed
7373 to the Indirect Additives Team, HFS-215, Office of Premarket Approval, Center for Food Safety and
7374 Applied Nutrition, 200 C Street, SW, Washington, DC 20204. It may be helpful or necessary to provide
7375 label/promotional information when inquiring about a specific component.

7376 7377 **2-405—Where to Wash**

7378
7379 Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross
7380 contamination. It is important that handwashing be done only at a properly equipped handwashing facility
7381 in order to help ensure that retail food employees effectively clean their hands. Handwashing facilities are
7382 to be conveniently located, always accessible for handwashing, maintained so they provide proper water
7383 temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels
7384 and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since
7385 this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may
7386 not be used for food employee handwashing since this practice may introduce additional hand
7387 contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a
7388 variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food
7389 preparation areas and toilet rooms and discharges from ill persons.

7390 7391 **2-406—Fingernails**

7392
7393 The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the
7394 cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails

7395 may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails
7396 after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability
7397 concerns and may harbor pathogenic organisms.

7398

7399 **2-407—Clothing**

7400

7401 Dirty clothing may harbor diseases that are transmissible through food. Retail food employees who
7402 inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination
7403 of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In
7404 addition, employees wearing dirty clothes send a negative message to consumers about the level of
7405 sanitation in the establishment.

7406

7407 **2-408—Jewelry**

7408

7409 Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry
7410 may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms
7411 transmissible through food.

7412

7413 The term "jewelry" generally refers to the ornaments worn for personal adornment and medical alert
7414 bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for
7415 transmitting disease-causing organisms to food. In the case of a retail food worker who wears a medical
7416 information or medical alert bracelet, the EEOC has agreed that this requirement can be met through
7417 reasonable accommodation in accordance with the Americans with Disabilities Act by the person in
7418 charge and the employee working out acceptable alternatives to the bracelet worn at the wrist. An
7419 example would be wearing the bracelet high on the arm or secured in a manner that does not pose a risk to
7420 the food but provides emergency medical information if it is needed.

7421

7422 An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item
7423 itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for
7424 consumers, such as chipped and/or broken teeth and internal cuts and lesions.

7425

7426 **2-5—Hygienic Practice**

7427

7428 **2-501—General**

7429

7430 Proper hygienic practices must be followed by retail food employees in performing assigned duties to
7431 ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the
7432 possibility of transmitting disease through food.

7433

7434 **2-502—Eating, Drinking, or Using Tobacco**

7435

7436 Smoking or eating by employees in food preparation areas is prohibited because of the potential that the
7437 hands, food, and food-contact surfaces may become contaminated. Unsanitary personal practices such as
7438 scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered
7439 sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also
7440 adversely affect consumer confidence in the establishment.

7441

7442 Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these
7443 areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas
7444 retail food employees are allowed to drink from closed containers that are carefully handled.

7445
7446 **2-503—Hair Restraints**
7447
7448 Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect
7449 vehicle of contamination. Retail food employees may contaminate their hands when they touch their hair.
7450 A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching
7451 their hair.
7452

Chapter 3—Food

7453
7454 **3-1—Characteristics**
7455
7456 **3-101—General**
7457
7458 A primary line of defense in ensuring that food meets these requirements is to obtain food from approved
7459 sources, the implications of which are discussed below. However, it is also critical to monitor food
7460 products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger
7461 their safety, make them adulterated, or compromise their honest presentation. The regulatory community,
7462 industry, and consumers should exercise vigilance in controlling the conditions to which foods are
7463 subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are
7464 swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act.
7465 Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential
7466 hazard.
7467
7468 Food, at all stages of production, is susceptible to contamination. The source of food is important because
7469 pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm
7470 environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which
7471 plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation
7472 water, and fishing waters can be incorporated into food plants and animals.
7473
7474 Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores
7475 that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern
7476 is the lethal toxin of *Clostridium botulinum*, an organism whose spores (i.e., survival stages for non-
7477 growth conditions) are found throughout the environment. Even slight underprocessing of low acid food
7478 which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn
7479 consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these
7480 foods are not processed to be commercially sterile, they must be received frozen or under proper
refrigeration.
7481
7482 Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their
7483 varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial
7484 contamination of food. Because commercial items seldom are eaten right away, the home kitchen's
7485 limited capacity for maintaining food at proper temperatures may result in considerable microbial growth
7486 and toxin production by microorganisms introduced through the diverse sources of contamination.
Controlled processing is required for the safe preparation of food entering commerce.
7487 **Labeling—General**
7488
7489 Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows
7490 consumers to make informed decisions about what they eat. Many consumers, as a result of an existing
7491 medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in

7491 ~~dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In~~
7492 ~~addition, consumers have a basic right to be protected from misbranding and fraud.~~
7493

7494

7495 Labeling for Raw Shell Eggs

7496 The Code of Federal Regulations 21 CFR 101.17 ~~Food Labeling warning, notice, and safe handling~~
7497 ~~statements~~, paragraph (h) *Shell eggs* state in subparagraph (1), "The label of all shell eggs, whether in
7498 intrastate or interstate commerce, shall bear the following statement: 'SAFE HANDLING
7499 INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are
7500 firm, and cook foods containing eggs thoroughly.'" Further, in subparagraph (4) it states, "Shell eggs that
7501 have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall
7502 be exempt from the requirements of paragraph (h) of this section."

7503 3-2—Sources and Specifications

7504

7505 3-201—Shellfish and Fish

7506

7507 Shellfish

7508

7509 Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or
7510 in an undercooked state and thus receive neither heat nor any other process that would destroy or
7511 inactivate microbial pathogens. For safety, these foods must be accompanied by certification that
7512 documents that they have been harvested from waters that meet the water quality standards contained in
7513 the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also
7514 provides confidence that processing, packaging, and shipping have been conducted under sanitary
7515 conditions.

7516

7517 Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers.
7518 Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final
7519 product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

7520

7521 Pathogens from the harvest area are of particular concern in molluscan shellfish because:

7522 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage,
7523 which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2)
7524 molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3)
7525 molluscan shellfish are often consumed whole, either raw or partially cooked.

7526

7527 To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign
7528 government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish
7529 are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan
7530 shellfish harvesting is allowed from some waters, not from others, and only at certain times or under
7531 certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan
7532 shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

7533

7534 Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan
7535 shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag
7536 that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a
7537 requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck
7538 molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that
7539 containers of shucked molluscan shellfish bear a label with the name, address, and certification number of
7540 the shucker packer or repacker.

7541

7542 Pathogens, such as *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, and *Listeria*
7543 *monocytogenes* that may be present in low numbers at the time that molluscan shellfish are harvested,

7544 may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the
7545 risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and
7546 refrigeration. The length of time is dependant upon either the month of the year or the average monthly
7547 maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control
7548 Authority.

7549
7550 Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as
7551 dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from
7552 the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated
7553 with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the
7554 U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, Dungeness crabs, tanner
7555 crabs, and red rock crabs.

7556
7557 Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of
7558 molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern
7559 Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and
7560 some suggestions of occurrence elsewhere.

7561
7562 For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However,
7563 instances have been documented in Japan, Southeast Asia, Scandinavia, Western Europe, Chile, New
7564 Zealand, and eastern Canada.

7565
7566 Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish
7567 from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of
7568 Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been
7569 identified as a problem in the viscera of Dungeness crab, tanner crab, red rock crab, and anchovies along
7570 the west coast of the United States.

7571
7572 Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However,
7573 products such as roe on scallops and whole scallops do present a potential hazard for natural toxins.

7574
7575 To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug
7576 Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a
7577 tripartite, cooperative action plan involving federal and state public health officials and the shellfish
7578 industry. Those groups work together to improve shellfish safety. States regularly monitor waters to
7579 ensure that they are safe before harvesting is permitted. FDA routinely audits the states' classification of
7580 shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed
7581 shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters.
7582 Bootlegging is a criminal activity and a major factor in shellfish borne illnesses. Purchasing from
7583 certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

7584
7585 Plastic containers commonly used throughout the shellfish industry for shucked product bear specific
7586 information regarding the source of the shellfish as required by the NSSP Guide for the Control of
7587 Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their
7588 subsequent reuse by shellfish packers, which could result in shucked product that is inaccurately
7589 identified by the label. The reuse of these containers within the food establishment must be assessed on
7590 the basis of the Regulation's criteria for multi-use containers and the likelihood that they will be properly
7591 relabeled to reflect their new contents.

7592

7593 ~~Accurate source identification of the harvesting area, harvester, and dealers must be contained on~~
 7594 ~~molluscan shellstock identification tags so that if a shellfish borne disease outbreak occurs, the~~
 7595 ~~information is available to expedite the epidemiological investigation and regulatory action.~~

7596
 7597 ~~Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to~~
 7598 ~~foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility~~
 7599 ~~continues throughout the distribution chain.~~

7600
 7601 ~~Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their~~
 7602 ~~source. Proper identification is needed for tracing the origin and determining conditions of shellfish~~
 7603 ~~processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of~~
 7604 ~~the problem may remain undetected. If no causative factors are identified in the food establishment,~~
 7605 ~~tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that~~
 7606 ~~may need to be closed to harvesting.~~

7607
 7608 ~~Accurate records that are maintained in a manner that allows them to be readily matched to each lot of~~
 7609 ~~shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak~~
 7610 ~~occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate~~
 7611 ~~actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus~~
 7612 ~~infections, which have an incubation period that is significantly longer than other shellfish borne diseases,~~
 7613 ~~to come to light. The 90 day requirement is based on the following considerations:~~

7614	Shelf life of the product	14 days
	Incubation period	56 days
	Medical diagnosis and confirmation	5 days
	Reporting	5 days
	Epidemiological investigation	10 days
	<hr/>	
	Total	90 days

7615 ~~In reality and as stated in the provision, the 90-day "clock" starts at the time the container of shellstock is~~
 7616 ~~emptied. Starting from the date of harvest is not correct because the shellstock may be sold/consumed in~~
 7617 ~~less than the 14 days of shelf life cited in the chart above. Therefore, the 90 days may expire and the tag~~
 7618 ~~discarded before an illness is reported and investigated.~~

7619 ~~Shellstock could be frozen in the food establishment during the 14-day estimated shelf life period, which~~
 7620 ~~would effectively stop the clock on the shelf life. The shellstock could be thawed and consumed past the~~
 7621 ~~14-day shelf life. In this case, the 90 days would expire before consumption if the clock started 90 days~~
 7622 ~~from the harvest date.~~

7623 ~~Freezing shellstock in the food establishment is not usually done because, although oysters in the shell~~
 7624 ~~can be frozen with fair results, they do not have the same texture and appearance of a fresh oyster when~~
 7625 ~~thawed. Commercially frozen oysters are frozen rapidly to retain product quality.~~

7626

7627

7628 **Fish**

7629

7630 After December 18, 1997, all processors of fish were required by 21 CFR 123 to have conducted a hazard
7631 analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a
7632 HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have
7633 complied with this requirement. Hazards known to be associated with specific fish species are discussed
7634 in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of
7635 Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and
7636 drugs.

7637

7638 The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21
7639 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family
7640 **Scombridae**, in which significant levels of histamine may be produced in the fish flesh by
7641 decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow
7642 the growth of mesophilic bacteria.

7643

7644 Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S.,
7645 Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean
7646 regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel,
7647 large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large
7648 predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and
7649 snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and
7650 barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

7651

7652 **3-202—Parasite Destruction**

7653

7654 Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or
7655 perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service
7656 as an alternative public health control to that which is provided by adequate cooking. Candling or other
7657 visual inspection techniques are not adequate to avoid the risk of parasites from fish, which have not been
7658 frozen.

7659

7660 The recommended control strategies refer to the ambient air temperature during freezing and to the length
7661 of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held
7662 after it is solid frozen, whichever is appropriate. The parasite hazard is not considered to be reasonably
7663 likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that
7664 contains the egg mass) and rinsed.

7665

7666 Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw
7667 consumption, they must be properly frozen before they are served. If this process is done off-premises,
7668 purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be
7669 provided. This is necessary because fish from natural bodies of water may carry parasitic worms that can
7670 infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated)
7671 herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough
7672 freezing kills these worms if the fish are subjected to a low-enough temperature for a long-enough time.

7673

7674 In response to information provided to the FDA Office of Seafood, the [Fish and Fisheries Products](#)
7675 [Hazards and Controls Guidance](#)³³ lists certain species of tuna as not being susceptible to parasites of
7676 concern and therefore exempted from the freezing requirements that apply to other fish species that are
consumed raw.

7677 The Fish and Fisheries Products Hazards and Controls Guidance states that species that normally have
7678 parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when
7679 raised on pelleted food in an aquaculture operation. On the other hand, aquacultured fish that are fed
7680 processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species
7681 do not normally have a parasite hazard. Feed must not contain any live parasites. For example, the use of
7682 fresh fish meat in feed could transmit such parasites. Only heat treated feed or feed otherwise produced in
7683 a manner that would kill parasite intermediate stages infective to the aquacultured fish, such as most
7684 pelleted feeds, should be used.

7685 Additionally, it should be noted that the Fish and Fisheries Products Hazards and Controls Guidance,
7686 Edition 3, Table 3.1 only lists fish with well documented parasite hazards. Fish species in Table 3.1 that
7687 do not have specific parasite hazards listed are not necessarily safe when consumed raw or undercooked.
7688 This is because fish species in Table 3.1 were not listed with a parasite hazard if the species were
7689 generally cooked before consumption. In addition, in some cases, there is insufficient information or data
7690 to be able to denote a specific parasite hazard or deem the species as naturally parasite free. The
7691 exemptions to freezing as specified in Section 3-202 of the *REGULATION* are inclusive of and in
7692 harmony with the information and recommendations provided in the Fish and Fisheries Products Hazards
7693 and Controls Guidance.

7694 **3-3 — Sources and Specifications**

7695

7696 **3-301 — Package Integrity**

7697 Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the
7698 contained food. If the integrity of the packaging has been compromised, contaminants such as
7699 *Clostridium botulinum* may find their way into the food. In anaerobic conditions (lack of oxygen),
7700 botulism toxin may be formed.

7701 Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods.
7702 Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many
7703 cases, suspect packaging may have to be inspected by trained persons using magnifying equipment.
7704 Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or
7705 imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat
7706 was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

7707 **3-302 — Hermetically Sealed Food**

7708

7709 Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores
7710 that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern
7711 is the lethal toxin of *Clostridium botulinum*, an organism whose spores (i.e., survival stages for non-
7712 growth conditions) are found throughout the environment. Even slight under processing of low acid food
7713 which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn
7714 consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these
7715 foods are not processed to be commercially sterile, they must be received frozen or under proper
7716 refrigeration.

7717

7718 Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the
7719 contained food. If the integrity of the packaging has been compromised, contaminants such as
7720 *Clostridium botulinum* may find their way into the food. In anaerobic conditions (lack of oxygen),
7721 botulism toxin may be formed.

7722

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7727 imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat
7728 was applied during processing (under processing). Suspect cans must be returned and not offered for sale.
7729

7730 Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may
7731 become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment,
7732 utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas
7733 must be designated for storing unsaleable goods.
7734

7735 **3-303—Dry Milk and Dry Milk Products**

7736 **3-304—Reconstitution of Dry Milk, Dry Milk Products and Non-Dairy Products**

7737 **3-305—Fluid Milk, Fluid Milk Products, and Frozen Dessert Mix**

7738
7739 Milk, which is a staple for infants and very young children with incomplete immunity to infectious
7740 diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-
7741 producing *Escherichia coli*, *Salmonella* spp., and *Listeria monocytogenes*, and provides a rich medium
7742 for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen
7743 contamination in milk and products derived from milk. Dairy products are normally perishable and must
7744 be received under proper refrigeration conditions.
7745

7746
7747 Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria
7748 and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other
7749 harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of
7750 unpasteurized products will stop microbial growth and may reduce their bacterial populations; however,
7751 some organisms will survive because neither process invariably kills bacteria. Under certain conditions,
7752 freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain
7753 cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.
7754

7755 **3-306—Wild Mushrooms**

7756
7757 Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never
7758 been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans
7759 whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous,
7760 whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper
7761 cooking.
7762

7763
7764 Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species.
7765 In most parts of the country there is at least one organization that includes individuals who can provide
7766 assistance with both identification and program design. Governmental agencies, universities, and
7767 mycological societies are examples of such groups. If a food establishment chooses to sell wild
7768 mushrooms, management must recognize and address the need for a sound identification program for
7769 providing safe wild mushrooms.
7770

7771
7772 Regulatory authorities have expressed their difficulty in determining what constitutes a "wild mushroom
7773 identification expert" and enforcing the Regulation provisions associated with it. In 1998, the Conference
7774 for Food Protection (CFP) attempted to alleviate this problem through the formation of a committee that
7775 was charged with determining what constitutes a wild mushroom expert. However, the committee was
unable to provide this information in a practical, useful manner for State and local regulators within the

7776 constraints of the Regulation. The 2000 CFP recommended and FDA accepted the committee's alternative
7777 solution that a brochure be developed that will provide information on what constitutes a wild mushroom
7778 expert, and to replace "identification by a wild mushroom expert" with "written buyer specifications."
7779

7780 The CFP's recommendation attempts to provide the necessary information in a practical, useful manner
7781 for all stakeholders, and yet still convey the highest level of public health protection. The CFP committee
7782 suggested that written buyer specifications place more responsibility on the food establishment to ensure
7783 that wild mushrooms are obtained from a safe source, and also provides state and local regulators a
7784 template to use in ensuring wild mushrooms sold at retail are obtained from a safe source. The following
7785 guidance is provided regarding the identification of wild mushrooms:

7786 A food establishment that sells or serves mushroom species picked in the wild shall have a written buyer
7787 specification that requires identification of:

7788 1. The Latin binomial name, the author of the name, and the common name of the mushroom
7789 species;

7790 2. That the mushroom was identified while in the fresh state;

7791 3. The name of the person who identified the mushroom;

7792 4. A statement as to the qualifications and training of the identifier, specifically related to mushroom
7793 identification.

7794 Additional information can be found on the [California Poison Control](#)¹⁴ web site.

7795 ~~3-307 Meat, Poultry, Game Animals and Exotic Species~~

7796
7797 The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals
7798 may be available as a source of food only if a regulatory inspection program is in place to ensure that wild
7799 animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae,
7800 bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the
7801 human host. In addition to the risk posed to consumers of game that is not subject to an inspection
7802 program, there is risk to those who harvest and prepare wild game because they may contract infectious
7803 diseases such as rabies or tularemia.
7804

7805 **Labeling for Meat and Poultry**

7806
7807 Retail food establishments that process and package meat or poultry in a form that is not ready to eat, are
7808 obligated by federal regulation to label the product with safe food handling instructions. The intent of this
7809 requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria
7810 and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the
7811 products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that
7812 handles only prepackaged and pre-labeled products or if they obtain their meat or poultry at an operation
7813 such as a supermarket with a meat processing operation or from a small neighborhood butcher.
7814
7815

7816

7817 **3-308—Eggs**

7818

7819 Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria
 7820 and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other
 7821 harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of
 7822 unpasteurized products will stop microbial growth and may reduce their bacterial populations; however,
 7823 some organisms will survive because neither process invariably kills bacteria. Under certain conditions,
 7824 freezing and drying may preserve microbes.

7825

7826 Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good
 7827 growth medium for many types of bacteria. Damaged eggs must not be used as food.

7828

7829 The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg
 7830 may be restricted because it is a/an:

7831

7832 (i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell
 7833 membranes intact and contents not leaking.

7834 (ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt,
 7835 foreign material, or prominent stains.

7836 (iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been
 7837 removed from incubation during the hatching operations as infertile or otherwise unhatchable.

7838 (iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots,
 7839 mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs,
 7840 eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

7841 (v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the
 7842 extent that the egg contents are exposed or are exuding or free to exude through the shell.

7843 (vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that
 7844 its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because
 7845 it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

7846 On December 5, 2000 Federal regulations were amended to require that shell egg cartons bear safe
 7847 handling instructions and be placed under refrigeration at 7.2°C (45°F) or lower upon delivery at retail
 7848 establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of
 7849 Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

7850 • 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5
 7851 Inapplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or
 7852 destruction of shell eggs.

7853 • 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling
 7854 statements, (h) *Shell eggs*.

7855 • 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

7856 The labeling rule became effective September 4, 2001, and the refrigeration rule is effective June 4, 2001.
 7857 This rule is one part of the larger Egg Safety Action Plan, a farm to table approach for ensuring the safety
 7858 of our nation's egg supply, which was announced by the President on December 11, 1999. The Plan, a
 7859 joint effort by the FDA and the USDA, seeks to reduce by 50 percent the number of *Salmonella*

7860 ~~Enteritidis, illnesses attributed to contaminated eggs by 2005 and eliminate egg-associated *Salmonella*~~
7861 ~~Enteritidis illnesses by 2010.~~

7862

7863 ~~3-309—Ice~~

7864

7865 Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice
7866 that comes into contact with food to cool it or that is used directly for consumption must be as safe as
7867 drinking water that is periodically tested and approved for consumption.

7868

7869 ~~3-310—Ice Used as Exterior Coolant, Prohibited as Ingredient~~

7870

7871 Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and
7872 other contaminants. For example, ice used to store or display fish or packaged foods could become
7873 contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient,
7874 it could contaminate the final product.

7875

7876 ~~3-311—Storage or Display of Food in Contact With Water or Ice~~

7877

7878 Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior
7879 surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water
7880 to the food that is unclaimed in the food's formulation and label.

7881

7882 Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing
7883 the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by
7884 water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

7885

7886 ~~3-312—Juice~~

7887

~~Labeling for Juice~~

7888 On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling
7889 regulations to require a warning statement on fruit and vegetable juice products that have not been
7890 processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this
7891 action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products.
7892 FDA expects that providing this information to consumers will allow them to make informed decisions on
7893 whether to purchase and consume such juice products, thereby reducing the incidence of foodborne
7894 illnesses and deaths caused by the consumption of these juices.

7895 On July 18, 2001 FDA announced a final rule designed to improve the safety of fruit and vegetable juice
7896 and juice products. Under the rule, juice processors must use Hazard Analysis and Critical Control Point
7897 (HACCP) principles for juice processing. Processors making shelf-stable juices or concentrates that use a
7898 single thermal processing step are exempt from the microbial hazard requirements of the HACCP
7899 regulation. Retail establishments where packaged juice is made and only sold directly to consumers (such
7900 as juice bars) are not required to comply with this rule.

7901 Rather, the rule requires fresh fruit or vegetable juices that are packaged at retail (untreated juices or
7902 beverages containing untreated juices that are offered to consumers as prepackaged foods) to be processed
7903 under HACCP with a 5 log reduction in pathogens of concern OR bear the warning statement as specified
7904 in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and,
7905 therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons
7906 with weakened immune systems." Refer to Chapter 1 for the definition of juice. It is important to note that

7907 the definition of "juice" includes pureed fruits and vegetables, which are commonly prepared for service
7908 to highly susceptible populations.

7909 Food establishments that serve a highly susceptible population (HSP) cannot serve prepackaged juice that
7910 bears the warning label and they must serve only pasteurized juice. For juice only, this population
7911 includes children who are age 9 or less and receive food in a school, day care setting, or similar facility
7912 that provides custodial care.

7913 Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5 log
7914 reduction nor a warning statement or other consumer advisory (juice is not an animal food and therefore
7915 not covered by section 3.801) when prepared and served at retail. Usually the juice is served by the glass
7916 or in small batches compared to a commercial juice processor. The risk of using "drops" and damaged
7917 fruits or vegetables is much less at retail because of buyer specs that provide higher quality produce,
7918 meaning that fruits for juicing are less likely to be of a lower quality or damaged.

7919 Additional information is available in the document, "[Guidance for Industry: Exemptions from the
7920 Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen
7921 Reduction; Final Guidance](#)"⁸", October 7, 2002 or obtained from the FDA Office of Nutritional Products
7922 Labeling and Dietary Supplements.

7923 **3-313—Whole Muscle, Intact Beef Steaks**

7924
7925 In order for a food establishment operator to know that a steak is a whole muscle, intact cut of beef that
7926 can therefore be undercooked and served without a consumer advisory, the incoming product must be
7927 labeled. Processors can accommodate this need at the retail level by developing proposed labels,
7928 obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately
7929 affixing the labels to their products.

7930 7931 **3-4—Protection From Contamination After Receiving**

7932 7933 **3-401—Preventing Contamination from Hands**

7934
7935 In November, 1999, the National Advisory Committee for Microbiological Criteria for Foods
7936 (NACMCF), concluded that bare hand contact with ready-to-eat foods can contribute to the transmission
7937 of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended
7938 exclusion/restriction of ill food workers, as the first preventative strategy and recognized that this
7939 intervention has limitations, such as trying to identify and manage asymptomatic food workers. When the
7940 FDA reviewed and analyzed epidemiological data on foodborne illness outbreaks caused by fecal-oral
7941 pathogens, 93% of the foodborne illnesses reported were caused by ill food workers preparing food. This
7942 finding illustrates the problem caused by ill food workers who continue to prepare food. This is a
7943 problem, which is exacerbated by an increasing global market place, a tight labor market and lack of
7944 knowledge and understanding of food safety among food workers, and the economic need for food
7945 workers to work even when ill.

7946
7947 Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as
7948 specified in the Regulation, may not be an adequate intervention to prevent the transmission of pathogenic
7949 microbes to ready-to-eat foods via hand contact with ready-to-eat foods. Handwashing as specified in the
7950 Regulation will reduce microbial contamination of the hands by 2-3 logs.

7951
7952 Food workers infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at
7953 levels up to 10⁸ viral particles or oocysts per gram of feces. Having a high potential contamination level

7954 on the hands combined with a very low infectious dose necessary to cause infection are the reasons that
7955 FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-
7956 oral pathogens. The infective dose for Giardia and Cryptosporidium is believed to be as low as 1-10
7957 oocysts, and as few as 10 virus particles can infect an individual with hepatitis A. The infective dose for
7958 Norwalk virus is also believed to be very small.

7959
7960 The CDC now estimates that Norwalk-like viruses are the leading cause of foodborne illness in the United
7961 States. The CDC has also reported that hands are the most important means by which enteric viruses are
7962 transmitted. Further, contamination of food by an infected food worker is the most common mode of
7963 transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate
7964 from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will
7965 significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial
7966 contamination of the hands, especially in the subungual space of the fingers, a basic 2-3 log reduction
7967 handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

7968
7969 The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral
7970 route, identified by the NACMCF, include exclusion/restriction of ill food workers; proper handwashing;
7971 and no bare hand contact with ready-to-eat foods. Each of these factors is inadequate when utilized
7972 independently and may not be effective. However, when all three factors are combined and utilized
7973 properly, the transmission of fecal-oral pathogens can be controlled.

7974
7975 Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is
7976 important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the
7977 food.

7978 If a ready-to-eat food is being added as an ingredient to a food item that is subsequently subjected to a
7979 pathogen kill step (such as adding cheese or other ready-to-eat toppings to a pizza dough or adding
7980 vegetables to a raw meat dish before cooking) then strict prohibition of bare hand contact is not necessary.
7981 Cooking foods to the temperatures required in the Regulation will reduce the likelihood of survival of
7982 pathogens that might be transferred from an employee's hands to the surface of the ready-to-eat foods.
7983 The exception specifically targets bare hand contact with ready-to-eat food at the time it is added as an
7984 ingredient to food that will be cooked in the food establishment to the minimum temperatures specified in
7985 the Regulation. The exception does not apply when adding ready-to-eat foods as ingredients to foods that
7986 will only be lightly heated, melted, or browned rather than cooked to the minimum temperatures specified
7987 in this section. Nor does this exception apply when adding ready-to-eat foods as ingredients to foods that
7988 are intended for preparation by the consumer offsite. When proper heat treatment is used in combination
7989 with the exclusion/restriction of ill food workers and proper handwashing, the proper heat treatment
7990 provides an additional means of interrupting disease transmission.

7991 Also refer to the public health reasons for Sections 2-401, 2-402, and 2-403.

7992

7993
7994

Clarification on accepting an alternative procedure to no bare hand contact

7995
7996
7997

Background:

7998 Infected food employees are the source of contamination in approximately one in five foodborne disease
7999 outbreaks reported in the United States with a bacterial or viral cause.¹ Most of these outbreaks involve
8000 enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the
8001 time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread
8002 these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in
8003 contamination of food. Viral, bacterial, and parasitic agents can be involved.

8004

8005 Traditionally, food regulations have required two methods of preventing the spread of foodborne disease
8006 by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are
8007 infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral
8008 transmission interventions, the Regulation provides focused and specific guidance about ill workers and
8009 when handwashing must occur. As a final barrier, bare hand contact with ready-to-eat food (i.e., food that
8010 is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and
8011 suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be
8012 used. Any alternative to this requirement must convincingly address how food employees will be
8013 managed to preclude food contamination and how management will ensure that thorough handwashing
8014 occurs after employees use the toilet.

8015 **Because highly susceptible populations include persons who are immunocompromised, the very**
8016 **young and elderly, establishments serving these populations may not use alternatives to the no bare**
8017 **hand contact with ready-to-eat food requirement.**

8018 **Objective:**

8019

8020 This guidance is provided to assist the regulatory authority in evaluating conformity with the principle of
8021 no bare hand contact through alternative practices and procedures. In this guidance, "hazard" means
8022 infected food workers spreading pathogens to food via the hands.

8023

8024 **Guidance:**

8025

8026 **1. Requirements prerequisite** to consideration of alternatives include compliance with all Regulation
8027 provisions, particularly those related to:

8028 **1. Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of
8029 handwashing that ensure food employees keep their hands and fingertips clean and handwashing
8030 occurs at the times specified in Section 2.402—including after using the toilet and between tasks
8031 that may recontaminate the hands.

8032 **2. Hygienic Practices** as specified in Part 2.5.

8033 **3. Employee Health** regarding:

8034 **1. Reporting of diseases and medical conditions, and**

11 ¹ Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks - United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

- 8035 2. ~~Exclusions and restrictions~~, i.e., that food employees (including applicants to whom a
8036 conditional offer of employment has been made) report their health status as specified in
8037 Section 2-202; ill food employees are restricted or excluded as specified in Section 2-202
8038 and 2-205; and the exclusions and restrictions are removed as specified in Section 2-204.
- 8039 4. ~~Demonstration of Knowledge~~—Section 2-102.
- 8040 5. ~~Duties of the Person in Charge~~—Section 2-103.
- 8041 6. ~~How the alternative practices and procedures will control the hazard through an active~~
8042 ~~managerial control program~~. Such a program includes monitoring and verifying the institution
8043 of the provisions described in paragraphs A–C above and satisfies the following:
- 8044 1. ~~The public health hazard associated with bare hand contact specific to the food~~
8045 ~~establishment operation is identified and understood. The regulatory authority needs~~
8046 ~~assurance that the permit holder recognizes that the hazard being addressed is the~~
8047 ~~possible contamination of ready-to-eat food by viral and parasitic as well as bacterial~~
8048 ~~pathogens that are transferred from employees' hands.~~
- 8049 2. ~~The ready-to-eat foods that will be contacted with bare hands are identified and both~~
8050 ~~procedures and practices are in place so that food employees wash their hands before~~
8051 ~~returning to their work station and cross-contamination from touching raw and ready-to-~~
8052 ~~eat food is precluded. For example, identifying the specific type of food to be prepared,~~
8053 ~~such as tacos, and the specific location, such as a situation where a food employee is~~
8054 ~~assigned solely to the designated taco work station. The work station is located~~
8055 ~~immediately adjacent to the taco assembly unit and the employee will be preparing only~~
8056 ~~the specified ready-to-eat food using bare hands. Another example could be a food~~
8057 ~~employee who is responsible solely for assembling a variety of ready-to-eat foods.~~
- 8058 3. ~~Institution of an effective training program for food employees that emphasizes not~~
8059 ~~working when ill with any of the gastrointestinal symptoms listed in the Regulation, and~~
8060 ~~explains good hygienic practices, proper handwashing procedures, and safe food~~
8061 ~~preparation procedures. This should include a documented training plan that specifies~~
8062 ~~how management responsibility for training has been designated, training program~~
8063 ~~content, and the frequency of administration including periodic refresher sessions.~~
- 8064 7. ~~The alternative procedure should clearly describe monitoring, documentation, and verification~~
8065 ~~actions to ensure that the practices and procedures are followed. Corrective actions need to be~~
8066 ~~predetermined for situations where the practices and procedures are not followed, e.g., an ill~~
8067 ~~employee is found preparing foods.~~
- 8068 8. ~~Documentation of the practices, procedures, and corrective actions related to an alternative to no~~
8069 ~~bare hand contact with ready-to-eat food must be maintained and readily available at the food~~
8070 ~~establishment at all times for use by the person in charge and for review by the regulatory~~
8071 ~~authority.~~
- 8072 H. ~~The regulatory authority should also consider industry's elective use, managerial control, and~~
8073 ~~monitoring and verification of additional preventive measures used in tandem with the~~
8074 ~~forementioned interventions, which could include one or more of the following:~~
- 8075 1. ~~Vaccination against hepatitis A for food employees including initial and booster shots or~~
8076 ~~medical evidence that a food employee has had a previous illness from hepatitis A virus;~~

- 8077 2. ~~Double handwashing;~~
- 8078 3. ~~Use of nail brushes;~~
- 8079 4. ~~Use of an FDA-accepted hand sanitizer after handwashing, i.e., approved as safe for~~
8080 ~~application to human skin and safe as an indirect food additive, or exempted as a food~~
8081 ~~additive under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food~~
8082 ~~Contact Articles; and~~
- 8083 5. ~~Motivation for food employees not to work when they are ill.~~

8084
8085 **3-402—Glove Use**

8086
8087 ~~Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable~~
8088 ~~requirements related to utensil construction, good repair, cleaning, and storage.~~

8089
8090 ~~Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens~~
8091 ~~that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat~~
8092 ~~food or may indirectly contaminate food if stored with articles that will be used in contact with food.~~
8093 ~~Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves.~~
8094 ~~Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants~~
8095 ~~enter the inside of the glove.~~

8096
8097 ~~Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could~~
8098 ~~contaminate the food.~~

8099
8100 ~~Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear~~
8101 ~~latex gloves during food preparation, and even in individuals eating food prepared by food employees~~
8102 ~~wearing latex gloves. This information should be taken into consideration when deciding whether single-~~
8103 ~~use gloves made of latex will be used during food preparation.~~

8104
8105 ~~Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively~~
8106 ~~reviewing its current policy on the use of disposable NRL gloves in food operations in light of the~~
8107 ~~possible transmission of the latex protein via food. To gain additional information regarding allergic~~
8108 ~~reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been~~
8109 ~~collecting reports of such reactions from consumers who have contacted the Agency. Several offices~~
8110 ~~within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and~~
8111 ~~other related efforts will be used to determine if policy changes regarding the use of latex in food~~
8112 ~~operations, based on food safety considerations, are warranted.~~

8113
8114 ~~The FDA, Office of Premarket Approval, Indirect Additives, reviews gloves submitted for food contact~~
8115 ~~use in the food industry on the basis of the glove's formulation or components.~~
8116 ~~FDA regulates NRL gloves used for medical purposes only.~~

8117
8118 ~~FDA is aware of the following information related to occupational hazards (not food safety hazards)~~
8119 ~~associated with the use of NRL gloves:~~

- 8120 • ~~The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled~~
8121 ~~"Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication~~
8122 ~~number 97-135) which is found at <http://www.cdc.gov/niosh/latexalt.html>.~~

8123 • The American College of Allergy, Asthma and Immunology (ACAAI) and the American
 8124 Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement discouraging
 8125 the routine use of NRL gloves by food handlers. (1997)
 8126 <http://allergy.mcg.edu/physicians/joint.html>

8127 The AAAAI provides information on latex allergies on the web at
 8128 <http://www.aaaai.org/patients/resources/fastfacts/latex.stm>

8129 The ACAAI provides information on latex allergies on the web at
 8130 <http://allergy.mcg.edu/physicians/ltxhome.html>

8131 • An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing
 8132 unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves
 8133 for food handling..." (1999) http://www.osha-slc.gov/dts/tib/tib_data/tib19990412.html

8134 OSHA addresses gloves in the following federal regulation, which can be found at
 8135 http://www.osha-slc.gov/OshStd_data/1910_0138.html:

8136 OSHA Regulations (Standards—29 CFR)

8137 Standard Number: 1910.138

8138 Standard Title: Hand Protection:

8139 SubPart Number: I

8140 SubPart Title: Personal Protective Equipment

8141 (a) General requirements. Employers shall select and require employees to use appropriate hand
 8142 protection when employees' hands are exposed to hazards such as those from skin absorption of
 8143 harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns;
 8144 thermal burns; and harmful temperature extremes.

8145 (b) Selection. Employers shall base the selection of the appropriate hand protection on an
 8146 evaluation of the performance characteristics of the hand protection relative to the task(s) to be
 8147 performed, conditions present, duration of use, and the hazards and potential hazards identified.

8148

8149 For further information on the OSHA requirements, see [59 FR 16362, April 6, 1994].

8150

8151 **3-403—Preventing Contamination When Tasting**

8152

8153 **3-404—General**

8154

8155 Food that is inadequately packaged or contained in damaged packaging could become contaminated by
 8156 microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons
 8157 delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing
 8158 the entry of microbes and other contaminants such as chemicals. These contaminants may be present on
 8159 the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when
 8160 the packaging is opened. The removal of food product overwraps may also damage the package integrity
 8161 of foods under the overwraps if proper care is not taken.

8162

8163 Pathogens can be transferred to food from utensils that have been stored on surfaces, which have not
 8164 been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly
 8165 from used tableware or food containers.

8166

8167 Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that
 8168 comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such

8169 contamination. The handles of utensils, even if manipulated with gloved hands, are particularly
8170 susceptible to contamination.

8171
8172 Probe-type price or identification tags are defined as a utensil. Probe-type price or product identification
8173 tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and
8174 maintained.

8175
8176 Food preparation activities may expose food to an environment that may lead to the food's contamination.
8177 Just as food must be protected during storage, it must also be protected during preparation. Sources of
8178 environmental contamination may include splash from cleaning operations, drips from overhead air
8179 conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing
8180 food in a building that is not constructed according to Regulation requirements.

8181
8182 **3-405—Cross-Contamination Control**

8183
8184 Cross contamination can be avoided by separating raw animal foods from ready-to-eat foods. Cross
8185 contamination may also occur when raw unprepared vegetables contact ready-to-eat potentially hazardous
8186 foods. Raw animal foods must also be separated from each other because required cooking temperatures
8187 are based on thermal destruction data and anticipated microbial load. These parameters vary with
8188 different types of raw animal foods.

8189
8190 **3-406—Packaged and Unpackaged Food—Separation, Packaging, and Segregation**

8191 It is important to separate foods in a ready-to-eat form from raw animal foods during storage, preparation,
8192 holding and display to prevent them from becoming contaminated by pathogens that may be present in or
8193 on the raw animal foods. An exception is permitting the storage and display of frozen, commercially
8194 packaged raw animal food adjacent to or above frozen, commercially packaged ready-to-eat food. The
8195 freezer equipment should be designed and maintained to keep foods in the frozen state. Corrective action
8196 should be taken if the storage or display unit loses power or otherwise fails. Raw or ready-to-eat foods or
8197 commercially processed bulk-pack food that is packaged on-site presents a greater risk of cross-
8198 contamination. Additional product handling, drippage during the freezing process, partial thawing or
8199 incomplete seals on the package increase the risk of cross-contamination from these products packaged
8200 in-house.

8201 With regard to the storage of different types of raw animal foods it is the intent of this Regulation to
8202 require separation based on anticipated microbial load and raw animal food type (species). Separating
8203 different types of raw animal foods from one another during storage, preparation, holding and display will
8204 prevent cross-contamination from one to the other. The required separation is based on a succession of
8205 cooking temperatures as specified under Section 3-502 which are based on thermal destruction data and
8206 anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are
8207 required to be cooked to an internal temperature of 62.8°C (145°F) for 15 seconds, shall be stored above
8208 or away from raw poultry, which is required to be cooked to an internal temperature of 74°C (165°F) for
8209 15 seconds due to its considerably higher anticipated microbial load. In addition, raw animal foods having
8210 the same cooking temperature, such as pork and fish, shall be separated from one another during storage
8211 and preparation by maintaining adequate spacing or by placing the food in separate containers because of
8212 the potential for allergen cross-contamination or economic adulteration via inadvertent species
8213 substitution.

8214 Storing or displaying comminuted or otherwise non-intact meats above whole muscle intact cuts of meat
8215 can also present a cross-contamination hazard unless they are packaged and displayed in a manner that
8216 creates a barrier to prevent leakage of contents from one package to the other. Cooking recommendations
8217 assume that lower levels of contamination will be present in whole muscle products than in non-intact

8218 meats. If the whole muscle product is subject to cross contamination, the recommended cooking
8219 temperature may not be sufficient to ensure the safety of the product.

8220 Food that is inadequately packaged or contained in damaged packaging could become contaminated by
8221 microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons
8222 delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing
8223 the entry of microbes and other contaminants such as chemicals. These contaminants may be present on
8224 the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when
8225 the packaging is opened. The removal of food product overwraps may also damage the package integrity
8226 of foods under the overwraps if proper care is not taken.

8227

8228 **3-407—Pasteurized Eggs, Substitute for Shell Eggs for Certain Recipes**

8229

8230 Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because
8231 the virulent organism **Salmonella Enteritidis** may be present in raw shell eggs.

8232 Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The
8233 pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

8234

8235 **3-408—Washing Fruits and Vegetables/Additives/Sulfites**

8236 Pathogenic microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present
8237 on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the
8238 majority of organisms and/or chemicals present; however, more recent studies have demonstrated
8239 washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells
8240 to survive under adverse environmental conditions and also reduces the ability to remove pathogens by
8241 washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and
8242 bagged produce, must be thoroughly washed under running, potable water or with chemicals before
8243 eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still
8244 important to remove soil and debris first.

8245 Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and
8246 vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing
8247 or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should
8248 be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain
8249 fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is
8250 recommended that soaking or submerging produce during cleaning be avoided. It is important to follow
8251 practices that minimize pathogens in the water or on the surface of produce. It is important that proper
8252 handwashing procedures are followed before and after handling fresh produce.

8253 Scrubbing with a clean brush is only recommended for produce with a tough rind or peel, such as carrots,
8254 cucumbers or citrus fruits, which will not be bruised easily or penetrated by brush bristles. Scrubbing firm
8255 produce with a clean produce brush and drying with a clean cloth towel or fresh disposable towel can
8256 further reduce bacteria that may be present. Washing fresh fruits and vegetables with soap, detergent or
8257 other surfactants should be avoided as they facilitate infiltration and may not be approved for use on food.
8258 Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes
8259 are unapproved or applied in excessive concentrations. Unless otherwise stipulated in 21 CFR 173.315,
8260 chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to
8261 accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to
8262 any indications as dictated on the product label.

8263 Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the
8264 package label, and can be used as ready-to-eat without further washing. The label should also state if
8265 further washing is recommended or necessary. Precut or prewashed produce in open bags should not be

8266 washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are
8267 considered potentially hazardous food (PHF) requiring time/temperature control for safety (TCS) and
8268 should be refrigerated at 5°C (41°F) or lower to prevent any pathogens that may be present from
8269 multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and
8270 other produce, you may consult the FDA Program Information Manual, [Retail Food Protection Storage
8271 and Handling of Tomatoes, dated October 5, 2007](#)⁴¹, the document, [Time as a Public Health Control for
8272 Cut Tomatoes, dated June 8, 2010](#)⁴² and the FDA Program Information Manual, [Recommendations for the
8273 Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments
8274 dated July 7, 2010](#)⁴³.

8275 On October 26, 1998 a voluntary guidance document that addresses practices commonly used by fresh
8276 fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance
8277 contains useful information related to washing fruits and vegetables as well as the application of
8278 antimicrobial agents. The "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and
8279 Vegetables" is available from FDA's Food Safety Initiative staff and also on the Internet at
8280 <http://www.fda.gov>.

8281 Additionally, in February 2008, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued
8282 ["Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and
8283 Vegetables"](#)²¹, which covers fresh-cut fruits and vegetables that have been minimally processed (e.g. no
8284 kill step) and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming with or
8285 without washing or other treatment, prior to being packaged for use by the consumer or a retail
8286 establishment.

8287 On January 11, 2006 FDA/CFSAN published additional [safe handling advice](#)²² on the purchase, storage,
8288 and preparation of fresh produce, as well as Q & A's for consumers on their website. This document is
8289 available in PDF (3.5 MB) format (also available in Spanish) and provides additional information on the
8290 cleaning of fresh produce.

8291 Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by
8292 food additive regulations could result in foodborne illness, including allergic reactions. For example,
8293 many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning"
8294 of fruits and vegetables or to cause ground meat to look "redder" or fresher.

8295
8296 It is imperative for safety that food supplies come from sources that are in compliance with laws
8297 regarding chemical additives and contaminants.

8298
8299 Food additives are substances, which, by their intended use, become components of food, either directly
8300 or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved
8301 application, additives may be harmful to the consumer. Unintentional contaminants or residues also find
8302 their way into the food supply. The tolerances or safe limits designated for these chemicals are
8303 determined by risk assessment evaluations based on toxicity studies and consumption estimates.

8304 Food and Color additives must be used in compliance with a federal food, or color additive regulation, an
8305 effective food contact notification, or a threshold of regulation exemption. Such regulations, notifications,
8306 and exemptions are generally composed of three parts: the IDENTITY of the substance,
8307 SPECIFICATIONS including purity or physical properties, and LIMITATIONS on the conditions of use.
8308 In order for a food, or color additive use to be in compliance, the use must comply with all three criteria.

8309 Federal Food Additive regulations are found in Title 21 CFR, Parts 172-180. Color additive regulations
8310 are found in Title 21 CFR Parts 73-Subpart A, 74-Subpart A, 81 and 82. Effective food contact
8311 notifications are listed at [Inventory of Effective Food Contact Substance \(FCS\) Notifications](#)¹⁵, and
8312 threshold of regulation exemptions are listed at [Threshold of Regulation Exemptions](#)¹⁶.

8313 Other substances that are added to food include those prior sanctioned for use in food by either the FDA
8314 or USDA, or those generally recognized as safe for their intended use in food. Some of these are listed in
8315 Title 21 CFR Parts 181–186, Title 9 CFR Section 424.21(b) and at [GRAS Notice Inventory](#)¹⁷. Tolerances
8316 and exemptions from tolerance for pesticide chemical residues in or on food are found in Title 40 CFR
8317 Part 180. Substances that are prohibited from use in human food are listed in Title 21 CFR Part 189.

8318

8319 **3-409—In-Use Utensils, Between-Use Storage**

8320

8321 Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously
8322 cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or
8323 intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that
8324 precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils
8325 may be safely stored in hot water maintained at 60°C (135°F) or above during intermittent use because
8326 microbial growth is controlled at such temperatures.

8327 Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that
8328 comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such
8329 contamination. The handles of utensils, even if manipulated with gloved hands, are particularly
8330 susceptible to contamination.

8331 A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to
8332 minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to
8333 determine if a utensil is improperly designed for the task or whether a food employee is misusing an
8334 appropriately designed utensil.

8335

8336 Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of
8337 food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil
8338 so that it may be used for another, use of soiled tableware to transfer food, and cross-contamination
8339 between foods, including a raw food to a cooked potentially hazardous food.

8340

8341 **3-410—Wiping Cloths**

8342 Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be
8343 transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must
8344 be stored in a sanitizer solution of adequate concentration between uses. Wiping cloths soiled with
8345 organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution
8346 must be changed as needed to minimize the accumulation of organic material and sustain proper
8347 concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with
8348 an appropriate chemical test kit.

8349 Wiping down a surface with a reusable wet cloth that has been properly stored in a sanitizer solution is an
8350 acceptable practice for wiping up certain types of food spills and wiping down equipment surfaces.
8351 However, this practice does not constitute cleaning and sanitizing of food contact surfaces where and
8352 when such is required to satisfy the methods and frequency requirements in Section 4-4 of the Regulation.

8353 The same is true of the practice of wiping down a surface using dry disposable towels and a spray bottle
8354 containing pre-mixed sanitizing solution. This practice is not prohibited, however it alone does not
8355 constitute proper cleaning and sanitizing of food contact surfaces where and when such is required to
8356 satisfy the methods and frequency requirements in Parts 4-4 of the Regulation.

8357 Further, for the purpose of wiping up food spills from surfaces in situations where full cleaning and
8358 sanitizing is not required (such as when a soft drink overflows onto the side of a cup or onto a countertop)
8359 the use of dry cloths and disposable towels is also acceptable as long as the cloth or towel is used for no

8360 other purpose. Again, this does not constitute a proper cleaning and sanitizing procedure for a food
8361 contact surface, when such is called for in 4.4 of the Regulation.

8362 In order to effectively clean and sanitize food contact surfaces, where and when required to satisfy the
8363 requirements in Parts 4.6 and 4.7 of the Regulation, the surface must be first cleaned properly to remove
8364 organic material. In most cases this requires use of detergents or other cleaners. After the surface is clean
8365 to sight and touch, a sanitizing solution of adequate temperature with the correct chemical concentration
8366 should then be applied to the surface. The sanitizing solution must stay on the surface for a specific
8367 contact time as specified in this Regulation and in accordance with the manufacturer's EPA registered
8368 label, as applicable.

8369 Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and
8370 contaminants that are found in the use environment. Because of their construction, sponges provide
8371 harborage for any number and variety of microbiological organisms, many of which may be pathogenic.
8372 Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use,
8373 food contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

8374

8375 **3.411—Re-Use of Tableware**

8376

8377 Pathogens can be transferred to food from utensils that have been stored on surfaces, which have not been
8378 cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly
8379 from used tableware or food containers.

8380

8381 **3.412—Refilling Returnables**

8382

8383 Pathogens can be transferred to food from utensils that have been stored on surfaces, which have not been
8384 cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly
8385 from used tableware or food containers.

8386

8387 The refilling of consumer owned beverage containers introduces the possibility of contamination of the
8388 filling equipment or product by improperly cleaned containers or the improper operation of the
8389 equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of
8390 consumer owned containers is limited to beverages that are not potentially hazardous. Equipment must be
8391 designed to prevent the contamination of the equipment and means must be provided to clean the
8392 containers at the facility.

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3-413—Food Storage

3-414—Food Storage, Prohibited Areas

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination.

3-415—Food Display

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

3-416—Condiments, Protection

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On or off site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

3-417—Consumer Self-Service Operations

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are potentially hazardous foods and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

8442

8443 **3-418—Reservice**

8444

8445 Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus.
8446 Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous and that
8447 have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic
8448 microorganisms from the initial consumer to the next if the food is served again.

8449

8450 **3-5—Destruction of Organisms of Public Health Concern**

8451

8452 **3-501—Temperature**

8453

8454 Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all,
8455 types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant
8456 levels in properly refrigerated foods that are not out of date.

8457

8458 High temperatures for a long enough time, such as those associated with thorough cooking, kill or
8459 inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced
8460 in foods by certain bacteria (such as the enterotoxins of *Staphylococcus aureus*). Cooking or hot holding
8461 that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the
8462 Regulation prevents significant regrowth of heat-injured microorganisms and prevents recontamination
8463 with bacteria that are newly introduced.

8464

8465 Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the
8466 temperature "Danger Zone" of 5°C to 60°C (41°F to 135°F) too long. Up to a point, the rate of growth
8467 increases with an increase in temperature within this zone. Beyond the upper limit of the optimal
8468 temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or
8469 cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

8470

8471 The ability of equipment to cool, heat, and maintain potentially hazardous foods at Regulation-required
8472 temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major
8473 contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold
8474 holding equipment with enough capacity to meet the heating and cooling demands of the operation.

8475

8476 **Cold Holding**

8477

8478 Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most
8479 microbes. The growth of some bacteria, such as *Listeria monocytogenes*, is significantly slowed but not
8480 stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to
8481 public health in ready-to-eat foods.

8482

8483 Except for raw shell eggs, control of the growth of *Listeria monocytogenes* is the basis for the list of cold
8484 holding temperature and time combinations. The list addresses time, in addition to temperature, as a
8485 control for the growth of *Listeria monocytogenes* in refrigerated, ready-to-eat, potentially hazardous food.
8486 The Regulation provisions for cold holding focus on environmental conditions that allow 1 log of growth
8487 of *Listeria monocytogenes*, and do not set an acceptable number of Lm in food. Neither do they imply that
8488 *Listeria monocytogenes* is in the product.

8489

8490 The times and temperatures in the 1999 FDA Model Food Code and the 1999 *Colorado Retail Food*
8491 *Establishment Rules and Regulations* were based on the USDA Pathogen Modeling Program (PMP),
8492 which is conservative in estimating how soon *Listeria monocytogenes* begins to grow and how fast. The

8493 PMP was based largely on observations of microbial growth in broth cultures, but some observations in
8494 specific foods were also included. The PMP allows for some variation in temperature, pH, and water
8495 activity, and gives a conservative estimate of safe times and temperatures for holding foods. The 1999
8496 Regulation estimated safe times and temperatures that would allow 3 logs of growth, based on the PMP.

8497
8498 During 2000, CFSAN researched published literature and compiled a listing of the growth potential of
8499 Lm in various food commodities using real food data. Based on this information, the 1999 Food Code
8500 times and temperatures of 5°C (41°F) for 7 days and 7.2°C (45°F) for 4 days were validated, but the
8501 underlying performance standard changed for the commodities studied. The research-based, food-specific
8502 times and temperatures allow no more than 1 log of growth instead of the 3 log growth predicted in the
8503 PMP. This more stringent performance standard of 1 log is consistent with the USDA/FSIS performance
8504 standard and the fact that the infectious dose of Lm remains unknown.

8505 FDA concluded that the 1999 Regulation time/temperature criteria hold true and provide both a greater
8506 level of safety and a more realistic basis for regulatory requirements without compromising public health
8507 protection.

8508 In October 2003, FDA, in cooperation with the USDA/FSIS and CDC, released the [Quantitative](#)
8509 [Assessment of the Relative Risk to Public Health from Foodborne LISTERIA MONOCYTOGENES](#)
8510 [Among Selected Categories of Ready-to-Eat Foods \(risk assessment\)](#)³⁶. This initiative included the
8511 development of 23 separate risk assessments and analysis of the relative risks of serious illness and death
8512 associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood,
8513 produce, meats, dairy products, and deli salads.

8514 The risk assessment identified several broad factors that affect consumer exposure to LM at the time of
8515 food consumption. Two of these factors, refrigerated storage temperature and duration of refrigerated
8516 storage before consumption, have a direct bearing on cold holding time/temperature combinations used in
8517 food establishments.

8518 FDA continues to have concerns about the potential for growth of LM in refrigerated, ready-to-eat,
8519 potentially hazardous food (time/temperature control for safety food), prepared and packaged in a food
8520 processing plant and held in a food establishment. Data from the risk assessment show a significant
8521 reduction in the projected cases of listeriosis when refrigerated storage is limited to 5°C (41°F). Based on
8522 these data and conclusions from the risk assessment, FDA continues to recommend that food
8523 establishments limit the cold storage of potentially hazardous (time/temperature control for safety), ready-
8524 to-eat foods to a maximum temperature of 5°C (41°F).

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Table 1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures*			
Maximum Refrigerator Temperature	Cases of Listeriosis^a		
	Median	5th Percentile	95th Percentile
Baseline^b	2105	3/4 ^e	3/4 ^e
7 °C (45 °F) maximum	656	331	761
5 °C (41 °F) maximum	28	1	126

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^aValues for the median, upper and lower uncertainty levels.

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^bThe baseline uses the full empirical distribution of refrigerator temperatures from the Audits International (1999) survey.

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^cThe baseline number of cases of listeriosis is fixed based on CDC surveillance data.

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^eThe scenario assumed the distribution of storage times is the same for all three temperature sets.

8532

Source: [Quantitative Assessment of the Relative Risk to Public Health from Foodborne LISTERIA MONOCYTOGENES Among Selected Categories of Ready-to-Eat Foods](#)³⁷

8533

8534

September 2003. Table VI-1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures.

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Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998) to require that shell eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2°C (45°F). This regulation, however, does not apply to eggs while held at all retail establishments. FDA is concerned that without continued refrigeration up until the time that the eggs are cooked, there would be an opportunity for the egg's defenses to degrade and growth of *Salmonella Enteritidis* to occur. The agency reviewed research indicating that *Salmonella Enteritidis* multiplies at temperatures of 10°C (50°F) and above but can be inhibited at lower temperatures, e.g., 8°C (46°F), 7.2°C (45°F) and 4°C (39°F). Based on this research and USDA's temperature requirement during transport, FDA implemented regulations that establish a maximum ambient air temperature of 7.2°C (45°F) for eggs stored and displayed at retail establishments. Amended federal regulations 21 CFR Part 115, Eggs, Refrigeration issued on December 5, 2000 and became effective on June 4, 2001.

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Although Congress did not expressly preempt State law in this area, FDA found preemption is needed because State and local laws that are less stringent than the Federal requirements will significantly interfere with the important public health goals of these regulations. FDA does not believe that preemption of State and local refrigeration and labeling requirements that are the same as or more stringent than the requirements of these regulations is necessary, as enforcement of such State and local requirements will not interfere with the food safety goals of these regulations. Accordingly, the preemptive effect of this rule is limited to State or local requirements that are not as stringent as the

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8555 requirements of these regulations; requirements that are the same as or more stringent than FDA's
8556 requirements remain in effect.

8557 **Hot Holding**

8558 In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods
8559 (NACMCF) recommended that the minimum hot holding temperature:

8560 • Be greater than the upper limit of the range of temperatures at which *Clostridium perfringens*
8561 and *Bacillus cereus* may grow; and

8562 • Provide a margin of safety that accounts for variations in food matrices, variations in temperature
8563 throughout a food product, and the capability of hot holding equipment to consistently maintain
8564 product at a desired target temperature.

8565 *C. perfringens* has been reported to grow at temperatures up to 52°C (126°F). Growth at this upper limit
8566 requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that
8567 lag phase duration and generation times are shorter at incubation temperatures below 49°C (120°F) than
8568 at 52°C (126°F). Studies also suggest that temperatures that preclude the growth of *C. perfringens* also
8569 preclude the growth of *B. cereus*.

8570 CDC estimates that approximately 250,000 foodborne illness cases can be attributed to *C. perfringens*
8571 and *B. cereus* each year in the United States. These spore-forming pathogens have been implicated in
8572 foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that
8573 preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an
8574 important public health intervention.

8575 Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food
8576 Protection meeting, FDA believes that maintaining food at a temperature of 57°C (135°F) or greater
8577 during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure
8578 in the prevention of foodborne illness.

8580 **3-502—Cooking Potentially Hazardous Foods**

8581
8582 Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include
8583 the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the
8584 food's bulk, which affects the time to achieve the needed internal product temperature. Other factors to be
8585 considered include post-cooking heat rise and the time the food must be held at a specified internal
8586 temperature.

8587
8588 Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal
8589 foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these
8590 products.

8591
8592 To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a
8593 scheduled process in which each of a series of continuous time/temperature combinations can be equally
8594 effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has
8595 reached 54.4°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has
8596 reached 62.8°C (145°F). The microbial lethality using these criteria will provide a 6.5-log₁₀ reduction of
8597 Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of
8598 each piece of meat for a least the stated time. The source of the time and temperature parameters is from
8599 the USDA/FSIS [Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For
8600 Certain Meat And Poultry Products](#)²⁹.

8601
8602 Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a
8603 microorganism is determined by its ability to survive heat. Different species of microorganisms have
8604 different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of
8605 bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same
8606 organism's survival form (the bacterial spore, protozoan cyst, or worm egg).
8607
8608 Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods
8609 at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the
8610 cooking vessel and the moisture content of food aid thermal destruction.

8611
8612 Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a
8613 layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food,
8614 cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

8615
8616 The temperature and time combination criteria specified in Part 3-5 of this Regulation are based on the
8617 destruction of *Salmonellae*. This Part includes temperature and time parameters that provide "D" values
8618 (decimal log reduction values) that may surpass 7D. For example, at 63°C (145°F), a time span of 15
8619 seconds will provide a 3D reduction of *Salmonella Enteritidis* in eggs. This organism, if present in raw
8620 shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats
8621 including commercially raised game animal meat, specified as acceptable for cooking at this temperature
8622 and time parameter are expected to have a low level of internal contamination. The parameters are
8623 expected to provide destruction of the surface contaminants on these foods.

8624
8625 **Slow-cooked roasts – Heating Deviations and Slow Come Up Time**

8626 (Source: USDA/FSIS [Appendix A Compliance Guidelines For Meeting Lethality Performance Standards](#)
8627 [For Certain Meat And Poultry Products](#)³⁰)

8628 Heating deviations, which most often involve slow come up time or an inordinate dwell time within the
8629 optimum temperature range for microorganism growth can foster the multiplication of many pathogens.
8630 This multiplication sometimes can be so prodigious that even additional cooking may be ineffective in
8631 rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of
8632 these toxins, such as those of **STAPHYLOCOCCUS AUREUS**, are extremely heat stable and are not
8633 inactivated by normal cooking temperatures.

8634 Further, the sampling of product following a heating deviation may not yield sufficient information to
8635 determine the safety of the product in question. Heating deviations can favor the multiplication of many
8636 types of bacteria. It would be difficult and expensive to sample for all of them. Depending on the
8637 circumstances, establishments may want to use computer modeling to estimate the relative multiplication
8638 of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an
8639 oven in which the temperature was inadvertently set to 35°C (95°F) for about 12 hours. Computer
8640 modeling was easily applied in this case because much of the dwell time was at one temperature. The
8641 USDA/FSIS determined that within a 6-hour time frame (with other growth conditions assumed to be
8642 favorable), the relative multiplication of many pathogens of concern could have exceeded 5 logs. Clearly
8643 the product could not be salvaged by reprocessing and was therefore destroyed. Under changing
8644 conditions of temperature, however, computer modeling becomes more difficult. One approach is to
8645 average lag/log times over small increments such as 5° and add these times to get an approximation of
8646 possible total relative growth over a larger increment of time. Establishments must keep in mind that the
8647 population of bacteria before processing is generally unknown and that assumptions in the high range
8648 often are used as input parameters in the modeling.
8649

8650 Seared Steak

8651

8652 The provision for allowing seared steaks was reviewed by the National Advisory Committee for
8653 Microbiological Criteria for Foods (NACMCF) and USDA.

8654

8655 USDA comments included, "For the purposes of this discussion, steak is a whole beef muscle. It does not
8656 include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross
8657 grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or
8658 Chateaubriand. Other species, such as poultry, pork and lamb, are not included."

8659

8660 NACMCF comments included, "Due to the low probability of pathogenic organisms being present in or
8661 migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be
8662 safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In
8663 addition, the cut (exposed) surfaces must receive additional heat to affect a complete sear across the cut
8664 surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared
8665 on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts
8666 a temperature at the surface of the intact steak of at least 62.8°C (145°F) to achieve a cooked color change
8667 on all external surfaces. The searing of all surfaces should be continuous until the desired degree of
8668 doneness and appearance are attained. This is considered a ready-to-eat food."

8669

8670 As reflected in the definition of "whole muscle, intact beef steak," marinating is a food safety concern
8671 when the fascia (exterior surface) of the steak is broken by scoring or other means, which allows the
8672 marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Regulation
8673 allowance for undercooking without a consumer advisory is negated.

8674

8675 Pork

8676

8677 In pork, *Trichinella spiralis*, *Toxoplasma gondii*, and *Taenia solium*, parasites causing foodborne illness,
8678 are inactivated at temperatures below 62.8°C (145°F). Therefore, pork roasts can be cooked like beef
8679 roasts (e.g., 62.8°C (145°F) for 3 minutes) and pork chops cooked like steaks to achieve an internal
8680 temperature of 62.8°C (145°F) for 15 seconds.

8681

8682 Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for
8683 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals
8684 commercially raised for food, and game animals that come under a USDA voluntary inspection program.
8685 Ratites such as ostrich, emu, and rhea are included in this list of raw animal foods because when cooked
8686 to a temperature greater than 68°C (155°F), ratites exhibit a (metallic) "off" taste.

8687

8688 When USDA established the time and temperature parameters, the Agency based the 5D for Salmonella
8689 on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a
8690 "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear
8691 relationship between the patty rule and roast beef time and temperature parameters. The patty rule also
8692 provided for an 8D reduction in the number of Shiga toxin-producing *Escherichia coli*. The time and
8693 temperature requirements in the Regulation for comminuted meats are comparable to the USDA
8694 requirements.

8695

8696 Temperature for Comminuted Meat at Less Than 1 Second

8697

8698 In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee for
8699 Microbiological Criteria for Foods' (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated
8700 on page 7, in Option (A), that:

8701 ~~"Based on the 1998 research data ... and an assumption that instantaneous is defined as~~
8702 ~~eight seconds, manufacturers would be required to process fully cooked meat patties at a~~
8703 ~~temperature of 69°C (157°F). Given the lack of any significant margin of safety in this~~
8704 ~~process, there should be no deviation below the 70°C (158°F) requirement."~~

8705
8706 In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures
8707 for cooking hamburger and advised FDA that cooking hamburger to 70°C (158°F) for less than one
8708 second is an adequate cook based on the following:

- 8709
- 8710 1. ~~_____ The cooking recommendations contained in the Regulation and in USDA guidance~~
8711 ~~provide a large margin of safety for killing vegetable enteric pathogens;~~
 - 8712 2. ~~_____ The concept of integrated lethality (the kill imparted during the entire heating and cooling~~
8713 ~~process) adds to the margin of safety; and~~
 - 8714 3. ~~_____ The time component of the time and temperature requirement will be exceeded before the~~
8715 ~~temperature can be determined.~~

8716
8717 The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C (165°F)
8718 or above for 15 seconds yield greater than a 7D reduction.

8719
8720 **Microwave Cooking**

8721
8722 The rapid increase in food temperature resulting from microwave heating does not provide the same
8723 cumulative time and temperature relationship necessary for the destruction of microorganisms as do
8724 conventional cooking methods. In order to achieve comparable lethality, the food must attain a
8725 temperature of 74°C (165°F) in all parts of the food. Since cold spots may exist in food cooking in a
8726 microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed
8727 from the oven and then allow the food to stand covered for two minutes post microwave heating to allow
8728 thermal equalization and exposure. Although some microwave ovens are designed and engineered to
8729 deliver energy more evenly to the food than others, the important factor is to measure and ensure that the
8730 final temperature reaches 74°C (165°F) throughout the food.

8731
8732 "The factors that influence microwave thermal processes include many of the same factors that are
8733 important in conventional processes (mass of objects, shape of objects, specific heat and thermal
8734 conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of
8735 the electric field involved in causing molecular friction. These factors are exemplified by moisture and
8736 salt contents of foods, which play a far more important role in microwave than conventional heating."
8737 (Reference: Heddelson and Doores)

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8741 **Plant Food Cooking for Hot Holding**

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8743 Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be
8744 cooked to the temperature required for hot holding. These foods do not require the same level of
8745 microorganism destruction as do raw animal foods since these fruits and vegetables are ready to eat at
8746 any temperature. Cooking to the hot holding temperature of 60°C (135°F) prevents the growth of
8747 pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced
8748 over time at the specified hot holding temperature.

8749

8750 **3-503—Non-Continuous Cooking of Raw Animal Foods**

8751 Close attention must be paid to control of biological hazards when a food establishment cooks raw animal
8752 foods using a process in which the food is partially cooked then cooled with the expectation of fully
8753 cooking the food at a later date or time. Section 3-503 requires that establishments wishing to use a non-
8754 continuous process for the cooking of raw animal foods establish and follow a written plan that ensures
8755 each stage of the process is completed within time and temperature parameters that adequately prevent
8756 pathogen survival and growth. Section 3-503 also requires that establishments take special precautions to
8757 ensure that raw animal foods that have only been initially heated to temperatures that are not lethal to the
8758 pathogens of concern are clearly identified so that they will not be inadvertently sold or served to the
8759 consumer in a partially cooked state.

8760 To ensure the food does not dwell for extended periods within temperature ranges that favor pathogen
8761 growth, Section 3-503 establishes limits on the time permitted to initially heat the food (initial "come-up"
8762 time) and the time permitted to cool the product to temperatures that are safe for refrigerated storage.
8763 Together, these limits should prevent food from remaining at temperatures at which pathogen growth to
8764 harmful levels may occur.

8765 The criteria in Section 3-503 were developed with consideration of the United States Department of
8766 Agriculture/Food Safety and Inspection Service (USDA/FSIS) PERFORMANCE STANDARDS FOR
8767 PARTIALLY COOKED AND CHAR-MARKED MEAT PATTIES AND PARTIALLY COOKED
8768 POULTRY BREAKFAST STRIPS found in [9 CFR 318.23](#)³¹ and [9 CFR 381.150](#)³².

8769 The maximum one-hour time limit for the initial heating stage was established based on estimates from
8770 predictive microbial modeling. It is intended to limit the cumulative growth of **CLOSTRIDIUM**
8771 **PERFRINGENS** that may occur during the come-up time and the subsequent cooling of the product.
8772 Unless properly controlled, processes in which animal foods are heated to sub-lethal temperatures and
8773 times and then cooled may create an environment for the growth of **CLOSTRIDIUM PERFRINGENS**,
8774 **CLOSTRIDIUM BOTULINUM** and other spore-forming, toxigenic bacteria.

8775 The product temperature achieved during the initial heating process may not be sufficient to destroy
8776 vegetative cells of **CLOSTRIDIUM BOTULINUM**, **CLOSTRIDIUM PERFRINGENS**, and
8777 **BACILLUS CEREUS**, if present. The concern is the generation of a large number of vegetative cells of
8778 **CLOSTRIDIUM PERFRINGENS** and/or **CLOSTRIDIUM BOTULINUM** before the final cooking
8779 stage. For **CLOSTRIDIUM BOTULINUM**, if enough vegetative cells are produced, toxigenesis can
8780 occur in the product before the product is fully cooked. The toxin is not destroyed at the minimum
8781 required cooking temperatures. For **CLOSTRIDIUM PERFRINGENS**, if a large number of vegetative
8782 cells are consumed, illness can result. In either case a high number of vegetative cells may challenge the
8783 lethality step of the ultimate cooking process to the extent that it will be unable to completely eliminate all
8784 of these vegetative cells. The cumulative growth of these bacterial pathogens must be taken into account
8785 during both the initial heating and cooling steps. The hazard may be compounded with an extended initial

8786 "come up" time and/or a prolonged cooling stage. Hence the degree of hazard may be dependent upon the
8787 ultimate effect of the initial heating and cooling, as well as the final cooking step.

8788 A full and adequate cook during the final cooking step is of critical importance to ensure destruction of
8789 any pathogens that may have survived and proliferated during any initial heating and cooling stages of the
8790 non-continuous cooking process. Section 3-503 requires that animal foods cooked by a non-continuous
8791 cooking process achieve a minimum final cook temperature that heats all parts of the food to a
8792 temperature of at least 74°C (165°F) for 15 seconds to ensure the destruction of vegetative microbial
8793 pathogens, no matter the size of the product. This provides for an additional safeguard beyond the
8794 minimum cooking temperature required for many types of animal foods that are cooked using a
8795 continuous, uninterrupted process. This requirement also precludes serving animal foods that have
8796 undergone non-continuous cooking in an undercooked or raw state. In other words, animal foods cooked
8797 using a non-continuous process are not covered in the exceptions provided for in Section 3-503 that allow
8798 for serving undercooked animal foods upon consumer request and with an adequate consumer advisory.

8799 Section 3-503 requires that an establishment using non-continuous cooking processes also establish
8800 procedures for identifying foods that have only been partially cooked and cooled. This is necessary to
8801 ensure these foods are not mistaken by food workers for foods that have been fully cooked and therefore
8802 ready to eat without a full cook. Partially cooked foods may appear to be fully cooked.

8803 Requiring that food establishments obtain prior approval by the regulatory authority before employing
8804 non-continuous cooking processes will help to ensure that the establishment has the proper procedures in
8805 place, as well as the necessary facilities and capacity to monitor the appropriate cooling, cooking,
8806 separation and product identification of the foods.

8807 8808 **3-504—Reheating**

8809
8810 When food is held, cooled, and reheated in a food establishment, there is an increased risk from
8811 contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper
8812 temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper
8813 reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective
8814 in reducing the numbers of *Clostridium perfringens* that may grow in meat, poultry, or gravy if these
8815 products were improperly cooled. Vegetative cells of *C. perfringens* can cause foodborne illness when
8816 they grow to high numbers. Highly resistant *C. perfringens* spores will survive cooking and hot holding.
8817 If food is abused by being held at improper holding temperatures or improperly cooled, spores can
8818 germinate to become rapidly multiplying vegetative cells.

8819
8820 Although proper reheating will kill most organisms of concern, some toxins such as that produced by
8821 *Staphylococcus aureus*, cannot be inactivated through reheating of the food. It is imperative that food
8822 contamination be minimized to avoid this risk.

8823
8824 The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods.
8825 This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product,
8826 are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition
8827 if temperature abuse occurs.

8828
8829 Refer also to the public health reason for Section 3-502.

8830 8831 **3-505—Preparation for Immediate Service**

8832 8833 **3-6—Limitation of Growth of Organisms of Public Health Concern**

8834

8835 **3-601—Thawing**

8836

8837 Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper
8838 thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce
8839 toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are
8840 preserved.

8841

8842 **3-602—Slacking**

8843

8844 Refer to the public health reason for Section 3-601.

8845

8846 **3-603—Cooling**

8847

8848 Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive
8849 time for cooling of potentially hazardous foods has been consistently identified as one of the leading
8850 contributing factors to foodborne illness. During slow cooling, potentially hazardous foods are subject to
8851 the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation
8852 temperatures, 21°C–52°C (70°F–126°F), is to be avoided. If the food is not cooled in accordance with
8853 this Regulation requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

8854 The Regulation provision for cooling provides for cooling from 57°C (135°F) to 5°C (41°F) or 7.2°C
8855 (45°F) in 6 hours, with cooling from 57°C (135°F) to 21°C (70°F) in 2 hours. The 6-hour cooling
8856 parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Regulation. The
8857 initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might
8858 involve cooling from 57°C (135°F) to 21°C (70°F) in 1 hour, in which case 5 hours remain for cooling
8859 from 21°C (70°F) to 5°C (41°F) or 7.2°C (45°F). Conversely, if cooling from 57°C (135°F) to 5°C
8860 (41°F) or 7.2°C (45°F) is achieved in 6 hours, but the initial cooling to 21°C (70°F) took 3 hours, the food
8861 safety hazards may not be adequately controlled.

8862 If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming
8863 organisms such as *Clostridium perfringens* or *Bacillus cereus* should be killed or inactivated. However,
8864 under substandard sanitary conditions, other pathogens such as *Salmonella* or *Listeria monocytogenes*
8865 may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that
8866 may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions.

8867

8868 **CFSAN/FSIS Joint Position Paper on Cooling**

8869

8870 The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate
8871 pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of
8872 *Clostridium botulinum* and *Clostridium perfringens* and other spore-forming bacteria. Furthermore,
8873 these organisms can thrive in the warm product since other competing organisms have been eliminated.
8874 Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

8875

8876 To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly
8877 after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells
8878 can multiply to hazardous levels. The presence of sufficient numbers of *C. botulinum* or other spore-
8879 forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these
8880 organisms will provide the greatest amount of safety.

8881 The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require
8882 a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of
8883 *C. botulinum* and no more than 1 log growth of *C. perfringens*. The performance standard of no more
8884 than 1 log growth of *C. perfringens* was based on the following reasons:

- 8885 1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of 10^5 or greater
8886 of *C. perfringens* per gram as one of the criteria for incriminating *C. perfringens* as a causative
8887 agent of foodborne illness in finished product. However, foods responsible for *C. perfringens*
8888 outbreaks were found usually to contain 10^6 vegetative *C. perfringens* cells per gram. In FSIS
8889 microbiological raw product surveys, samples were found to contain more than 1000 *C.*
8890 *perfringens* per gram. There is some probability that greater than 10^4 *C. perfringens* per gram
8891 can occur in the raw product on rare occasions. It is a conservative assumption that the great
8892 majority of *C. perfringens* in the raw product are spores.
- 8893 2. Heating activates spores that, during cooling, become vegetative cells that can multiply to
8894 hazardous levels. If there are more than 10^4 *C. perfringens* (spores) per gram on raw product, it is
8895 possible that there may be more than 10^4 vegetative *C. perfringens* per gram in the product if it is
8896 improperly cooled after cooking.
- 8897 3. Based on the CDC recommended upper limit of 10^5 which should not be exceeded, it was
8898 determined that a limit of no more than 1 \log_{10} growth of *C. perfringens* would be appropriate to
8899 ensure that there would be no more than 10^5 *C. perfringens* per gram on the finished product after
8900 cooling.
- 8901 4. The performance standard was discussed with experts on clostridia research. The experts agreed
8902 that limiting the relative growth of *C. perfringens* to no more than 1 \log_{10} would be reasonable
8903 and somewhat conservative with respect to product safety. (Federal Register 64: (3): 732-749)
- 8904 The FSIS compliance guideline for the cooling performance standards, which can be found at
8905 <http://www.fsis.usda.gov/OA/fr/95033F-b.htm>, is that product must be cooled from 54.5°C (130°F) to
8906 27°C (80°F) in 1.5 hours and from 27°C (80°F) to 4.4°C (40°F) in 5 hours. This cooling rate can be
8907 applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and
8908 poultry products. The guideline results in continuous and rapid cooling of the product in the temperature
8909 range where the spore-forming organisms can grow rapidly.
- 8910
8911 The former USDA guideline of cooling from 49°C (120°F) to 12.8°C (55°F) in no more than 6 hours is
8912 also included in the new compliance guidelines. In using this guideline, chilling should begin within 90
8913 minutes after the cooking cycle is completed, and cooling should continue until product reaches 4.4°C
8914 (40°F). The 6 hour rule begins when the product reaches 49°C (120°F), and product should not be
8915 shipped until the product reaches 4.4°C (40°F). This older cooling guideline results in a significantly
8916 smaller margin of safety, especially if the product is non-intact. In using this older guideline, the
8917 establishment has to ensure that cooling is as rapid as possible, especially between 49°C (120°F) and
8918 27°C (80°F), and should monitor the cooling closely to prevent any deviation. If product remains between
8919 these temperatures for more than an hour, compliance with the performance standard is less certain.
- 8920
8921 The FSIS cooling guideline for meat and poultry products containing 100 ppm added nitrite is
8922 54.4°C (130°F) to 27°C (80°F) in 5 hours and from 27°C (80°F) to 7.2°C (45°F) in 10 hours, a total of 15
8923 hours cooling time. This cooling process provides a narrow margin of safety. In case of cooling
8924 deviations, the establishment should assume that their process has exceeded the performance standard for
8925 controlling the growth of *C. perfringens*, and should take corrective action. However, the presence of
8926 nitrite should ensure compliance with the performance standard for *C. botulinum*.
- 8927
8928 The Regulation provision for cooling is similar, though not identical to the FSIS cooling compliance
8929 guidelines. It provides for cooling from 60°C (135°F) to 21°C (70°F) in 2 hours and from 60°C (135°F)
8930 to 5°C (41°F) in 6 hours and is based on the same food safety concerns as FSIS' guidance. The Regulation
8931 provides prescriptive cooling time/temperature combinations without a HACCP plan in place. Federally
8932 inspected meat and poultry establishments are required to implement a HACCP plan for their operations.

8933
8934 The Conference for Food Protection (CFP) at its 2000 meeting recommended that FSIS and FDA ask the
8935 National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the data on
8936 safe cooling times for cooked, potentially hazardous foods. The review would include data from a study,
8937 submitted to the CFP, showing that cooling of a meat product from 54.4°C (130°F) to 7.2°C (45°F) can
8938 safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the
8939 study, continuous cooling of a meat product from 54.4 °C (130°F) to 7.2°C (45°F) in 15 hours permitted
8940 about 1 log growth of *C. perfringens*.

8941
8942 In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data
8943 referenced in the CFP recommendation do not support a change in the FSIS guidance or the Regulation §
8944 3-503 and considered it inadvisable to ask the NACMCF to undertake the task requested for several
8945 reasons:

- 8946 1. The study did not address growth of *C. botulinum*.
- 8947 2. The results are from a carefully controlled laboratory study in which cooling of the product was
8948 steady and continuous, conditions difficult to maintain in most commercial processing or retail
8949 environments even with data loggers and other control mechanisms in place.
- 8950 3. The study was done only on ground beef and may not be applicable to other meat and poultry or
8951 to other potentially hazardous foods.

8952 As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position
8953 paper to clarify their joint position on the cooling issues.

8954

8955 **Shell Eggs**

8956

8957 FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not
8958 found the ionizing radiation process to be unsafe for shell eggs. However, shell eggs that have been
8959 subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell
8960 egg pasteurization requires the egg to have been subjected to a 5 log kill process for *Salmonella*
8961 *Enteritidis*, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction.
8962 Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot
8963 be guaranteed that *Salmonella Enteritidis* will be eliminated in all treated eggs. Further, irradiated eggs
8964 must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

8965

8966 Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a potentially
8967 hazardous food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be
8968 a potentially hazardous food after cooling because pathogens, which may be present in the water, may
8969 pass through the egg shell during cooling.

8970

8971 *Salmonella Enteritidis* has been shown to have an extended lag phase in shell eggs due to inhibitory
8972 characteristics of the albumen. Research indicates that the organisms are physically located near the
8973 exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear
8974 until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron,
8975 become available to the organisms.

8976 Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under
8977 refrigeration at an ambient temperature not to exceed 7.2°C (45°F). Packed shell eggs must be labeled
8978 indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to
8979 include a certification that the eggs, at all times after packing, have been stored and transported at an
8980 ambient temperature of no greater than 7.2°C (45°F).

8981 On December 5, 2000 federal regulations were amended to require that shell egg cartons bear safe
8982 handling instructions and be placed under refrigeration at 7.2°C (45°F) or lower upon delivery at retail
8983 establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of
8984 Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

8985 • 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5
8986 Inapplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or
8987 destruction of shell eggs...

8988 • 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling
8989 statements, (h) *Shell eggs*.

8990 • 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

8991 Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of
8992 maintaining an ambient air temperature of 7.2°C (45°F). With the newly established federal requirement
8993 for eggs to be in an ambient storage and transportation temperature of 7.2°C (45°F), and with
8994 refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that
8995 allow the growth of *Salmonella* spp. should be shortened. Additionally, this requirement negates the need
8996 to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation
8997 of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

8998 **3-604—Cooling Methods**

9000 Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool
9001 because of the mass and volume from which heat must be removed. By reducing the volume of the food
9002 in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen
9003 growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e.,
9004 the time required for cooling and the time the food is exposed to optimal temperatures for bacterial
9005 multiplication or toxin production are increased.

9006 Alternatives to conventional methods include avoiding the need to cool larger masses by preparing
9007 smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice
9008 water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool
9009 large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures
9010 quickly by using very low temperatures and high rates of air circulation.

9011 **3-605—Time as a Public Health Control**

9012 The 2000 Conference for Food Protection (CFP) recommended that FDA ask the National Advisory
9013 Committee on Microbiological Criteria for Foods (NACMCF) to review the Regulation provision that
9014 addresses using time alone as a public health control. In response to the CFP recommendation, FDA, in
9015 consultation with USDA/FSIS, determined that there is sufficient scientific information available to
9016 support the current provision in the Regulation without requesting consideration by the NACMCF. As an
9017 alternative response, FDA informed CFP that it would provide the following position paper on using time
9018 alone as a public health control.

9019 **Position Paper**

9020 The Rules and Regulations allows potentially hazardous food (PHF) that is ready to eat (RTE) to be
9021 stored without temperature control for up to 4 hours, after which it must be discarded or consumed. The
9022 following information is provided to explain the reasoning in allowing time alone to be used as a public
9023 health control for food safety.

9029

9030 Background information:

9031

9032 Food kept without temperature control allows product to warm or cool as it equilibrates with the
9033 environment. Each temperature scenario incurs different risks in regard to the type of foodborne
9034 pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions,
9035 growth depends on the amount of time the food spends in an optimum growth temperature range during
9036 its equilibration with its surroundings. Several factors influence the rate of temperature change in a food,
9037 such as the type of food, thickness of the food, and temperature differential between the food and its
9038 surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products
9039 and environmental parameters must be selected to create a worst-case scenario for pathogens growth and
9040 possible toxin production.

9041

9042 Holding Cold Food with Temperature Control

9043

9044 When a food is removed from refrigerated storage and begins to warm to room temperature, *Listeria*
9045 *monocytogenes* is a primary organism of concern. Even while food is held at refrigeration temperatures,
9046 the growth potential of *L. monocytogenes* warrants concern for potentially hazardous RTE foods.

9047 Although the FDA and USDA have a zero tolerance for

9048 *L. monocytogenes* in RTE food, conditions are permitted in the Regulation that would allow *L.*

9049 *monocytogenes* cells 1 log of growth (3.3 generations). *Salmonella* is also a concern especially with

9050 products containing eggs. However *L. monocytogenes* grows more rapidly than *Salmonella* at

9051 refrigeration and room temperatures. By ensuring minimal *Listeria* growth in food, the threat from

9052 *Salmonella* would be negligible. Warming conditions will allow food to remain exposed to temperatures

9053 that allow *B. cereus* to produce emetic toxin. However the 4-hour time constraint in the Regulation is

9054 sufficient to prevent any toxin formation.

9055

9056 For food refrigerated at 5°C (41°F) or 7.2°C (45°F) then transferred to an ambient temperature of 23.9°C

9057 (75°F) for 4 hours, the growth rate of *L. monocytogenes* remains slow enough to ensure that the critical

9058 limit of 1 log growth is not reached. Published generation times at 23.9°C (75°F) for *L. monocytogenes* in

9059 food were not found, however published values at 20°C (68°F) and 21°C (70°F) in egg and milk products

9060 confirmed slow *L. monocytogenes* growth at room temperatures.

9061

9062 Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8,

9063 0.5% NaCl, 0.0% nitrite, *L. monocytogenes* would require more than 4 hours to grow 1 log at 23.9°C

9064 (75°F). The PMP is based on broth studies and not on food products. Therefore, the growth rates reported

9065 at various temperatures by the PMP are faster than growth rates in most food products. Another factor

9066 exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the

9067 food product spent all 4 hours at 23.9°C (75°F). Obviously food equilibrates with the surrounding

9068 environment at a gradual rate and would not equilibrate instantly.

9069

9070 Unfortunately there are no models that take changing temperatures into consideration when predicting

9071 growth. Likewise there are very few published papers dealing with the growth of organisms in food

9072 during warming. The conservative nature of the 4-hour limit for keeping foods without temperature

9073 control allows for a needed margin of safety if the temperature of the environment is higher than 23.9°C

9074 (75°F).

9075

9076 Holding Hot Food without Temperature Control

9077

9078 The second scenario for food without temperature control exists when food is cooked according to

9079 Regulation recommendations, then kept at room temperature for 4 hours before discarding. Foodborne

9080 pathogens of concern for an uncontrolled temperature scenario are sporeformers including *Clostridium*
9081 *perfringens* and *Bacillus cereus*. Food cooked according to Regulation guidelines should be free of
9082 vegetative cells. However, the heat requirements are not sufficient to kill spores of *C. perfringens* or *B.*
9083 *cereus* and may actually serve as a heat shock that activates the spores. *B. cereus* is found commonly in
9084 outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a
9085 multitude of food products. *C. perfringens* is found commonly in outbreaks attributed to inadequate hot
9086 holding of beef and poultry. Despite the prevalence of both spores in nature, *C. perfringens* cases are
9087 estimated to be more numerous than *B. cereus* cases by a factor of 10.

9088
9089 *B. cereus* can produce emetic toxin in food, and the optimum temperature for the production of toxin is
9090 between 25°C (77°F) and 30°C (86°F). However, the time needed to produce the toxin is longer than the
9091 time the food will be exposed to any temperature range with a 4-hour holding limit. Both *C. perfringens*
9092 and *B. cereus* produce enterotoxin inside the intestine of the infected host if substantial numbers of
9093 vegetative cells are present in the food (10⁵⁻⁷ CFU/g). Although the reported levels of both spores in raw
9094 foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-
9095 1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in
9096 food.

9097
9098 During the time without temperature control, the temperature of the food could decrease slowly enough to
9099 expose spores of both organisms to optimal growth conditions for a significant length of time. Like
9100 warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of
9101 foods prepared it would be impossible to generalize how fast a typical product loses temperature after
9102 cooking. As with warming, it is prudent to imagine a worst case scenario where heat loss is slowed. A
9103 beef roast slow cooked to 54.4°C (130°F) for the appropriate time according to the Regulation was used
9104 as consideration for possible spore growth. Cooking roast beef to 54.4°C (130°F) can create an anaerobic
9105 environment in both the meat and gravy. The low internal temperature creates a small temperature
9106 differential with the environment (assumed at 23.9°C (75°F)), allowing for a slower decrease in the food's
9107 temperature.

9108
9109 After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or
9110 rolled meat product would lose heat quickly enough to discourage significant growth of either *C.*
9111 *perfringens* or *B. cereus*. If all spores were distributed on the surface of the product by either pre- or
9112 post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe.
9113 Likewise, products that are stirred or products that lose heat faster than a roast would also be considered
9114 safe.

9115
9116 ----- **End of position paper** -----

9117

9118 At the 2004 meeting of the CFP, a committee submitted and the Conference accepted a document that
9119 examined scientific research related to the growth of **LISTERIA MONOCYTOGENES**, and the
9120 influence of time and temperature on its growth.

9121 The 2004 CFP report stated that the USDA PMP program can be used as a tool to estimate time periods
9122 for a 1-log increase in growth for **LISTERIA MONOCYTOGENES** in ideal (laboratory media) growth
9123 conditions. Using this modeling approach, at 5°C (41°F), 7.2°C (45°F), and 10°C (50°F), the time for a 1-
9124 log increase was, 87.8, 53.9, and 34.7 hours, respectively. At room temperature (21°C (70°F)) a 1-log
9125 increase was noted at 5.2 hours and at ideal growth temperatures (35°C (95°F)), the reported time for a 1-
9126 log increase was 3.0 hours. In general, the data from the USDA PMP program provides very conservative
9127 growth data and, in most cases, growth would be expected to be less rapid in a food system. This table

9128 does provide comparative information relative to growth rates at different holding temperatures in the
9129 event that time was used as a factor in managing food safety.

9130 The report further recommended that food could safely be held for up to 6 hours without external
9131 temperature control as long as the food temperature did not exceed 21°C (70°F). Based on that report and
9132 data from the [Quantitative Assessment of the Relative Risk to Public Health from Foodborne LISTERIA
9133 MONOCYTOGENES Among Selected Categories of Ready-to-Eat Foods](#)⁴⁰, September 2003, the Food
9134 Code allows potentially hazardous food (time/temperature control for safety) to be stored up to 6 hours
9135 without external temperature control provided that the food temperature does not exceed 21°C (70°F) and
9136 the food is discarded or consumed at the end of the 6 hours.

9137 **The Safety of the Time as a Public Health Control Provision from Cooking Temperatures (135°F or
9138 above) to Ambient**

9139 FDA conducted in-house laboratory experiments to test the safety of the existing TPHC provisions of 4
9140 hours without temperature control starting with an initial temperature of 60°C (135°F) or above.
9141 *CLOSTRIDIUM PERFRINGENS* was chosen to represent a worst case scenario pathogen for foods
9142 allowed to cool from cooking temperatures to ambient without temperature control because its spores can
9143 survive normal cooking procedures, it can grow at relatively high temperatures (>49°C (120°F)) and it
9144 has a short lag period. *C. PERFRINGENS* spores were inoculated into foods that were cooked and then
9145 cooled to yield a cooling curve that would promote outgrowth as quickly as possible. The growth data
9146 suggest that the existing 4-hour TPHC provision will be safe for 6 hours after cooking, with the additional
9147 2-hour margin of safety built in for consumer handling.

9148 **Consumer Handling Practices**

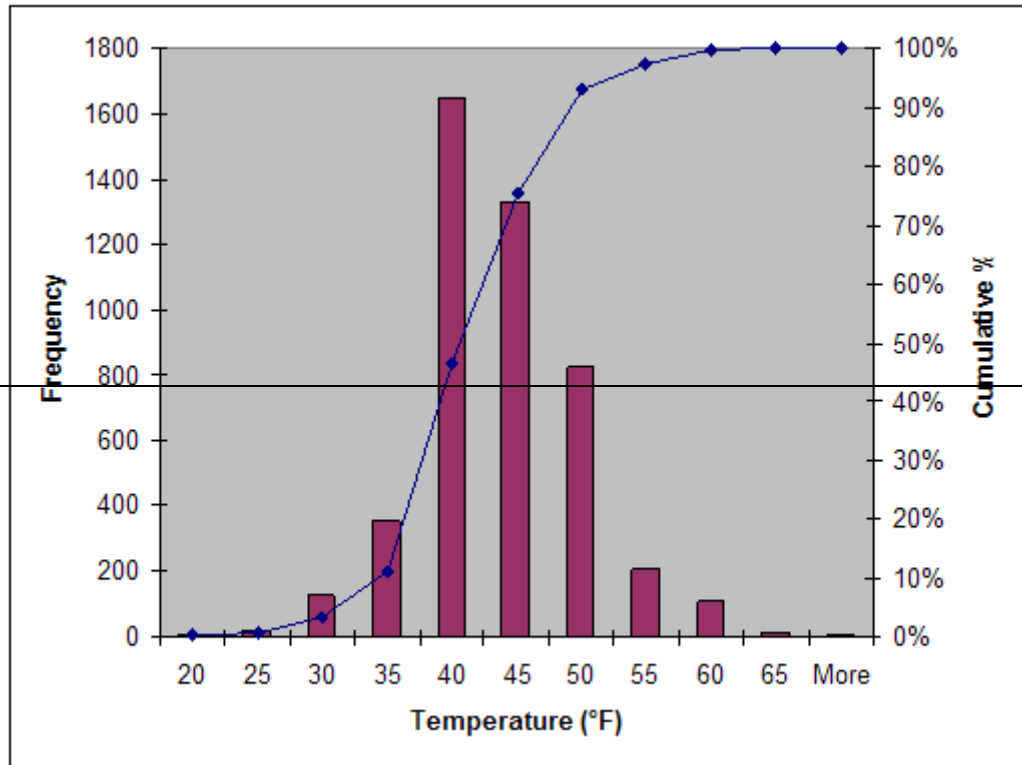
9149 An Audits International study was funded in 1999 by FDA to determine the food handling practices of
9150 consumers purchasing food at retail and returning home to refrigerate their items. Forty-six (46) states are
9151 represented, and the data comprises several food groups purchased from different grocery store types.
9152 The food groups represented were: pre-packaged lunch meat, deli-counter products, seafood, fresh meat,
9153 pre-packaged deli product, liquid dairy, semi-solid dairy product, ice cream, frozen entrées, frozen
9154 novelties and whipped topping.

9155 The study evaluated information regarding time and food temperature at retail food stores, time to reach
9156 home refrigeration, temperature after transport home, location and type of retail establishment where
9157 purchase was made and type of product purchased.

9158 For product temperature at retail and after transportation, 5 product categories were used: pre-packaged
9159 lunch meat, pre-packaged deli product, deli-counter products, seafood and fresh meat. These categories
9160 were considered most applicable to the TPHC recommendations. The temperature ranges for these
9161 products at retail and after transport to the home are summarized in Figures 1 and 2 respectively. The data
9162 suggest that with current retail refrigeration practices, 25% of items are held above 7.2°C (45°F) (Figure
9163 1). The data also show that by the time the product arrives at the home, 98% of products were at 18.3°C
9164 (65°F) or less (Figure 2).

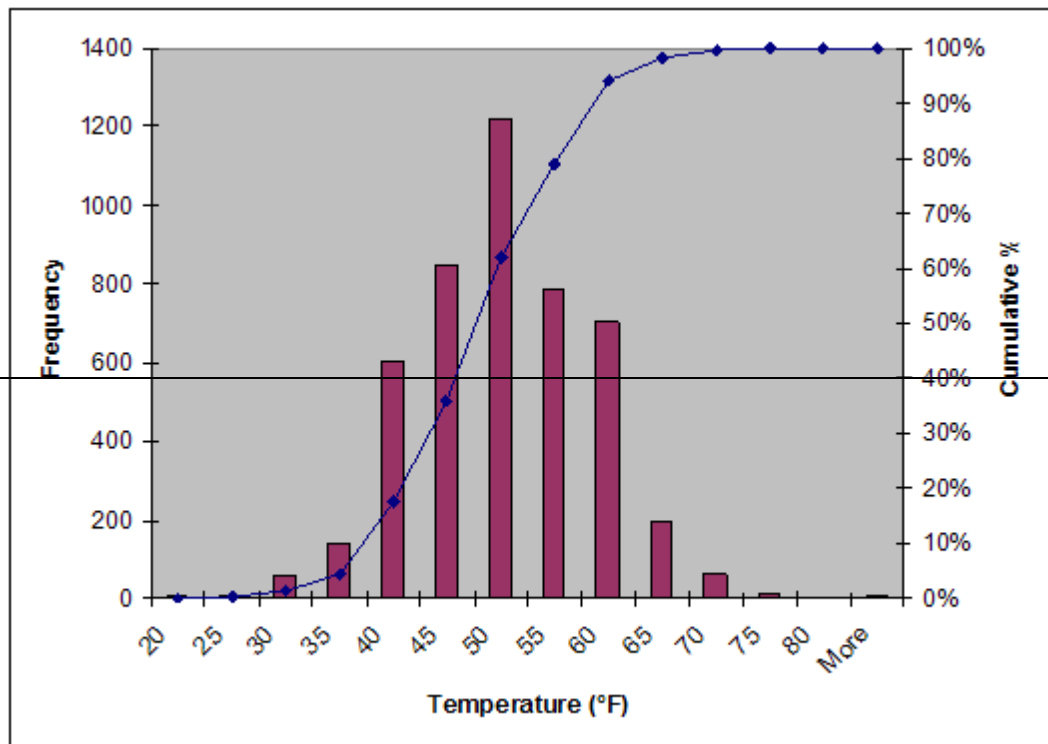
9165 The time of transport for all food categories from the retail establishment to home refrigeration was also
9166 recorded. The data summarized in Figure 3 shows that over 97% of the foods purchased were ready to be
9167 placed in refrigeration within 2 hours of purchase. For this histogram, all food categories except for
9168 frozen entrées were included. Because all foods end up bagged and transported together, the time each
9169 product was transported to the home was considered a valid data point and therefore used. Based on the
9170 data, a benchmark was established that PHF/TCS foods purchased in a food establishment would be
9171 either consumed, or placed under temperature control, within 2 hours.

9172 **Figure 1.** Temperatures of refrigerated products at retail (Audits International)-



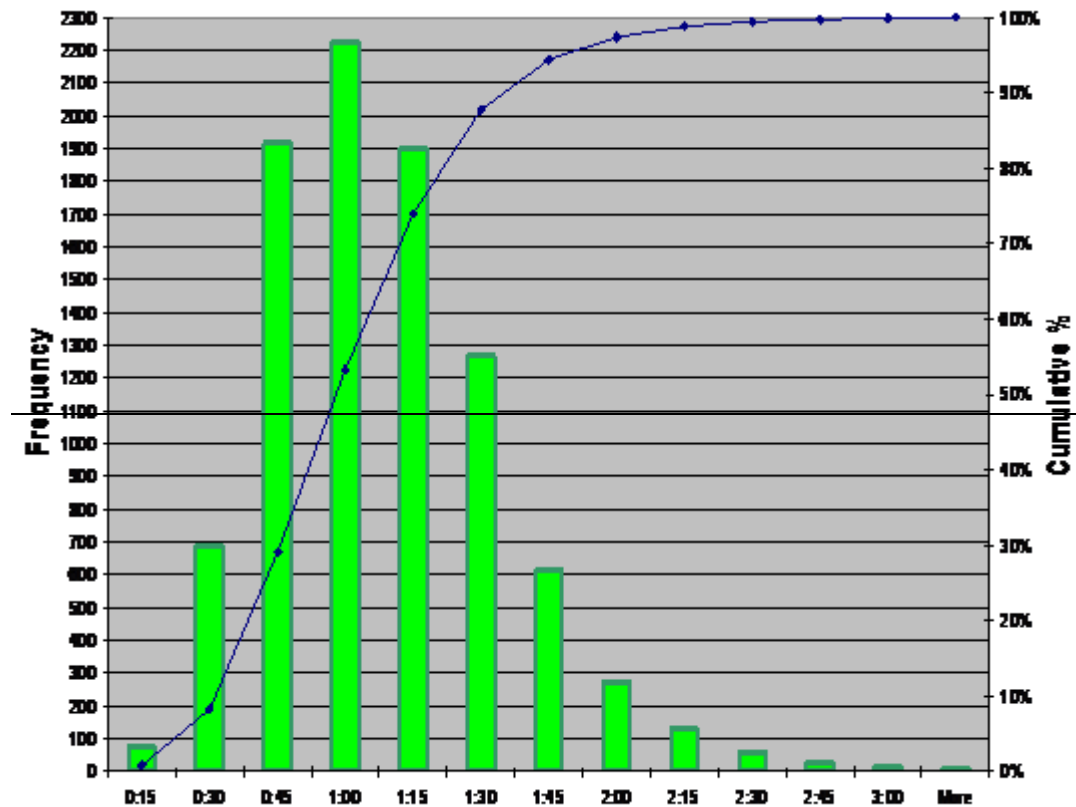
9173

9174 **Figure 2.** Product temperatures after transport to the home (Audits International)-



9175

9176 **Figure 3.** Times reported for transport of grocery items from the retail outlet to the home (Audits
 9177 International).



9178

9179 **The Safety of the Time as a Public Health Control Provision from Refrigeration Temperatures (5°C**
 9180 **(41°F) or less) to Ambient**

9181 As noted above, the current TPHC provision has two time provisions. Food can be kept with no
 9182 temperature stipulations for 4 hours in a food establishment, at which time the food must be cooked and
 9183 served, served if RTE, or discarded within the four hours. However, if food does not exceed 21°C (70°F),
 9184 it may be held for 6 hours and cooked and served, served if RTE or discarded within the six hours. For
 9185 foods warming from refrigeration to ambient temperatures, the data from the Audits International study
 9186 outlined above, along with simulations from the USDA Pathogen Modeling Program (PMP), were used to
 9187 determine the safety of the existing TPHC recommendations.

9188 Assuming pathogen growth in foods going from refrigeration (5°C (41°F) or less) to ambient temperature,
 9189 the following parameters were used for the PMP simulation:

- 9190
- 18.3°C (65°F) was used as the temperature for the entire simulation;
 - 2 hours were added to all times (4h or 6h) allowed in the current TPHC recommendation, to factor in transportation time (per the Audits International study outlined above);
 - The data were generated from PMP broth models (pH 6.8), with the minimal NaCl and no sodium nitrite.

9195

9196

9197 Table 1 summarizes the predicted growth of *BACILLUS CEREUS* (vegetative), *ESCHERICHIA COLI*,
 9198 *LISTERIA MONOCYTOGENES*, *SALMONELLA* spp., *SHIGELLA FLEXNERI*, and
 9199 *STAPHYLOCOCCUS AUREUS*, using the PMP and based on the assumptions discussed above. The
 9200 data predicted that less than 1 log growth would be seen for each organism, during the 8 hour time period.
 9201 Thus, the data show that the current 4 and 6 hour TPHC provisions from 5°C (41°F) or less to ambient,
 9202 allow minimal growth of a number of pathogens of concern.

Table 1. The USDA Pathogen Modeling Program estimation of growth (Log CFU/g) of several pathogens for 6 hours or 8 hours, at 65°F.		
Pathogens	6 Hours	8 hours
B. CEREUS (vegetative cells)	0.62	0.87
E. COLI	0.35	0.52
L. MONOCYTOGENES	0.47	0.71
SALMONELLA SPP.	0.25	0.41
S. FLEXNERI	0.26*	0.34*
S. AUREUS	0.38*	0.51*

9203 * Model predictions were in 5 hour increments, the
 9204 6 and 8 hour data was extrapolated between 5 hour
 9205 and 10 hour predictions.

9206 **References**

9207 U.S. Department of Agriculture. 1997. PATHOGEN MODELING PROGRAM. USDA Agricultural
 9208 Research Service, Wyndmoor, PA.

9209 Food and Drug Administration. 2006. Growth of *CLOSTRIDIUM PERFRINGENS* inoculated into
 9210 beef roasts and meatloaf (unpublished data).

9211 -----End of Summary of Consumer Handling Practices study-----

9212

9213

9214 **Raw eggs**

9215 Recipes in which more than one egg is combined carry an increased risk of illness and possible serious
9216 consequences for certain people. It is due to this increased risk, and documented occurrences of
9217 foodborne illness and death among highly susceptible populations from temperature-abused raw shell
9218 eggs contaminated with *Salmonella Enteritidis*, that the use of time as a public health control in
9219 institutional settings is not allowed.

9220

9221 **3-606—Specialized Processing Methods**

9222 Specialized food processes have historically resulted in more foodborne illness than standard processes.
9223 They present a significant health risk if not conducted under strict operational procedures. These types of
9224 operations may require the person in charge and food employees to use specialized equipment and
9225 demonstrate specific competencies. The requirement for Department approval is designed to ensure that
9226 the proposed method of operation is carried out safely.

9227 **3-607—Reduced Oxygen Packaging**

9228 Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal
9229 environment of the package contains less than the normal ambient oxygen level (typically 21% at sea
9230 level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere
9231 packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food
9232 establishments has the advantage of providing extended shelf life to many foods because it inhibits
9233 spoilage organisms that are typically aerobic.

9234 This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package
9235 (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh
9236 produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial
9237 activity also plays a role here. Packaging materials that readily allow the transmission of oxygen is
9238 usually designated by an Oxygen Transfer Rate of 10,000 cc/m²/24 hours at 24 °C. A reduced oxygen
9239 atmosphere will result with an Oxygen Transmission rate of 10-100. The process of cooking drives off
9240 oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus,
9241 microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen
9242 transmission.

9243 Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or
9244 anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage
9245 temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some
9246 pathogenic microorganisms but non-proteolytic *C. botulinum* and *L. monocytogenes* are able to multiply
9247 well below 5°C (41°F). For this reason, *C. botulinum* and *L. monocytogenes* become the pathogens of
9248 concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

9249 When followed as written, the ROP methods in this section all provide controls for the growth and/or
9250 toxin production of *C. botulinum* and *L. monocytogenes*. Section 3-607 (A) identifies an ROP method
9251 with secondary barriers that will control *C. botulinum* and *L. monocytogenes* when used in conjunction
9252 with a food storage temperature of 5°C (41°F) or less. They include a_w of 0.91 or less; pH of 4.6 or less;
9253 cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high
9254 levels of competing microorganisms. *C. botulinum* will not produce toxin below an a_w of 0.91. Nitrite,
9255 used in meat and poultry curing, inhibits the outgrowth of *C. botulinum* spores. Most foodborne
9256 pathogens do not compete well with other microorganisms, therefore foods that have a high level of

9257 spoilage organisms or lactic acid bacteria can safely be packaged using ROP. Other intrinsic or extrinsic
9258 factors can also control the growth and/or toxin production of *C. botulinum* and *L. monocytogenes*.

9259 Naturally fermented cheeses, as identified in Section 3-607(D), that meet the Standards of Identity for
9260 hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187,
9261 respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary
9262 barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of
9263 factors could include some or all of the following: a lower pH, production of organic acids, and natural
9264 antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low
9265 moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred
9266 that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or
9267 cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient
9268 air temperatures. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago
9269 old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized
9270 process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey,
9271 Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and
9272 Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of *L.*
9273 *monocytogenes* under modified atmosphere conditions.

9274 When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary
9275 barriers such as a_w, pH, nitrite in cured meat products, high levels of competing microorganisms or
9276 intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of
9277 *C. botulinum* and *L. monocytogenes*. Non proteolytic *C. botulinum* spores are able to germinate and
9278 produce toxin at temperatures down to 3°C (38°F). Therefore, to control for toxin production by *C.*
9279 *botulinum*, an anaerobe, ROP foods must be held at 3°C (38°F) or less. *Listeria monocytogenes* is able to
9280 grow, although very slowly, at temperatures down to -1°C (30°F). The lag phase and generation time of
9281 both pathogens becomes shorter as the storage temperature increases. In Section 3-607, cook-chill
9282 processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing
9283 where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only
9284 barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking
9285 to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold
9286 storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential.
9287 Four separate options are provided in Section 3-607. These time-temperature combinations will provide
9288 equivalent food safety protection without need for a variance. The first is cooling the bagged product to
9289 1°C (34°F) and holding for up to 30 days after the product is sealed in the bag. The second is cooling
9290 bagged product to 1°C (34°F), removing product to a different refrigeration unit and holding at any
9291 temperature up to 5°C (41°F) for up to 72 hours with the total storage time not to exceed 30 days. This
9292 situation is often encountered when a central kitchen prepares and stores the bagged product at 1°C
9293 (34°F) then transports it to a satellite kitchen under their control where it can be held at 5°C (41°F) or
9294 less. The third option is cooling to 3°C (38°F) and holding for no more than 72 hours from packaging.
9295 The fourth option can be used without a restricted shelf life while the bagged product is held frozen until
9296 thawed to be consumed or used in another preparation.

9297 Since there are no other controlling factors for *C. botulinum* and *L. monocytogenes* in a cook-chill or
9298 sous vide packaging system, temperature control must be continuously monitored electronically and
9299 visually examined twice daily to verify that refrigeration temperatures are adequate. New technology
9300 makes it relatively easy to continuously and electronically monitor temperatures of refrigeration
9301 equipment used to hold cook-chill and sous vide products at 1°C (34°F) or 3°C (38°F) or less.
9302 Thermocouple data loggers can connect directly with commonly available thermocouple probes.
9303 Recording charts are also commonly used. Temperature monitors and alarm systems will activate an
9304 alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record

9305 temperatures which can be displayed using computer software. Since surveys have shown that
9306 temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide
9307 processing methods cannot be distributed outside the control of the food establishment doing the
9308 packaging.

9309 Time is also a factor that must be considered in ROP. The 14 day "use by" date is required label
9310 information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by"
9311 date. This is considered a safe time period because two barriers to growth are required to be present.
9312 When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life
9313 for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing
9314 recontamination, and then refrigerating at 1°C (34°F) or less with an option of 3°C (38°F) for up to 72
9315 hours after packaging with stringent temperature monitoring and recording requirements. These criteria
9316 allow both institutional sized cook chill operations that may feed thousands daily, often including
9317 transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast
9318 chillers to safely use cook chill and sous vide processes.

9319 The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors
9320 in these cheeses plus the normal refrigeration temperature of 5°C (41°F) or less to maintain safety.

9321 A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing
9322 procedures. *C. botulinum* and *L. monocytogenes* are potential hazards which must be controlled in most
9323 foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified
9324 food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping,
9325 corrective actions, and verification procedures will vary based on the type of food and type of ROP
9326 technology used.

9327 Unfrozen raw fish and other seafood are specifically excluded from ROP because of these products'
9328 natural association with *C. botulinum* type E which grows at or above 3°C (37-38°F). Fish and seafood
9329 that are frozen before, during and after the ROP packaging process are allowed.

9330 **3-608—Breading Mixtures**

9331

9332 **3-7—On-Premises Labeling**

9333

9334 **3-701—Labeling**

9335

9336 Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows
9337 consumers to make informed decisions about what they eat. Many consumers, as a result of an existing
9338 medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in
9339 dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In
9340 addition, consumers have a basic right to be protected from misbranding and fraud.

9341

9342 Certain foods may be difficult to identify after they are removed from their original packaging.

9343 Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the
9344 consumer has specifically requested that it not be used, may result in severe medical consequences.

9345

9346 The mistaken use of food from unlabeled containers could result in chemical poisoning. For example,
9347 foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant
9348 formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble
9349 cleaning compounds are also of particular concern.

9350 The identity of a food in terms of origin and composition is important for instances when a food may be
9351 implicated in a foodborne illness and for nutritional information requirements. Ingredient information is

9352 needed by consumers who have allergies to certain food or ingredients. The appearance of a food should
9353 not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

9354 Recent illnesses and deaths from Shiga toxin-producing *Escherichia coli* have occurred across the United
9355 States as a result of people eating hamburgers that were contaminated and then undercooked. USDA
9356 issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe handling label
9357 or sticker or be accompanied by a leaflet that contains information on proper handling and cooking
9358 procedures.

9359 Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997.
9360 The following attempts to provide guidance regarding those requirements and exemptions as they relate to
9361 the retail environment and to alert regulators to authority that has been given to them by the Nutrition
9362 Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a
9363 comprehensive understanding of the labeling requirements.

9364 I.—The following foods need not comply with nutrition labeling in the CFR if they do not bear a
9365 nutrient claim, health claim, or other nutrition information:

9366 (A)—Foods packaged in a food establishment if:

9367 (1)—The food establishment has total annual sales to consumers of no more than
9368 \$500,000 (or no more than \$50,000 in food sales alone), and

9369 (2)—The label of the food does not bear a reference to the manufacturer or processor
9370 other than the food establishment;

9371 (B)—Low volume food products if:

9372 (1)—The annual sales are less than 100,000 units for which a notification claiming
9373 exemption has been filed with FDA's Office of Nutritional Products Labeling and
9374 Dietary Supplements Food Labeling by a small business with less than 100 full-
9375 time equivalent employees; or

9376 (2)—The annual sales are less than 10,000 units by a small business with less than 10
9377 full time equivalent employees;

9378 (C)—Foods served in food establishments with facilities for immediate consumption such as
9379 restaurants, cafeterias, and mobile food establishments, and foods sold only in those
9380 establishments;

9381 (D)—Foods similar to those specified in the preceding bullet but that are sold by food
9382 establishments without facilities for immediate consumption such as bakeries and grocery
9383 stores if the food is:

9384 (1)—Ready to eat but not necessarily for immediate consumption;

9385 (2)—Prepared primarily in the food establishment from which it is sold, and

9386 (3)—Not offered for sale outside the food establishment;

9387 (E)—Foods of no nutritional significance such as coffee;

9388 (F)—Bulk food for further manufacturing or repacking; and

- 9389 (G) — Raw fruits, vegetables, and fish.
- 9390 H. — Game animal meats shall provide nutrition information which may be provided by labeling
9391 displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some
9392 other appropriate device.
- 9393 III. — Food packaged in a food processing plant or another food establishment, shall meet the
9394 requirements specified in § 3-602.11 and enforcement by the regulatory authority is authorized in
9395 the NLEA, Section 4. State Enforcement.
- 9396 In 1998, 21 CFR Part 73, Section 73.75 was amended to address canthaxanthin as a color additive for
9397 salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink
9398 salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout,
9399 cutthroat trout, and brown trout. This color additive may be in the feed that is fed to aquacultured fish,
9400 and when those fish are placed into a bulk container for shipment, the bulk container must bear a label
9401 declaring the presence of canthaxanthin. That same label information must be displayed at retail when
9402 those fish are offered for sale.
- 9403 The 21 CFR Section 73.75(d)(4) requires that the presence of the color additive in salmonid fish that have
9404 been fed feeds containing canthaxanthin be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2)
9405 and 101.100(a)(2). For additional information, see the Federal Register announcement 63 FR 14814,
9406 March 27, 1998, Listing of Color Additives Exempt from Certification; Canthaxanthin.
- 9407 On August 2, 2004, President Bush signed into law the Food Allergen Labeling and Consumer Protection
9408 Act of 2004 (Public Law 108-282). This new law amended Sections 201 and 403 of the Federal Food,
9409 Drug, and Cosmetic Act to establish food allergen labeling requirements for all packaged foods regulated
9410 by FDA. The new provisions require that all affected packages of food labeled on or after January 1, 2006
9411 must identify on the label the names of the food sources of any major food allergens (i.e., the following
9412 eight foods and any protein derived from them: milk, egg, fish, crustacean shellfish, tree nuts, wheat,
9413 peanuts, and soybeans) used as ingredients in the food. The names of the food sources are the same as the
9414 names of the eight foods that are major food allergens, with the exception that for fish, crustacean
9415 shellfish, and tree nuts, their respective food source names are the specific species of fish (e.g., bass,
9416 flounder, or cod), the specific species of crustacean shellfish (e.g., crab, lobster, or shrimp), and the
9417 specific types of tree nuts (e.g., almonds, pecans, or walnuts).
- 9418 **3-702—Special Requirements for Highly Susceptible Populations**
- 9419
- 9420 The Regulation provisions that relate to highly susceptible populations are combined in this section for
9421 ease of reference and to add emphasis to special food safety precautions that are necessary to protect
9422 those who are particularly vulnerable to foodborne illness and for whom the implications of such illness
9423 can be dire.
9424
- 9425 **Date Marking**
- 9426 Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most
9427 microbes. The growth of some bacteria, such as **LISTERIA MONOCYTOGENES**, is significantly
9428 slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase
9429 their risk to public health in ready-to-eat foods.
- 9430 Based on a predictive growth curve modeling program for **LISTERIA MONOCYTOGENES**, ready-to-
9431 eat, potentially hazardous food (time/temperature control for safety food) may be kept at 5°C (41°F) a
9432 total of 7 days. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by

9433 date marking to ensure its safety based on the total amount of time it was held at refrigeration
9434 temperature, and the opportunity for **LISTERIA MONOCYTOGENES** to multiply, before freezing and
9435 after thawing. Potentially hazardous (time/temperature control for safety) refrigerated foods must be
9436 consumed, sold or discarded by the expiration date.

9437 Date marking is the mechanism by which the Regulation requires active managerial control of the
9438 temperature and time combinations for cold holding. Industry serving a highly susceptible population
9439 must implement a system of identifying the date or day by which the food must be consumed, sold, or
9440 discarded. Date marking requirements apply to containers of processed food that have been opened and to
9441 food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is
9442 under the control of the food establishment. This provision applies to both bulk and display containers. It
9443 is not the intent of the Regulation to require date marking on the labels of consumer size packages.

9444 A date marking system may be used which places information on the food, such as on an overwrap or on
9445 the food container, which identifies the first day of preparation, or alternatively, may identify the last day
9446 that the food may be sold or consumed on the premises. A date marking system may use calendar dates,
9447 days of the week, color-coded marks, or other effective means, provided the system is disclosed to the
9448 Regulatory Authority upon request, during inspections.

9449 **FDA/USDA/CDC LISTERIA MONOCYTOGENES Risk Assessment**

9450 In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the [Quantitative](#)
9451 [Assessment of the Relative Risk to Public Health from Foodborne LISTERIA MONOCYTOGENES](#)
9452 [Among Selected Categories of Ready-to-Eat Foods](#)³⁸. This initiative included the development of 23
9453 separate risk assessments and analysis of the relative risks of serious illness and death associated with
9454 consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats,
9455 dairy products, and deli salads.

9456 In examining these closely, FDA showed that 5 factors are important in measuring the public health
9457 impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of
9458 consumption of a ready-to-eat food; (2) frequency and levels of **L. MONOCYTOGENES** in a ready-to-
9459 eat food; (3) potential of the food to support growth of the bacterium during refrigeration; (4) refrigerated
9460 storage temperature; and (5) duration of refrigerated storage before consumption.

9461 Based on these 5 factors, the 23 categories of ready-to-eat foods were ranked according to their relative
9462 risk of contamination and growth of **LISTERIA MONOCYTOGENES**. The risk categories used were:
9463 very high risk; high risk; moderate risk; low risk; and very low risk.

9464 **IMPACT OF THE LISTERIA MONOCYTOGENES RISK ASSESSMENT ON DATE MARKING**

9465 Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food
9466 Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on
9467 very high and high risk foods, while at the same time, exempting foods that present a very low, or low
9468 risk of contamination and growth of **LISTERIA MONOCYTOGENES**. Based on this evaluation, date
9469 marking provisions of the Regulation do not apply to the following foods:

9470

9471

9472 **DELI SALADS PREPARED AND PACKAGED IN A FOOD PROCESSING PLANT**

9473 Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato
 9474 salad, and macaroni salad, manufactured according to 21 CFR 110. According to data from the risk
 9475 assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along
 9476 with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of **LISTERIA**
 9477 **MONOCYTOGENES**. There are estimates that 85% of all deli salads are prepared and packaged in a
 9478 food processing plant and do not support growth. Based on discussions with deli salad manufacturers and
 9479 trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli
 9480 salads to add one or more preservatives that inhibit the growth of **LISTERIA MONOCYTOGENES**.
 9481 Based on their wide use within this segment of the industry and their effectiveness at inhibiting the
 9482 growth of **LISTERIA MONOCYTOGENES**, all deli salads prepared and packaged in a food processing
 9483 plant are exempt from date marking. However, all deli salads prepared in a food establishment require
 9484 date marking.

9485

HARD AND SEMI-SOFT CHEESES

9486 In December, 1999, FDA issued an [exemption from date marking](#)³⁹ for certain types of hard and semi-soft
 9487 cheeses, based on the presence of several factors that may control the growth of **LISTERIA**
 9488 **MONOCYTOGENES**. These factors may include organic acids, preservatives, competing
 9489 microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this
 9490 interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are
 9491 exempt from date marking.

List of Some Hard and Semi-Soft Cheese Exempt from Date Marking

Asadero	Asiago soft	Pecorino
Abertam	Battelmatt	Queso Anejo
Appenzeller	Bellelay (blue veined)	Queso Chihuahua
Asiago medium or old	Blue	Queso de Prensa
Bra	Briek	Romanello
Cheddar	Camosum	Romano
Christalinna	Chantelle	Reggiano
Colby	Edam	Sapsago
Cotija Anejo	Fontina	Sassenage (blue veined)
Cotija	Gorgonzola (blue veined)	Stilton (blue veined)
Coon	Gouda	Swiss
Derby	Havarti	Tignard (blue veined)
Emmentaler	Konigskase	Vize
English Dairy	Limburger	Wensleydale (blue veined)
Gex (blue veined)	Milano	Queso de la Tierra
Gloucester	Manchego	Robbiolo
Gjetost	Monterey	Roquefort (blue veined)
Gruyere	Muenster	Samsoe
Herve	Oka	Tilsiter
Lapland	Port du Salut	Trappist
Lorraine	Provolone	
Oaxaca	Queso de Bola	
Parmesan	Queso de la Tierra	

9492 **CULTURED DAIRY PRODUCTS**

9493 Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21
9494 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation.
9495 Data from the risk assessment show that **LISTERIA MONOCYTOGENES** does not grow in these
9496 foods and therefore, these products are exempt from date marking.

9497 **PRESERVED FISH PRODUCTS**

9498 Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products,
9499 manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or
9500 acidity of these products does not allow for the growth of **LISTERIA MONOCYTOGENES** and
9501 therefore, these products are exempt from date marking. This exemption does not apply to hot or cold
9502 smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved
9503 on-site, in a food establishment, such as ceviche.

9504 **USDA-regulated products**

9505 Date marking provisions of the Regulation do not apply to shelf-stable ready-to-eat meat and poultry
9506 products. Shelf-stable ready-to-eat meat and poultry products are not required by USDA to be labeled
9507 "Keep Refrigerated." For these products, the nitrite and salt in the cure and the lower pH resulting from
9508 fermentation give additional protection against microbial growth. Some fermented sausages and salt-
9509 cured products are shelf-stable, do not require refrigeration, and do not bear the label "Keep
9510 Refrigerated." To be shelf-stable, a product manufactured under USDA inspection must have a process
9511 that results in a product that meets one of the recognized objective criteria for shelf stability, such as
9512 water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are
9513 exempt from the Regulation date marking requirements.

9514 Shelf-stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date
9515 marked. Shelf-stable salt-cured products such as prosciutto, country-cured ham, or Parma ham do not
9516 require refrigeration or Regulation date marking. Other salt-cured products include basturma, breasaola,
9517 coppa, and capocollo.

9518 Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the
9519 USDA-required label "Keep Refrigerated." Examples of these products are cooked bologna, cooked
9520 salami, and sliced country ham which are ready-to-eat fermented products that need refrigeration.
9521 Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

9522 Regarding the exemption from date marking for shelf-stable sausages in a casing, the exemption does not
9523 apply if the casing is removed. The intact casing on shelf-stable sausages may be overwrapped to protect
9524 the cut face of the sausage. With shelf-stable (not potentially hazardous (time/temperature control safety))
9525 sausages, the intact casing provides a barrier to contamination (although not an absolute one), the exposed
9526 face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face
9527 is exposed. The coagulated protein that occurs on the surface of some nonshelf-stable cooked sausages is
9528 not a casing.

9529 Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do
9530 need to be date marked.

9531 If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment,
9532 the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is
9533 not required by USDA/FSIS and if applied, would not supercede or replace date marking requirements
9534 established by the Regulation that apply after the food is opened in a retail establishment.

9535

Manufacturer's use-by dates

9536 It is not the intent of this provision to give a product an extended shelf life beyond that intended by the
9537 manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not
9538 occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are
9539 voluntarily placed on food packages.

9540 Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer's use-by date
9541 is its recommendation for using the product while its quality is at its best. Although it is a guide for
9542 quality, it could be based on food safety reasons. It is recommended that food establishments consider the
9543 manufacturer's information as good guidance to follow to maintain the quality (taste, smell, and
9544 appearance) and salability of the product. If the product becomes inferior quality-wise due to time in
9545 storage, it is possible that safety concerns are not far behind.

9546 It is not the intention of this provision that either the manufacturer's date or the date marked by the food
9547 establishment be placed on consumer packages.

Juice

9548

9549

9550 As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from
9551 juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable
9552 form in a hermetically sealed container. It is important to note that the definition of "juice" includes
9553 puréed fruits and vegetables, which is commonly prepared for service to highly susceptible populations.
9554 There are documented cases of foodborne illness throughout the United States that were associated with
9555 the consumption of various juice products contaminated with microorganisms such as *Cryptosporidium*,
9556 Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Vibrio cholera*. As new information
9557 becomes available, the Regulation will be modified or interim interpretive guidance will be issued
9558 regarding foodborne illness interventions for on-site juicing and puréeing.

9559

9560 The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This
9561 includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include
9562 freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly
9563 susceptible population.

9564

9565 In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile
9566 products (canned juices) are acceptable for service to a highly susceptible population. Persons providing
9567 pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are
9568 produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food
9569 safety.

9570

Eggs

9571

9572

9573 *Salmonella* often survives traditional preparation techniques. It survives in a lightly cooked omelet,
9574 French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of
9575 ***Salmonella* Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs
9576 remain a major source of these infections, causing large outbreaks when they are combined and
9577 undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added
9578 precautions need to be in place with those most susceptible to foodborne illness.

9579

9580 Operators of food establishments serving highly susceptible populations may wish to discuss buyer
9581 specifications with their suppliers. Such specifications could stipulate eggs that are produced only by
9582 flocks managed under a ***Salmonella* Enteritidis** control program that is recognized by a regulatory

9583 agency that has animal health jurisdiction. Such programs are designed to reduce the presence of
9584 *Salmonella Enteritidis* in raw shell eggs. In any case, the food establishment operator must use adequate
9585 time and temperature controls within the establishment to minimize the risk of a foodborne illness
9586 outbreak relating to *Salmonella Enteritidis*.

9587

9588 **Raw Seed Sprouts**

9589

9590 Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United
9591 States. The FDA and CDC have issued health advisories that persons who are at a greater risk for
9592 foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in
9593 place to improve the safety of these products. For further information, see the FDA Talk Paper entitled,
9594 "Interim Advisory on Alfalfa Sprouts" issued on August 31, 1998 and available on the FDA web site
9595 (www.fda.gov). Since this issue continues to be under investigation, FDA recommends that interested
9596 persons check the FDA web site periodically for more recent, updated information.

9597

9598 **3-8 — Consumer Advisory**

9599

9600 **3-801 — Consumption of Animal Foods That Are Raw, Undercooked, or Not Otherwise Processed** 9601 **to Eliminate Pathogens**

9602 **Purpose:**

9603 At issue is the role of government agencies, the regulated industry, and others in providing notice to
9604 consumers that animal derived foods that are not subjected to adequate heat treatment pose a risk because
9605 they may contain biological agents that cause foodborne disease. The deliverance of a balanced message
9606 that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk
9607 in perspective based on the consumer's health status and the food being consumed is part of the challenge.
9608 Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect
9609 behavior. The following information is to alert the reader to the options available to food establishments
9610 in advising consumers of the increased possibility of foodborne illness when animal derived foods are
9611 eaten raw or undercooked.

9612 **Background:**

9613 Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA
9614 included a codified provision for a point of purchase consumer advisory:

9615 "FDA has requested comments and will consider the responses as well as other information that
9616 is available related to the risks involved and methods of risk communication to determine what
9617 action may be necessary by FDA to effectively inform consumers."

9618

9619

9620 Consumer Focus Groups:

9621 During 1996—1998, FDA conducted two different consumer focus group studies. Because the first set of
9622 focus groups (conducted before the 1997 Food Code) were not receptive to the language recommended at
9623 the 1996 Conference for Food Protection (CFP) meeting, that language was not included in the 1997 Food
9624 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified
9625 approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer
9626 acceptance and receptiveness to menu-based advisories emerged.

9627 It became apparent that there is a general appreciation for "**disclosure**" of what consumers view as
9628 "hidden ingredients," for example, whether a particular menu item contains raw egg. In addition to
9629 disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a "**reminder**" that
9630 consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the
9631 food-establishment venue, consumers are less willing to accept a message that extends beyond a reminder
9632 and becomes a lesson or an educational message.

9633 Satisfactory Compliance:

9634 FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that
9635 incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that
9636 **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a**
9637 **disclosure and reminder are provided**, as described in Section 3-801 of the Regulation. **Disclosure** is
9638 achieved when there is clear identification of animal-derived foods that are sold or served raw or
9639 undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such
9640 raw or undercooked ingredients. A third option for the consumer "reminder" was added later. The
9641 **reminder** is a notice about the relationship between thorough cooking and food safety.

9642 Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a
9643 menu statement that advises consumers that food safety information about the disclosed items is available
9644 upon request. Essential criteria for such written information are available from FDA through the Retail
9645 Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College
9646 Park, Maryland 20740. All brochures must meet these essential criteria. The other option is a short notice
9647 alerting consumers to the increased risk of consuming the disclosed menu items.

9648 In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8,
9649 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of
9650 illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

9651 The information contained in both the disclosure and reminder should be publicly available and readable
9652 so that consumers have benefit of the total message (disclosure and reminder) before making their order
9653 selections.

9654 It is not possible to anticipate all conceivable situations. Therefore, there will always be need for
9655 discussion between the food establishment and the Regulatory Authority as to the most effective way to
9656 meet the objectives of satisfactory compliance.

9657 Locating the Advisory:

9658 Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of
9659 consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure
9660 and the reminder need to accompany the information from which the consumer makes a selection. That

9661 information could appear in many forms such as a menu, a placarded listing of available choices, or a
9662 table tent.

9663 **Educational Messages:**

9664 Educational messages are usually longer, more didactic in nature, and targeted to consumers who have
9665 been alerted to the food safety concern and take the initiative to obtain more detailed information. It is
9666 expected that, in most cases, educational messages that are provided pursuant to Section 3-801 (i.e., in
9667 situations where the option for referring the consumer to additional information is chosen), will be
9668 embodied in brochures that will not be read at the site where the immediate food choice is being made.
9669 Nonetheless, such messages are viewed as an important facet of arming consumers with the information
9670 needed to make informed decisions and, because the information is being requested by the consumer, it
9671 would be expected to play a role in subsequent choices.

9672 **Applicability:**

9673 **FOOD ESTABLISHMENTS:**

9674 The consumer advisory is intended to apply to all food establishments where raw or undercooked animal
9675 foods or ingredients are sold or served for human consumption in a raw or undercooked form. This
9676 includes ~~all types of food establishments whenever there is a reasonable likelihood that the food will be~~
9677 ~~consumed without subsequent, thorough cooking~~ such as restaurants, raw bars, quick service operations,
9678 carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood
9679 departments.

9680 ~~"... OTHERWISE PROCESSED TO ELIMINATE PATHOGENS...":~~

9681 This phrase is included in Section 3-801 to encompass new technologies and pathogen control/reduction
9682 regimens ~~as they are developed and validated~~ as fulfilling a specific performance standard for pathogens
9683 of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the
9684 Regulation, the level of pathogen reduction that is required before a raw or undercooked animal food is
9685 allowed to be offered without a consumer advisory must be equivalent to the levels provided by Section
9686 3-502 for the type of food being prepared.

9687 The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are
9688 insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions
9689 achieved in Section 3-502. Irradiated poultry provides a 3D kill which does not provide the level of
9690 protection of the 7D kill that results from the cooking regimen in the Regulation. Therefore, irradiated
9691 meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is
9692 intended that future Regulation revisions will address time/temperature requirements that take into
9693 consideration the pathogen reduction that occurs with irradiated foods.

9694 **RECOGNITION OF OTHER PROCESSES:**

9695 Animal derived foods may undergo validated processes that target a specific pathogen. In such instances,
9696 along with the required consumer advisory may appear additional language that accurately describes the
9697 process and what it achieves. For example, a technology for reducing **VIBRIO VULNIFICUS** in oysters
9698 to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be
9699 labeled with a truthful claim that appropriately describes the product. That is, a statement could be made
9700 such as, "pasteurized to reduce **VIBRIO VULNIFICUS**" or "temperature treated to reduce **VIBRIO**
9701 **VULNIFICUS**." Such a claim must be in accordance with labeling laws and regulations, accurate, and
9702 not misleading. The claim would not, however, negate the need for a consumer advisory because the
9703 treatment only reduces the level of one pathogenic organism.

9704 **PRODUCT SPECIFIC ADVISORIES:**

9705 Consumer advisories may be tailored to be product specific if a food establishment either has a limited
9706 menu or offers only certain animal derived foods in a raw or undercooked ready to eat form. For
9707 example, a raw bar serving molluscan shellfish on the half shell, but no other raw or undercooked animal
9708 food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder,
9709 option #3, which would highlight the increased risk incurred when persons with certain medical
9710 conditions ingest shellfish that has not been adequately heat treated.

9711 **MILK:**

9712 In addition, "milk" is not mentioned in the actual on-site advisory language. The sale or transportation of
9713 final packaged form of unpasteurized milk into interstate commerce is specifically prohibited by 21 CFR
9714 1240.61. Also the consumption of raw milk is not recommended by FDA (this statement is in the form of
9715 an official [FDA position statement](#)⁴²). Nonetheless, approximately 25 states allow unpasteurized milk in
9716 intrastate commerce which usually involves direct dairy farm to consumer procurement.

9717 **MOLLUSCAN SHELLSTOCK:**

9718 In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be
9719 provided when a seafood department or seafood market offers raw molluscan shellstock for sale or
9720 service. There is a risk of death from **VIBRIO** infections from consuming raw molluscan shellstock for
9721 persons who have certain medical conditions.

Chapter 4 – Warewashing, Equipment, Utensils, and Linens

9722

9723 **4-1 — Materials For Construction and Repair**

9724

9725 **4-101 — General**

9726

9727 Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has
9728 been stipulated that: "For food equipment programs, standards that establish sanitation requirements shall
9729 be specified government standards or standards that have been ratified by a public health approval step.
9730 ANSI shall verify that this requirement has been met by communicating with appropriate standards
9731 developing organizations and governmental public health bodies."

9732

9733 The term "certified" is used when an item of food equipment has been evaluated against an organization's
9734 own standard. The term classified is used when one organization evaluates an item of food equipment
9735 against a standard developed by another organization.

9736

9737 Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended
9738 period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared
9739 which could lead to foodborne illness. In addition, some materials can affect the taste of the food being
9740 prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used
9741 could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit
9742 adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes
9743 contaminated.

9744

9745 Equipment and utensils must be designed and constructed to be durable and capable of retaining their
9746 original characteristics so that such items can continue to fulfill their intended purpose for the duration of

9747 their life expectancy and to maintain their easy cleanability. If they cannot maintain their original
9748 characteristics, they may become difficult to clean, allowing for the harborage of pathogenic
9749 microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that
9750 parts do not break and end up in food as foreign objects or present injury hazards to consumers. A
9751 common example of presenting an injury hazard is the tendency for tines of poorly designed single
9752 service forks to break during use.

9753

9754 Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to
9755 operate as designed. Failure to properly maintain equipment could lead to violations of the associated
9756 requirements of the Regulation that place the health of the consumer at risk. For example, refrigeration
9757 units in disrepair may no longer be capable of properly cooling or holding potentially hazardous foods at
9758 safe temperatures.

9759

9760 The safety and quality of food can be adversely affected through single service and single use articles that
9761 are not constructed of acceptable materials. The migration of components of those materials to food they
9762 contact could result in chemical contamination and illness to the consumer. In addition, the use of
9763 unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors
9764 transferred to the food.

9765

9766 **4-102—Equipment Requirements**

9767

9768 **4-2—Design and Construction**

9769

9770 **4-201—Food Contact Surfaces**

9771

9772 The purpose of the requirements for multiuse food contact surfaces is to ensure that such surfaces are
9773 capable of being easily cleaned and accessible for cleaning. Food contact surfaces that do not meet these
9774 requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have
9775 imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once
9776 established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and
9777 sanitizing efforts. *The requirement for easy disassembly recognizes the reluctance of food employees to*
9778 *disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.*

9779

9780 Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of
9781 pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms
9782 from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

9783

9784 Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced
9785 because they can no longer be adequately cleaned and sanitized. Can openers must be designed to
9786 facilitate replacement. The cutting or piercing parts of can openers may accumulate metal fragments that
9787 could lead to food containing foreign objects and, possibly, result in consumer injury.

9788

9789 Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to
9790 clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or
9791 accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

9792

9793 **4-202—Use Limitations**

9794

9795 Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended
9796 period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared

9797 which could lead to foodborne illness. In addition, some materials can affect the taste of the food being
9798 prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used
9799 could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit
9800 adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes
9801 contaminated.

9802
9803 Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of
9804 pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms
9805 from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

9806
9807 Equipment and utensils constructed of cast iron meet the requirement of durability as intended in Sections
9808 4-101 and 4-201. However, the surface characteristics of cast iron tend to be somewhat porous which
9809 renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces
9810 the residues in the porous surface are not of significant concern as heat destroys potential pathogens that
9811 may be present.

9812 **Lead—**

9813
9814 Historically, lead has been used in the formulation and/or decoration of these types of utensils.
9815 Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused
9816 high concentrations of lead to leach into the food they contain.

9817
9818 Lead poisoning continues to be an important public health concern due to the seriousness of associated
9819 medical problems. Lead poisoning is particularly harmful to the young and has caused learning
9820 disabilities and medical problems among individuals who have consumed high levels. The allowable
9821 levels of lead are specific to the type of utensil, based on the average contact time and properties of the
9822 foods routinely stored in each item listed.

9823
9824 FDA has established maximum levels (see FDA Compliance Policy Guide Section 545.450 Pottery
9825 (Ceramics); Imported and Domestic—Lead Contamination (CPG 7117.07) for leachable lead in
9826 ceramieware, and pieces that exceed these levels are subject to recall or other agency enforcement action.
9827 The levels are based on how frequently a piece of ceramieware is used, the type and temperature of the
9828 food it holds, and how long the food stays in contact with the piece. For example, cups, mugs and pitchers
9829 have the most stringent action level, 0.5 parts per million, because they can be expected to hold food
9830 longer, allowing more time for lead to leach. Also, a pitcher may be used to hold fruit juice. And a coffee
9831 mug is generally used every day to hold a hot acidic beverage, often several times a day.

9832
9833 The FDA allows use of lead glazes because they're the most durable, but regulates them tightly to ensure
9834 their safety. Commercial manufacturers employ extremely strict and effective manufacturing controls that
9835 keep the lead from leaching during use. Small potters often can't control the firing of lead glazes as well
9836 so their ceramics are more likely to leach illegal lead levels, although many do use lead-free glazes.

9837
9838 In 21 CFR 109.16, FDA requires high lead leaching decorative ceramicware to be permanently labeled
9839 that it's not for food use and may poison food. Such items bought outside the United States may not be so
9840 labeled, potentially posing serious risk if used for food.

9841
9842 Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals.
9843 Solder may be composed of tin and lead alloys. Lead has been linked to many health problems especially
9844 among the young. Consequently, the amount of lead allowed in food equipment is subject to limitation.

9845
9846 **Copper**

9847

9848 High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper
9849 alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released
9850 into a water supply because of an ineffective or nonexistent backflow prevention device between a
9851 carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide
9852 leaches copper from the plumbing components and the leachate is then transferred to beverages, causing
9853 copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and
9854 have resulted in, the leaching of both copper and lead into carbonated beverages.

9855
9856 Brass is an alloy of copper and zinc and contains lead, which is used to combine the two elements.
9857 Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are
9858 subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.
9859

9860 Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast
9861 during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal
9862 to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of
9863 copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation
9864 (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.
9865

9866 Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel lined copper
9867 equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer
9868 following the hot brewing steps in the beer making process. Some also use pitch coated oak vats or glass-
9869 lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is
9870 common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for
9871 successful fermentation.
9872

9873 The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage
9874 from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in
9875 order to optimize enzymatic activity. The pH is commonly lowered to 5.1–5.2, but may be adjusted to as
9876 low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 2½ hours or more. After
9877 boiling, the wort is cooled, inoculated with brewer's yeast, and fermented. The use of copper equipment
9878 during the prefermentation and fermentation steps typically result in some leaching of copper.
9879

9880 **Galvanized Containers**

9881
9882 Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized
9883 containers into foods that are high in water content. The risk of leaching increases with increased acidity
9884 of foods contacting the galvanized container.
9885
9886

9887

9888 Pewter

9889

9890 Pewter refers to a number of silver gray alloys of tin containing various amounts of antimony, copper,
9891 and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized
9892 metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of
9893 acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

9894

9895 Wood

9896

9897 The limited acceptance of the use of wood as a food contact surface is determined by the nature of the
9898 food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface
9899 may become difficult to clean. In addition, wood that is treated with preservatives may result in illness
9900 due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are
9901 allowed.

9902

9903 Nonstick Surfaces

9904

9905 Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware
9906 a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of
9907 this material as safe for food contact surfaces. The Agency has determined that neither the particles that
9908 may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this
9909 nonstick finish may be scratched by sharp or rough edged kitchen tools, the manufacturer's
9910 recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or
9911 cleaners avoided.

9912

9913 Linens

9914

9915 Because of their absorbency, linens and napkins used as liners that contact food must be replaced
9916 whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to
9917 become fomites.

9918

9919 4-203—Nonfood-Contact Surfaces

9920

9921 Nonfood contact surfaces of equipment routinely exposed to splash or food debris are required to be
9922 constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes
9923 the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and
9924 insects.

9925

9926 Hard to clean areas could result in the attraction and harborage of insects and rodents and allow the
9927 growth of foodborne pathogenic microorganisms. Well designed equipment enhances the ability to keep
9928 nonfood contact surfaces clean.

9929

9930 4-204—Clean In Place (CIP) Equipment

9931

9932 Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to
9933 disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be
9934 monitored via access points to ensure that cleaning has been effective throughout the system.

9935

9936 The CIP design must ensure that all food contact surfaces of the equipment are contacted by the
9937 circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas that are not contacted by
9938 the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic
9939 microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the
9940 system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-
9941 draining.

9942

9943 **4-205 —“V” Threads, Use Limitation**

9944

9945 V-type threads present a surface, which is difficult to clean routinely; therefore, they are not allowed on
9946 food contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on
9947 the high temperatures that are used in this equipment. The high temperature in effect sterilizes the
9948 equipment, including debris in the "V" threads.

9949

9950 **4-206 —Hot Oil Filtering Equipment**

9951

9952 The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible
9953 for replacement. Filtering the oil reduces the likelihood that off odors, tastes, and possibly toxic
9954 compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is
9955 necessary for the filter to be accessible for replacement.

9956

9957 **4-207 —Bearings and Gear Boxes, Leakproof**

9958

9959 It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation
9960 of these types of equipment could contaminate food or food contact surfaces if the equipment is not
9961 properly designed and constructed.

9962

9963 Food contact surfaces must be lubricated in a manner that does not introduce contaminants to those
9964 surfaces. Equipment must be reassembled in a way that food contact surfaces are not contaminated.

9965

9966 Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants
9967 used must be approved as food additives or generally recognized as safe. Lubricants that are not safe
9968 present the possibility of foodborne illness if they find their way into the food.

9969

9970 **4-208 —Beverage Tubing, Separation**

9971

9972 Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct
9973 contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and
9974 drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

9975

9976 The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may
9977 be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment,
9978 mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

9979

9980 **4-209 —Ice Units, Separation of Drains**

9981

9982 Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination
9983 due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice
9984 through condensate migrating along the exterior of the lines.

9985

9986 Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that
9987 are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for
9988 mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae
9989 that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in
9990 the bin.

9991

9992 **4-210—Condenser Unit, Separation**

9993

9994 A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-
9995 contact areas from contamination by dust that is accumulated and blown about as a result of the
9996 condenser's operation.

9997

9998 **4-211—Molluscan Shellfish Tanks**

9999

10000 Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in
10001 the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow
10002 concentration of pathogenic viruses and bacteria.

10003

10004 Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of
10005 pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in
10006 molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in
10007 a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination
10008 must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the
10009 tank including the filtering and disinfection system.

10010

10011 **4-212—Ventilation and Ventilation Hood Systems**

10012

10013 If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings
10014 of the food establishment, causing an unsanitary condition and possible deterioration of the surfaces of
10015 walls and ceilings. The accumulation of grease and condensate may contaminate food and food contact
10016 surfaces as well as present a possible fire hazard.

10017

10018 The dripping of grease or condensation onto food constitutes adulteration and may involve contamination
10019 of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use
10020 articles that are subjected to such drizzle are no longer clean.

10021

10022 When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls,
10023 ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and
10024 no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

10025

10026 Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

10027

10028 **4-3—Location and Installation**

10029

10030 **4-301—Equipment, and Storage Cabinets, Contamination Prevention**

10031

10032 Food equipment and the food that contacts the equipment must be protected from sources of overhead
10033 contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects.

10034 When equipment is installed, it must be situated with consideration of the potential for contamination
10035 from such overhead sources.

10036

10037 ~~Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and~~
10038 ~~single service and single use articles can become contaminated before their intended use in a variety of~~
10039 ~~ways such as through water leakage, pest infestation, or other unsanitary condition.~~

10040

10041 ~~The improper storage of clean and sanitized equipment, utensils, laundered linens, and single service and~~
10042 ~~single use articles may allow contamination before their intended use. Contamination can be caused by~~
10043 ~~moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic~~
10044 ~~materials, litter, dust, and other materials. The contamination is often related to unhygienic employee~~
10045 ~~practices, unacceptable high risk storage locations, or improper construction of storage facilities.~~

10046

10047 ~~4-302—Fixed Equipment, Spacing or Sealing~~

10048

10049 ~~This section is designed to ensure that fixed equipment is installed in a way that:~~

10050

10051 ~~1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes~~
10052 ~~the need for cleaning due to closely abutted surfaces;~~

10053

~~2. Ensures that equipment that is subject to moisture is sealed;~~

10054

~~3. Prevents the harborage of insects and rodents; and~~

10055

~~4. Provides accessibility for the monitoring of pests.~~

10056

10057 ~~The inability to adequately or effectively clean areas under equipment could create a situation that may~~
10058 ~~attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through~~
10059 ~~food.~~

10060

10061 ~~The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed~~
10062 ~~equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or~~
10063 ~~prohibitively expensive, sealing to prevent contamination is required.~~

10064

10065 ~~The economic impact of the requirement to elevate display units in retail food stores, coupled with the~~
10066 ~~fact that the design, weight, and size of such units are not conducive to casters or legs, led to the~~
10067 ~~exception for certain units located in consumer shopping areas, provided the floor under the units is kept~~
10068 ~~clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer~~
10069 ~~units in the consumer shopping areas requires a rigorous cleaning schedule.~~

10070

10071 ~~This requirement is intended to protect both the machine dispensed, unpackaged, liquid foods and the~~
10072 ~~machine components from contamination. Barriers need to be provided so that the only liquid entering the~~
10073 ~~food container is the liquid intended to be dispensed when the machine's mechanism is activated.~~

10074

10074 ~~Recessing of the machine's components and self closing doors prevent contamination of machine ports by~~
10075 ~~people, dust, insects, or rodents. If the equipment components become contaminated, the product itself~~
10076 ~~will be exposed to possible contamination.~~

10077

10077 ~~A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the~~

10078

10078 ~~food.~~

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10080 ~~The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation~~

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10081 ~~does not meet Regulation requirements, debris could accumulate and create a situation that may attract~~

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10082 ~~insects and rodents.~~

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~~4-4 Equipment and Utensil Cleaning and Sanitization-Testing Devices~~

~~4-401—Temperature Measuring Devices~~

~~The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.~~

~~When determining the temperature of thin foods, those having a thickness less than 13 mm (1/2 inch), it is particularly important to use a temperature sensing probe designed for that purpose. Bimetal, bayonet style thermometers are not suitable for accurately measuring the temperature of thin foods such as hamburger patties because of the large diameter of the probe and the inability to accurately sense the temperature at the tip of the probe. However, temperature measurements in thin foods can be accurately determined using a small diameter probe 1.5 mm (0.063 inch), or less, connected to a device such as thermocouple thermometer.~~

~~Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.~~

~~The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988), which requires the use of metric values. The $\pm 1.5^{\circ}\text{C}$ requirement is more stringent than the 3°F previously required since $\pm 1.5^{\circ}\text{C}$ is equivalent to $\pm 2.7^{\circ}\text{F}$. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers. If Fahrenheit thermometers are used, the 3°F requirement applies because of the calibrated intervals of Fahrenheit thermometers.~~

~~The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves. The accuracy specified for a particular food temperature measuring device is applicable to its entire range of use, that is, from refrigeration through cooking temperatures if the device is intended for such use.~~

~~A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance. The accuracy specified for a particular air or water temperature measuring device is applicable to its intended range of use. For example, a cold holding unit may have a temperature measuring device that measures from a specified frozen temperature to 20°C (68°F). The device must be accurate to specifications within that use range.~~

~~The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Regulation requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all potentially hazardous foods are stored at least at the minimum temperature required in Chapter 3.~~

~~Installing an air thermometer in some open display refrigerators can be difficult without physically impairing the usability of the case and interfering with cleaning and sanitation. Use of a temperature~~

10136 ~~monitoring system that uses probe-like sensors that are placed in material resembling the density of food~~
10137 ~~is an acceptable alternative. Thus, the direct temperature of the substitute product is measured by use of~~
10138 ~~this product mimicking method.~~

10139
10140 ~~A permanent temperature measuring device is required in any unit storing potentially hazardous food~~
10141 ~~because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed~~
10142 ~~Regulation requirements. In order to facilitate routine monitoring of the unit, the device must be clearly~~
10143 ~~visible.~~

10144
10145 ~~The exception to requiring a temperature measuring device for the types of equipment listed is primarily~~
10146 ~~due to equipment design and function. It would be difficult and impractical to permanently mount a~~
10147 ~~temperature measuring device on the equipment listed. The futility of attempting to measure the~~
10148 ~~temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the~~
10149 ~~equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point.~~
10150 ~~In such cases, it would be more practical and accurate to measure the internal temperature of the food.~~

10151
10152 ~~The importance of maintaining potentially hazardous foods at the specified temperatures requires that~~
10153 ~~temperature measuring devices be easily readable. The inability to accurately read a thermometer could~~
10154 ~~result in food being held at unsafe temperatures.~~

10155
10156 ~~The required incremental gradations are more precise for food measuring devices than for those used to~~
10157 ~~measure ambient temperature because of the significance at a given point in time, i.e., the potential for~~
10158 ~~pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the~~
10159 ~~ambient temperature of the storage unit; it will depend on many variables including the temperature of the~~
10160 ~~food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time~~
10161 ~~the food is stored in the unit.~~

10162
10163 ~~A utensil or food temperature measuring device can act as a source of contamination to the food it~~
10164 ~~contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not~~
10165 ~~maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature~~
10166 ~~problem may not be detected, or conversely, a corrective action may be needlessly taken.~~

10167 **4-402—Testing Devices**

10168
10169
10170 ~~Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:~~

- 10171
10172 ~~1.—The use of chemical sanitizers requires minimum concentrations of the sanitizer~~
10173 ~~during the final rinse step to ensure sanitization; and~~
- 10174 ~~2.—Too much sanitizer in the final rinse water could be toxic.~~

10175
10176 ~~The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the~~
10177 ~~sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the~~
10178 ~~chemical sanitizer solution.~~

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10182 **4-403—Manual Cleaning and Sanitization**

10183

10184 **Manual**

10185

10186 During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or
10187 sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and
10188 utensils, it is necessary to clean the surface of warewashing equipment before use and periodically
10189 throughout the day.

10190

10191 The 3-compartment requirement allows for proper execution of the 3-step manual warewashing
10192 procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water
10193 and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

10194 Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must
10195 provide for accomplishment of the same 3 steps:

10196

10197 1.—Application of cleaners and the removal of soil;

10198

2.—Removal of any abrasive and removal or dilution of cleaning chemicals; and

10199

3.—Sanitization.

10200

10201 Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other
10202 and from the food preparation area in order to preclude contamination of cleaned items and of food.

10203

10204 Drainboards allow for the control of water running off equipment and utensils that have been washed and
10205 also allow the operator to properly store washed equipment and utensils while they air-dry.

10206

10207 Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating
10208 device is necessary to ensure that the minimum temperature is reached.

10209

10210 The rack or basket is required in order to safely handle the equipment and utensils being washed and to
10211 ensure immersion. Water at this temperature could result in severe burns to employees operating the
10212 equipment.

10213

10214 The draining requirement in equipment components is needed to prevent the pooling of water. Pooled
10215 water whether from drainage, condensate, drippage, or melting ice could contain or provide a favorable
10216 environment for pathogens and other contaminants.

10217

10218 Water temperature is critical to sanitization in warewashing operations. This is particularly true if the
10219 sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined
10220 by the temperature of the water used. A temperature measuring device is essential to monitor manual
10221 warewashing and ensure sanitization. If the temperature during the hot water sanitizing step is less than
10222 77°C (171°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be
10223 subsequently transferred from utensils to food.

10224

10225 The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of
10226 the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 21 CFR
10227 178.1010 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is
10228 critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards
10229 required in the Regulation.

10230

10231 ~~With respect to chemical sanitization, the Rules and Regulations addresses the proper make-up of the~~
10232 ~~sanitizing solution, i.e., chemical concentration, pH, and temperature at the required MINIMUM levels~~
10233 ~~specified when considered together (and, with respect to quaternary ammonia sanitizers, the MAXIMUM~~
10234 ~~hardness level). If these minimums (maximum hardness) are not as specified, then this provision is~~
10235 ~~violated.~~
10236
10237 ~~If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing~~
10238 ~~and thawing foods, contamination of equipment and utensils could occur.~~
10239
10240 ~~Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create~~
10241 ~~safety concerns for the employee and consumer. For example, employees could suffer chemical burns,~~
10242 ~~and chemical residues could find their way into food if detergents or cleaners are used carelessly.~~
10243
10244 ~~Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or~~
10245 ~~detergents are used.~~
10246
10247 ~~Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing~~
10248 ~~operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.~~
10249
10250 ~~The wash solution temperature required in the Regulation is essential for removing organic matter. If the~~
10251 ~~temperature is below 43°C (110°F), the performance of the detergent may be adversely affected, e.g.,~~
10252 ~~animal fats that may be present on the dirty dishes would not be dissolved.~~
10253
10254 ~~Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-~~
10255 ~~contact surfaces are sanitized before coming in contact with food and before use.~~
10256
10257 ~~Some chemical sanitizers are not compatible with detergents when a 2-compartment operation is used.~~
10258 ~~When using a sanitizer that is different from the detergent sanitizer of the wash compartment, the~~
10259 ~~sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.~~
10260
10261 ~~It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or~~
10262 ~~inactivating the sanitizer.~~
10263
10264 ~~Some pieces of equipment are too large (or fixed) to be cleaned in a sink. Nonetheless, cleaning of such~~
10265 ~~equipment requires the application of cleaners for the removal of soil and rinsing for the removal of~~
10266 ~~abrasive and cleaning chemicals, followed by sanitization.~~
10267
10268 ~~Effective sanitization procedures destroy organisms of public health importance that may be present on~~
10269 ~~wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse~~
10270 ~~solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its~~
10271 ~~maximum benefit.~~
10272
10273 ~~Efficacious sanitization is dependent upon warewashing being conducted within certain parameters. Time~~
10274 ~~is a parameter applicable to both chemical and hot water sanitization. The time that hot water or~~
10275 ~~chemicals contact utensils or food contact surfaces must be sufficient to destroy pathogens that may~~
10276 ~~remain on surfaces after cleaning. Other parameters, such as temperature or chemical concentration, are~~
10277 ~~used in combination with time to deliver effective sanitization.~~
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4-404—Mechanical Cleaning and Sanitization

Mechanical

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Regulation requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Exposure time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved. The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

The presence of adequate detergents and sanitizers is necessary to affect clean and sanitized utensils and equipment. The automatic dispensing of these chemical agents, plus a method such as a flow indicator, flashing light, buzzer, or visible open air delivery system that alerts the operator that the chemicals are no longer being dispensed, ensures that utensils are subjected to an efficacious cleaning and sanitizing regimen.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line pressure as a final sanitization rinse. It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated

10331 sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-
10332 pressure. A pressure below the design pressure results in inadequate spray patterns and incomplete
10333 coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water
10334 droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

10335
10336 The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The
10337 chemicals used may not adequately perform their function if the temperature is too low. Therefore, the
10338 manufacturer's instructions must be followed. The temperatures vary according to the specific equipment
10339 being used.

10340
10341 The temperature of the hot water delivered to the warewashing machine manifold must be maintained
10342 according to the equipment manufacturer's specification to ensure that the surfaces of utensils or
10343 tableware accumulate and build up enough heat to destroy pathogens that may be present on such
10344 surfaces. The surface temperature should reach at least 71°C (160°F) as measured by an irreversible
10345 registering temperature indicator to affect sanitization.

10346
10347 If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing
10348 solution may be inadequate to reach all surfaces of equipment or utensils.

10349
10350 Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure
10351 adequate cleaning. Items, which are stacked, or trays, which are heavily loaded with silverware, cannot
10352 receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

10353
10354 Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to
10355 facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned,
10356 detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be
10357 presoaked or scrubbed with an abrasive.

10358
10359 Items must be allowed to drain and to air dry before being stacked or stored. Stacking wet items such as
10360 pans prevents them from drying and may allow an environment where microorganisms can begin to grow.
10361 Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to
10362 equipment or utensils.

10363 **4-405—Drainboard and Dishtable Requirements**

10364 10365 **4-406—Drying**

10366 10367 **4-407—Food-Contact Surfaces of Equipment and Utensils**

10368
10369 The purpose of the requirements for multiuse food contact surfaces is to ensure that such surfaces are
10370 capable of being easily cleaned and accessible for cleaning. Food contact surfaces that do not meet these
10371 requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces, which have
10372 imperfections such as cracks, chips, or pits, allow microorganisms to attach and form biofilms. Once
10373 established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and
10374 sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to
10375 disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

10376
10377
10378 The objective of cleaning focuses on the need to remove organic matter from food contact surfaces so that
10379 sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic
10380 microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

10381

10382 Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers,
10383 or other food contact surfaces. Food contact surfaces and equipment used for potentially hazardous foods
10384 should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent
10385 the growth of microorganisms on those surfaces.

10386
10387 Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary
10388 to clean every four hours. However, the time period between cleaning equipment and utensils may not
10389 exceed 24 hours. A time-temperature chart is provided in Section 4-405 to accommodate operations that
10390 use equipment and utensils in a refrigerated room or area that maintains a temperature between 5°C
10391 (41°F) or less and 13°C (55°F).

10392
10393 Surfaces of utensils and equipment contacting food that is not potentially hazardous such as iced tea
10394 dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending
10395 equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent
10396 the development of slime, mold, or soil residues that may contribute to an accumulation of
10397 microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry,
10398 develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide
10399 cleaning specifications for food contact surfaces of equipment that are not readily visible, the person in
10400 charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular
10401 items of equipment.

10402
10403 Regarding the possible adulteration from one species of meat to another between cleaning of food contact
10404 surfaces, USDA/FSIS does not automatically consider species adulteration as a health hazard. FSIS stated
10405 in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between
10406 safety and economic adulteration (65 FR 14486, March 17, 2000). FSIS will review public comments
10407 received on the species adulteration issue and further review the scientific literature and risk assessment
10408 mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is
10409 generally considered by FSIS as an economic issue. However, investigations by FSIS of species
10410 adulteration incidents may include a determination regarding the impact of species adulteration as a health
10411 hazard on a case-by-case basis.

10412
10413 Food contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede
10414 heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect
10415 attractant when not in use.

10416 10417 **4-408—Nonfood-Contact Surfaces**

10418
10419 The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for
10420 the growth of microorganisms, which employees may inadvertently transfer to food. If these areas are not
10421 kept clean, they may also provide harborage for insects, rodents, and other pests.

10422 10423 **4-409—Dry Equipment Cleaning Methods**

10424
10425 Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not
10426 potentially hazardous. Under some circumstances, attempts at wet cleaning may create microbiological
10427 concerns.

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~~4-5 — Laundry Facilities~~

~~4-501 — Laundry Facilities~~

~~To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.~~

~~If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single service and single use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.~~

~~Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.~~

~~Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood contact surfaces.~~

~~Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single service and single use articles.~~

~~Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.~~

~~Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.~~

~~Cloths that are air dried must be dried so that they do not drip on food or utensils and so that the cloths are not contaminated while air drying.~~

~~4-6 — Equipment and Utensil Handling and Storage~~

~~4-601 — Equipment and Utensil Storage~~

~~Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single service and single use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other unsanitary condition.~~

~~The improper storage of clean and sanitized equipment, utensils, laundered linens, and single service and single use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high risk storage locations, or improper construction of storage facilities.~~

10479

4-602—Single-Service and Single-Use Articles

10481

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

10484

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

10488

The reuse of mollusk and crustacean shells as multiuse utensils is not allowed in food establishments.

This prohibition does not apply to the removal of the oyster or other species from the shell for

preparation, then returning the same animal to the same shell for service.

10492

The shell itself may be potentially unsafe for use as a food utensil because of residues from natural and environmental contamination occurring after the mollusk or crustacean is removed. In addition, natural shells are not durable or easily cleanable as specified under section 4-502.13. When mollusk or crustacean shells (from commercial sources) are re-used by filling them with shucked shellfish, the food is considered misleading and not honestly presented.

10498

4-603—Preset Tableware

10499

The presentation and/or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food and lip-contact surfaces.

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10503

Chapter 5—Water, Plumbing, and Waste

10504

5-1—Water Supply

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5-101—General

10508

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or man-made chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

10514

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

10516

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary

10523

10524 to ensure the safety of drinking water used in the establishment. The most recent water sampling report
10525 must be kept on file to document a safe water supply.

10526

10527 Availability of sufficient water is a basic requirement for proper sanitation within a food establishment.
10528 An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and
10529 utensils and of food employees' hands.

10530

10531 Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This
10532 requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be
10533 safe, through a distribution system, which is protected.

10534

10535 **5-102—System Flushing and Disinfection**

10536

10537 During construction, repair, or modification, water systems may become contaminated with microbes
10538 from soil because pipes are installed underground or by chemicals resulting from soldering and welding.
10539 Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as
10540 oils may also be present on or in the components of the system. To render the water safe, the system must
10541 be properly flushed and disinfected before being placed into service.

10542

10543 Contaminants of various types may be introduced into a water system during construction or repair or
10544 other incidents. The system must be flushed and sanitized after maintenance and before it is placed into
10545 service to prevent contamination of the water introduced into the tank.

10546

10547 **5-103—Bottled Drinking Water**

10548

10549 Bottled water is obtained from a public water system or from a private source such as a spring or well.
10550 Either means of production must be controlled by public health law to protect the consumer from
10551 contaminated water.

10552

10553 **5-104—Transportation**

10554

10555 Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed
10556 and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport
10557 vehicles and containers, may result in contamination of safe water and render it hazardous to human
10558 health.

10559

10560 **5-105—Emergency Alternative Water Supply**

10561

10562 Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed
10563 and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport
10564 vehicles and containers, may result in contamination of safe water and render it hazardous to human
10565 health.

10566

10567 **5-106—Non-Drinking Water**

10568

10569 Food establishments may use non-drinking water for purposes such as air conditioning or fire protection.
10570 Non-drinking water is not monitored for bacteriological or chemical quality or safety as is drinking water.
10571 Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking
10572 water, or food-contact surfaces. Identifying the piping designated as non-drinking waterlines and
10573 inspection for cross connections are examples of safety precautions.

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5-107—Pressure and Temperature

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Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashing machines operate according to manufacturer's specifications.

5-108—Hot Water

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashing machines that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization cannot be reached. Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

5-109—Steam**5-2—Plumbing System****5-201—General**

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

Non-drinking water may be of unknown or questionable origin. Wastewater is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation of warewashing equipment or other equipment, which depends on sufficient volume and pressure to perform its intended functions.

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5-202—Backflow

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashing machines. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system.

Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative. To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

When carbon dioxide is mixed with water, carbonic acid, a weak acid, is formed. Carbonators on soft drink dispensers form such acids as they carbonate the water to be mixed with the syrups to produce the soft drinks. If carbon dioxide backs up into a copper water line, carbonic acid will dissolve some of the copper. The water containing the dissolved copper will subsequently be used in dispensing soft drinks and the first few customers receiving the drinks are likely to suffer with the symptoms of copper poisoning. An air gap or a vented backflow prevention device meeting ASSE Standard No. 1022 will prevent this occurrence, thereby reducing incidences of copper poisoning.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as

10677 inspection and maintenance schedules for these devices, must be strictly followed to prevent failure
10678 during operation.

10679
10680 Improper plumbing installation or maintenance may result in potential health hazards such as cross
10681 connections, back siphonage or backflow. These conditions may result in the contamination of food,
10682 utensils, equipment, or other food contact surfaces. It may also adversely affect the operation of
10683 equipment such as warewashing machines.

10684 **5-203—Conditioning Device, Design**

10685
10686 Water conditioning devices must be designed for easy disassembly for servicing so that they can be
10687 maintained in a condition that allows them to perform the function for which they were designed.

10688
10689 When not located for easy maintenance, conditioning devices will be inconvenient to access and devices
10690 such as filters, screens, and water softeners will become clogged because they are not properly serviced.

10691 **5-204—Grease Trap / Grease Interceptor**

10692
10693 Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the
10694 harborage of vermin and/or the failure of the sewage system.

10695 **5-205—Food Waste Grinders/Garbage Disposals**

10696 **5-206—Drainage of Equipment**

10697 **5-207—Drainage System Installation**

10698
10699 The drainage system must be designed and installed properly to prevent the backup of sewage and the
10700 possible contamination of foods or food contact surfaces in the establishment.

10701 **5-208—Handwashing, Lavatory, Water Temperature, and Flow**

10702
10703 Because handwashing is such an important factor in the prevention of foodborne illness, sufficient
10704 facilities must be available to make handwashing not only possible, but likely.

10705
10706 Hands are probably the most common vehicle for the transmission of pathogens to foods in an
10707 establishment. Hands can become soiled with a variety of contaminants during routine operations. Some
10708 employees are unlikely to wash their hands unless properly equipped handwashing facilities are
10709 accessible in the immediate work area. Facilities, which are improperly located, may be blocked by
10710 portable equipment or stacked full of soiled utensils and other items, rendering the facility unavailable for
10711 regular employee use. Nothing must block the approach to a handwashing facility thereby discouraging
10712 its use, and the facility must be kept clean and well stocked with soap and sanitary towels to encourage
10713 frequent use.

10714
10715 Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An
10716 adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands.
10717 ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of
10718 $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ (100 to 107°F).

10719
10720 An inadequate flow or temperature of water may lead to poor handwashing practices by food employees.
10721 A mixing valve or combination faucet is needed to provide properly tempered water for handwashing.

10728 ~~Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding~~
10729 ~~is a possible hazard.~~

10730

10731 ~~Facilities must be maintained in a condition that promotes handwashing and restricted for that use.~~

10732 ~~Convenient accessibility of a handwashing facility encourages timely handwashing, which provides a~~
10733 ~~break in the chain of contamination from the hands of food employees to food or food contact surfaces.~~

10734 ~~Sinks used for food preparation and warewashing can become sources of contamination if used as~~
10735 ~~handwashing facilities by employees returning from the toilet or from duties, which have contaminated~~
10736 ~~their hands.~~

10737

10738 ~~Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on~~
10739 ~~hands.~~

10740

10741 ~~Provisions must be provided for hand drying so that employees will not dry their hands on their clothing~~
10742 ~~or other unclean materials.~~

10743

10744 ~~Waste receptacles at handwashing lavatories are required for the collection of disposable towels so that~~
10745 ~~the paper waste will be contained, will not contact food directly or indirectly, and will not become an~~
10746 ~~attractant for insects or rodents.~~

10747

10748 ~~Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of~~
10749 ~~the food employee for proper and routine handwashing to prevent contamination of the food and food-~~
10750 ~~contact surfaces.~~

10751

10752 ~~Handwashing facilities must be maintained in operating order at all times so they will be used.~~

10753

10754 ~~5-209 Toilets and Urinals~~

10755

10756 ~~Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries~~
10757 ~~pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.~~

10758 ~~Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food~~
10759 ~~contamination and to motivate employees to use sanitary practices in the establishment.~~

10760

10761 ~~Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of~~
10762 ~~flies and other insects between the toilet facility and food preparation areas.~~

10763

10764 ~~To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use~~
10765 ~~of toilet facilities. Toilet tissue must be supplied to meet the demand.~~

10766

10767 ~~Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use~~
10768 ~~of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.~~

10769

10770 ~~5-210 Utility Facility~~

10771

10772 ~~Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Liquid wastes~~
10773 ~~generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and~~
10774 ~~food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks~~
10775 ~~such as food preparation and handwashing sinks.~~

10776

10777 ~~5-211 Sewage~~

10778

10779 Many diseases can be transmitted from one person to another through fecal contamination of food and
10780 water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal
10781 contamination. This Regulation provision is intended to ensure that wastes will not contaminate ground
10782 surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or
10783 insects to serve as vectors of disease from this source.

10784
10785 Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations
10786 of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

10787 10788 **5-212 — Water Reservoir of Fogging Devices, Cleaning**

10789
10790 Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol
10791 or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with
10792 respiratory pathogens such as *Legionella pneumophila*. This organism is extremely infectious and can be
10793 transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's
10794 cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by
10795 this bacterium.

10796 10797 **5-3 — Refuse, Recyclables, and Returnables**

10798 10799 **5-301 — Containers**

10800
10801 Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors,
10802 prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents,
10803 and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates
10804 nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of
10805 food, equipment, and utensils.

10806
10807 Outside receptacles must be constructed with tight fitting lids or covers to prevent the scattering of the
10808 garbage or refuse by birds, the breeding of flies, or the entry of rodents.

10809
10810 Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of
10811 garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

10812 10813 **5-302 — Storage**

10814
10815 Garbage containers should be available wherever garbage is generated to aid in the proper disposal of
10816 refuse.

10817
10818 Storage areas for garbage, refuse, compost and recyclables containers must be constructed so that they
10819 can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In
10820 addition, such storage areas must be large enough to accommodate all the containers necessitated by the
10821 operation in order to prevent scattering of the garbage and refuse.

10822
10823 All containers must be maintained in good repair and cleaned as necessary in order to store garbage and
10824 refuse under sanitary conditions as well as to prevent the breeding of flies. If refuse areas are not graded
10825 properly, wastewater will pool and attract insects and rodents.

10826
10827 Waste materials and empty product containers are unclean and can be an attractant to insects and rodents.
10828 Food, equipment, utensils, linens, and single service and single use articles must be protected from
10829 exposure to filth and unclean conditions and other contaminants. This Regulation provision addresses

10830 these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas,
10831 and to preclude creation of a nuisance.

10832

10833 **5-303—Disposal**

10834

10835 Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of
10836 the original contents. Spillage from these containers soils receptacles and storage areas and becomes an
10837 attractant for insects, rodents, and other pests. The handling of these materials entails some of the same
10838 problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these
10839 materials are removed from the premises at a reasonable frequency.

10840

10841 **5-304—Storage Areas, Redeeming Machines, Equipment, and Receptacles, Location**

10842

10843 Alternative means of solid waste disposal must be conducted properly to prevent environmental
10844 consequences and the attraction of insects, rodents, and other pests.

10845

10846

Chapter 6—Physical Facilities

10847

10848 **6-1—Floors**

10849

10850 **6-101—Floor Construction**

10851

10852 Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Floor
10853 surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of
10854 foods from dust and organisms from pooled moisture. Grading of the floor to drain allows liquid wastes
10855 to be quickly carried away, thereby preventing pooling which could attract pests such as insects and
10856 rodents or contribute to problems with certain pathogens such as *Listeria monocytogenes*.

10857

10858 Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is
10859 intended to ensure that the physical facilities are properly maintained in order to serve their intended
10860 purpose.

10861

10862 **6-102—Floor Carpeting**

10863

10864 The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture
10865 are intended to ensure that the cleanability of these surfaces is retained.

10866

10867 Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective
10868 cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for
10869 carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or
10870 waste is likely.

10871

10872 **6-103—Utility Line Installation**

10873

10874 Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are
10875 intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is
10876 minimized.

10877

10878

10879

10880 6-104—Floor Junctures

10881

10882 Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are
10883 intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is
10884 minimized.

10885

10886 When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is
10887 required to provide a surface that is conducive to water flushing.

10888

10889 6-105—Prohibited Floor Covering

10890

10891 Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are
10892 intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is
10893 minimized.

10894

10895 Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become
10896 a nuisance to the food operation.

10897

10898 6-106—Mats and Duckboards

10899

10900 Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is
10901 possible and that accumulation of dirt and waste is prevented.

10902

10903 6-2—Walls and Ceilings

10904

10905 6-201—Construction

10906

10907 Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and
10908 effectively cleaned.

10909

10910 Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and
10911 debris, and flying insects.

10912

10913 Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is
10914 intended to ensure that the physical facilities are properly maintained in order to serve their intended
10915 purpose.

10916

10917 6-202—Attachments, Exposed Construction

10918

10919 Special requirements related to the attachment of accessories and exposure of wall and ceiling studs,
10920 joists, and rafters are intended to ensure the cleanability of these surfaces.

10921

10922 Heating and air conditioning system vents that are not properly designed and located may be difficult to
10923 clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or
10924 other accumulated soil from the exhaust vents.

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6-3 — Lighting

6-301 — Light Intensity

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

6-302 — Light Bulbs, Protective Shielding

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single service and single use articles from glass fragments should the bulb break.

6-4 — Operation and Maintenance

6-401 — Cleaning Physical Facilities

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes, which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

6-402 — Cleaning Equipment Storage

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food contact surfaces. These items must be stored in a manner that precludes such contamination.

10977

10978 **6-5 — Premises**

10979

10980 **6-501 — General**

10981

10982 The requirements concerning surface characteristics of outdoor areas are intended to facilitate
10983 maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide
10984 durable exterior building surfaces, and prevent the attracting, harboring, or breeding of insects, rodents,
10985 and other pests where refuse, recyclables, or returnables are stored.

10986

10987 If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the
10988 establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and
10989 driving surfaces may also attract rodents and breed insects.

10990

10991 The presence of unnecessary articles, including equipment, which is no longer used, makes regular and
10992 effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.
10993 Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary
10994 manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and
10995 insects.

10996

10997 **6-502 — Living Areas**

10998

10999 Areas or facilities that are not compatible with sanitary food establishment operations must be located
11000 and/or separated from other areas of the establishment to preclude potential contamination of food and
11001 food contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly
11002 designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

11003

11004 Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure
11005 in their homes against unreasonable search and seizure. This provision could hinder the regulatory
11006 authority's access to conduct routine inspections of a food establishment operated in the living area of a
11007 private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be
11008 difficult to obtain and might not authorize the necessary inspectional activities.

11009

11010 **6-503 — Dressing Rooms and Locker Areas**

11011

11012 Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because
11013 street clothing and personal belongings carry contaminants, areas designated to accommodate employees'
11014 personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-
11015 service and single-use articles must not be in jeopardy of contamination from these areas.

11016

11017

Chapter 7 – Poisonous or Toxic Materials

11018

7-1 Labeling and Identification

11020

7-101 – Identifying Information, Prominence

11022

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

11026

7-102 – Working Containers

11028

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

11034

7-103 – Separation

11036

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

11041

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

11045

7-104 – Restriction

11047

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

11051

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

11059

7-105 – Use of Materials

11061

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

11064

11065
11066 Particular precautions must be taken during the application of poisonous or toxic materials to prevent the
11067 contamination of food and other food contact surfaces. Residues of certain materials are not discernible to
11068 the naked eye and present an additional risk to the employee and consumer.

11069
11070 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used
11071 in accordance with requirements listed in the Regulation of Federal Regulations (CFR). Large
11072 concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the
11073 materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered
11074 safe.

11075
11076 Whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40
11077 CFR 180.940, Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations
11078 (food contact sanitizing solutions) or 40 CFR 180.2020, Non food determinations. Because there is no
11079 EPA registration of solutions generated and used on site, the user of the equipment should look to the
11080 equipment manufacturer for data to validate the efficacy of the solution that is generated by the device as
11081 well as the conditions for use of the solution.

11082 11083 **7-106—Food Containers**

11084
11085 Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of
11086 the potential for contamination of the food. The risk of serious medical consequences to anyone
11087 consuming food stored in these containers coupled with the lack of confidence that all of the material
11088 could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

11089 11090 **7-107—Chemicals for Washing Fruits and Vegetables, Criteria**

11091
11092 21 CFR Section 173.315 specifically identifies chemicals that may be used in washing fruits and
11093 vegetables, regardless of whether the chemicals are commercially produced or generated on site. Sodium
11094 hypochlorite is listed in 21 CFR 173.315 for use in washing fruits and vegetables at levels not exceeding
11095 the minimum amount required to accomplish the intended technical effect. FDA has no objection to the
11096 use of calcium hypochlorite in the place of sodium hypochlorite under 21 CFR 173.315.

11097 11098 **7-108—Boiler Water Additives, Criteria**

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11100 Boiler water additives that may be safely used in the preparation of steam that may contact food, and their
condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

11101 11102 **7-109—Drying Agents, Criteria**

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11104 If the sanitizer, chemical wash, boiler water additive, or drying agent used is not made up of components
11105 that are approved as food additives or generally recognized as safe, illness may result. This could be due
11106 to residues that may remain from the use of compounds such as unrecognized drying agents. This is why
only those chemicals that are listed in the CFR can be used.

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11108 Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive
11109 Petition. Sanitizers, wash chemicals, and drying agents are classified as food additives because of the
11110 possibility that they may end up in food. Therefore, they are subject to review before being used or listed
11111 in the CFR.

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7-110—Personal Medications and Cosmetics

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage.

There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials. Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food contact surfaces.

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food contact surfaces if they are not properly labeled and stored.

7-111—First Aid Supplies

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Regulation in order to preclude the accidental contamination of food, food equipment, and other food contact surfaces.

Chapter 8—Insect, Rodent and Animal Control

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8-1—Prevention

8-101—Outer Openings, Protected

Insects and rodents are vectors of disease causing microorganisms, which may be transmitted to humans by contamination of food and food contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

In the National Fire Protection Association's NFPA 101, Life Safety Regulation®, 1994 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Regulation does not require exterior doors used as exits to be self closing, but they can be.

The intent of this requirement is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self closing device. Doors not requiring a self closing device include exterior emergency exit doors that open into a public way from a fire.

8-102—Controlling Pests

Insects and other pests are capable of transmitting disease to man by contaminating food and food contact surfaces. Effective measures must be taken to control their presence in food establishments.

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8-103—Insect Control Devices, Design and Installation

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Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Regulation requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food contact surfaces.

8-104—Pesticide Application

Because of the toxicity of restricted use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted use pesticides are applied.

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food contact surfaces and ultimately in the food being prepared or served.

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

8-105—Removing Birds, Insects, Rodents, and Other Pests

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

8-106—Prohibiting of Animals

Animals carry disease causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with service animals are required to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for "service animal" is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 2010 (42 U.S.C. 12101 et seq.). A service animal is dog or miniature horse that performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by "seeing eye dogs"; alerting persons with hearing impairments to sounds;

11213 pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and
11214 assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.
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11216 Under Title III of the ADA, privately owned businesses that serve the public are prohibited from
11217 discriminating against individuals with disabilities. The ADA requires these businesses to allow people
11218 with disabilities to bring their service animals onto business premises in whatever areas customers are
11219 generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all,
11220 are licensed or certified and have identification papers.

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11222 Decisions regarding a food employee or applicant with a disability who needs to use a service animal
11223 should be made on a case-by-case basis. An employer must comply with health and safety requirements,
11224 but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is
11225 available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S.
11226 Equal Employment Opportunity Commission, the federal agency which has the lead in these matters, in
11227 documents such as, "National Network Information, Guidance and Training on the Americans with
11228 Disabilities Act—Service Animals" and "Service Animals Welcome—Service Animals & the ADA". The
11229 ADA Information Line is 800-949-4232 (voice/TTY) and the Internet Home Page address is
11230 www.adata.org.

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11232 Dogs and other animals, like humans, may harbor pathogens that are transmissible through food.
11233 Handling or caring for animals that may be legally present is prohibited because of the risk of
11234 contamination of food employee hands and clothing.
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