



**COLORADO**  
Department of Public  
Health & Environment

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**To:** Members of the State Board of Health

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

**Date:** November 15, 2017

**Subject:** **Rulemaking Hearing**  
Proposed Amendments to 6 CCR 1010-2, *Colorado Retail Food Establishment Rules and Regulations*, for the rulemaking to occur in November 2017

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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 adopt the revised regulation 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; improving 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.

[Informational Comment: Following the Request for Rulemaking Hearing held on September 20, 2017, and based on Board of Health and stakeholder feedback, amendments were made and highlighted for ease of reference.]

**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 2015, the General Assembly of the State of Colorado passed house bill 15-1226, which established a triennial review for Colorado's retail food program to be completed by program stakeholders. These stakeholders include CDPHE, local public health agencies, county commissioners, retail food establishments and other interested parties. This review studies retail food establishments, inspection programs, program funding, program costs, and the uses of program revenue for the uniform statewide administration, implementation, interpretation, and enforcement of the retail food program. Based on the 2015 triennial review, stakeholders approved a 50% increase in retail food license fees through house bill 16-1401, along with new statutory performance standards to ensure uniformity and the efficient and effective administration of the program.

Pursuant to the expectations of house bills 15-1226 and 16-1401, and 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 Coloradoans 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 **U.S. Food and Drug Administration's 2013 model Food Code** and the **2015 Supplement to 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. Industry studies published between 2009 and 2016 have shown that the presence of a certified food protection manager reduces the number of critical violations encountered during inspections and the number of foodborne illness outbreaks reported per million persons per year. 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 times 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 Food

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.

➤ ***Elaborate upon the Food Code temporary retail food establishments requirements***

In response to stakeholder feedback, the department added specific language concerning temporary retail food establishments. This revision enables consistent application of the Food Code and this rule to an evolving area of food service delivery. The revisions aligns with the Food Code and state statute.

➤ ***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.

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**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, and 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, including the new requirement for a certified food protection manager, which are scientifically based to prevent the occurrence of foodborne illness. Industry studies published between 2009 and 2016 have shown that the presence of a certified food protection manager reduces the number of critical violations encountered during inspections and the number of foodborne illness outbreaks reported per million persons per year. For example, the Maryland study "*The Impact of Local Environmental Health Capacity on Foodborne Illness Morbidity in Maryland*", published in the American Journal of Public Health, August 2011, Vol. 101, No. 8, indicated that jurisdictions with a certified food manager requirement saw between an 8.3% and 39% reduction in foodborne illness compared with jurisdictions without this requirement.

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, thereby,

enabling industry 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 or 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 provide 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 requirements 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 and customers, as both are 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 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, an 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 an 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 to 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 support 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 and 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 needed 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.

Short and long-term consequences were analyzed along with the expectations of recent legislation that has added performance and efficiency requirements for the retail food program. Specifically, house bill 16-1401 increased funding to the retail food program and introduced statutory performance standards to ensure uniformity and the efficient and effective administration of the program. Additionally, house bill 15-1226 established a triennial review for Colorado's retail food program to be completed by program stakeholders. These stakeholders include CDPHE, local public health agencies, county commissioners, retail food establishments and other interested parties. This review studies retail food establishments, inspection programs, program funding, program costs, and the uses of program revenues for the uniform statewide administration, implementation, interpretation, and enforcement of the retail food program.

Additionally, the department reviewed references to the current retail food regulation in the 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:

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
- Fiene, Vanessa, Tri-County Health Department
- Flores, Israel(Izzy), Le Peep
- Gamboa, Britt, Broomfield County Public Health
- Glenn, Monika, San Juan Basin Health Department
- Gonzales, Tom, El Paso County Public Health
- Griffen, Lee, El Paso County Public Health
- Groth, Sara, Tri-County Health Department
- Hartzell, Gary, Elbert County Public Health
- Hatterman, Meredith, Tri-County Health Department
- Hendershott, Dan, Summit County
- Hoover, Nick, CO Restaurant Association
- Howes, Chris, Colorado Retail Council
- Hunsworth, Lynnette, San Juan Basin Public Health
- Irwin, Christopher, USDA
- Jaura, Ferah, Tri-county Health Department



- Johnson, Michael, Chumley Subs, LLC
- Johnston, Amanda, Larimer County Public Health
- Joseph, Dan, Weld County Public Health
- Keith, Carol, Alamosa County Public Health
- Kelley, Kristi, WalMart
- Korbit, Su, Otero County Health Department
- Kulick, Maya, Summit County Public Health
- Lee, Danica M., Denver Dept. of Environmental Health
- Lemmons, Andrew, Park County Public Health
- Lewandowski, Claire, Eagle County Public Health
- Lewis, Alan, Natural Grocers
- Lewis, Anica, Lake County Public Health
- Littlepage, Jackie, Lake County Public Health
- Lovett, Heidi, Gunnison County Public Health
- Macpherson, Claire, San Juan Basin Public Health
- Malinoski, Joe, Boulder County Public Health
- Martinez, John, Las Animas-Hueffano County District
- McClain, Tenzin, Whole Foods
- McFadden, Katherine, USDA
- Melzer, Rick, Routt County Dept. Env. Health
- Merry, Ray, Eagle County Health Department
- Mull, Monique, Mesa County Health Dept.
- Nara, Heather, Mesa County Health Dept.
- Nordstrom, Ken, Delta County Health Dept.
- Odette, Seth, Prowers County Public Health
- Oliver, CJ, Aspen Environmental Health Dept.
- Opp, Carla, Jefferson County Public Health
- Pasquarelli, Antonio, Denver Dept of Environmental Health
- Petersen, Nelle, Silver Thread Public Health District, Lake City
- Peterson, Alison, City and County of Denver
- Porter, Carlyn, City of Aspen
- Rada, Jim, Jefferson County Public Health
- Ramig, Mindi, Jefferson County Public Health
- Rappold, Lynnea, Alamosa County Public Health
- Riess, Jeannine, CSU
- Riggs, Sonia, CO Restaurant Association
- Riley, Brehan, CO Dept. of Education
- Ritter, Rick, Otero County Health Department
- **Ross, Richard, PathTracer Laboratory & Consulting Services**
- Savalox, Heather, Routt County Environmental Health
- Scallan, Elaine, UC Denver
- Scheller, Carol, Hindsdale County Public Health
- Seminara Jr., Mario, FDA
- Smith, Chris, San Miguel County Public Health
- **Spilos, Amanda, Chipotle Mexican Grill**
- Stillwell, Stephen, Broomfield County Public Health
- Stauffer, Vera, Montrose County Health and Human Services
- Taube, Kerry, Las Animas County Public Health
- Tew, Daniel, Yum! Brands
- Tsevdos, Natalie, Garfield County Public Health
- Urbonas, Wayne (Wano), Chaffee County Public Health
- Wallingford, Shelly, Starbucks
- Williams, Josh, Garfield County Public Health
- Zielbauer, Kelly, Albertsons/Safeway

**CDPHE staff:**

- Brandt, Matthew, CDPHE/DEHS
- Brucha, Joan, CDPHE/PSD
- Cassell, Cheryl, CDPHE/PSD
- Cronquist, Alicia, CDPHE-DCEED
- Decelles, Jon, CDPHE/DEHS
- Gammel, Amy, CDPHE/DEHS
- Garber, Sarah, CDPHE/DEHS
- Herlily, Rachel, CDPHE/DCEED
- Herrero, Diana, CDPHE/DCEED
- Huffman, Troy, CDPHE/DEHS
- Lancelot, Kelly, CDPHE/DEHS
- Lawrence, Jeff, CDPHE/DEHS
- Lewis, Meagan, CDPHE/DEHS
- McConnell, Greg, CDPHE/DEHS
- Miller, Tracy, CDPHE/PSD
- Pilonetti, Therese, CDPHE/DEHS
- Rael, Brianne, CDPHE/DEHS
- Rossiter, Shannon, CDPHE/DCEED
- Ruble, Cary, CDPHE/DEHS
- Sax, Joanne, CDPHE/DEHS

- Schoblaski, Emily, CDPHE/DEHS
- Scott, Sean, CDPHE/DEHS
- Siemsen, Keith, CDPHE/OPPI
- Strauss, Jon, CDPHE/DEHS
- Trubee, Justin, CDPHE/DEHS
- Turpin, Brad, CDPHE/DEHS
- Ulric, Erin, CDPHE/PSD
- Vanwagenen, Laura, CDPHE/DEHS
- Warwick, Robert, CDPHE/DEHS

### 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 **primary** 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. **After the conclusion of the formal stakeholder meetings, a few LPHAs expressed concerns on four specific areas. These areas included: the allowance of domestic equipment, the lack of a requirement for a food preparation sink, the plan review process, and temporary retail food establishments. Based on these concerns a meeting was held with LPHAs on October 11, 2017. The outcome of this meeting was the**

addition of section 2.7 to the proposed regulations to address and further clarify the requirements associated with temporary retail food establishments. The remaining three issues were resolved through this stakeholder discussion.

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.



Colorado Board of Health  
Department of Public Health & Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246

October 18, 2017

Dear Board Members:

Mesa County has 750 licensed food retail establishments serving a population of more than 150,000. As the Director of Mesa County Public Health who oversees the licensing of these establishments, I write to you with my full support of the State Board of Health's full adoption of the 2103 FDA Food Code as Colorado's Retail Food Regulations.

The proposed changes will maintain or increase public health protections while allowing the State and local public health agencies that perform this work increased access to federal resources including multi-language materials, federal training, and grant opportunities. The changes will also minimize variance requests and the workload for retail food establishments and local public health agencies. Most importantly, the proposed changes will improve data collection across the state and provide the opportunity to draw upon national data to inform decision-making, increasing efficiency in the rulemaking process, and, allowing the State and local public health agencies to target our limited resources to the greatest opportunities to protect our public health.

Adoption of the Food Code is favored by the retail food 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. 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.

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. It is for these reasons I am encouraging your adoption of the proposed changes.

Sincerely,

Jeff Kuhr, PhD  
Executive Director

Department of Health & Human Services  
Environmental Health Division  
1845 South Townsend Avenue  
Montrose, Colorado 81401  
970.252.5067

October 13, 2017

Jeff Lawrence, Director  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246

The Montrose County Department of Health and Human Services supports the State Board of Health adoption of the 2013 FDA Food Code as our state retail food regulation. The CDPHE Division of Environmental Health and Sustainability (DEHS) has demonstrated great effort to thoughtfully communicate the advantages of adopting the Code and has convened multiple stakeholder meetings to hear broadly from as many interested parties as possible. From a local health agency perspective, DEHS has actively solicited our input, listened to our concerns, answered our questions, and committed to devoting their resources to ensure the smoothest possible implementation of the new code.

Jim Austin  
Environmental Health Director  
Department of Health & Human Services  
Environmental Health Division  
1845 South Townsend Avenue  
Montrose, Colorado 81401  
(970) 252-5067  
[jaustin@montrosecounty.net](mailto:jaustin@montrosecounty.net)



Teller County Public Health and Environment  
PO Box 928  
11115 W. Hwy. 24, Unit 2C  
Divide, CO 80814  
(719) 687-6416  
FAX: (719) 687-6501

October 23, 2017

Colorado Department of Public Health and Environment  
Division of Environmental Health and Sustainability  
4300 Cherry Creek S Dr  
Denver, CO, 80246

To Whom it May Concern,

I am writing in support of the proposed revisions to the Colorado Retail Food Establishment Rules and Regulations 6 CCR 1010-2 and incorporation by reference of the FDA Food Code to the Colorado Retail Food Establishment Rules and Regulations.

With Colorado prioritizing national standardization and uniformity it is my belief that the incorporation of the FDA Food Code will be able to provide the template regulation that Colorado may utilize to further succeed in meeting this goal of uniformity. With the incorporation of the FDA Food Code Colorado will be able to establish a nationally uniform regulatory foundation while also allocating additional time, normally used for routine detailed revisions of the current Colorado regulation, to be used for supplementary activities promoting uniform application and education of Food Code regulations.

Colorado has also begun the implementation of the risk based inspection method, prioritizing the assessment and correction of direct foodborne illness risk factors present in retail food establishments during routine inspections. The FDA Food Code, in my opinion, has been written to accompany the risk based inspection method and any incorporation of the Food Code would further equip local regulatory staff with the support material to assist them with the task of performing higher quality risk based inspections.

It is my personal conclusion that the proposed revision to the Colorado Retail Food Establishment Rules and Regulations and incorporation by reference of the FDA Food Code will support the State of Colorado's goals to implement a more nationally uniform system of regulation, assist local regulatory partners in performing higher quality risk based inspections, identify and resolve prominent foodborne illness risk factors, and overall create a government that is more efficient at protecting the public by reducing the incidence of foodborne illness.

Thank you for your consideration,

Andrew Lemmons  
Environmental Health Officer  
Teller County Public Health and Environment

**FREMONT COUNTY  
DEPARTMENT OF PUBLIC HEALTH & ENVIRONMENT**

201 N 6<sup>TH</sup> STREET

CANON CITY, CO 81212

(719) 276-7450 FAX NUMBER (719) 276-7451

[sid.darden@fremontco.com](mailto:sid.darden@fremontco.com)



TO: Colorado Department of Public Health & Environment  
Division of Environmental Health & Sustainability (DEHS)

FROM: Sid Darden, Fremont County Environmental Health Officer

SUBJECT: Support for the adoption of the FDA Food Code for Colorado

DATE: October 24, 2017

A handwritten signature in blue ink, appearing to read "SID", is located to the right of the "FROM:" line.

As the person primarily responsible for the inspection of restaurants and other food facilities in Fremont County for the past 30 year, I've been through several versions of the Colorado Retail Food Establishment Rules & Regulations during that period of time. Each process has been very time consuming especially for the staff at DEHS (previously the Consumer Protection Division) as well as local health departments and various other groups that participated in the process.

As the Colorado regulations have moved closer and closer to the FDA Food Code with each new version, it just makes sense for so many reasons, to finally adopt the FDA Food Code as the Colorado regulation. I am in support of this effort.

Thank you.

**HEALTH AND HUMAN SERVICES DEPARTMENT**

Human Services Phone: (970) 641-3244 Fax: (970) 641-3738  
Public Health Phone: (970) 641-0209 Fax: (970) 641-8346  
225 N Pine, Gunnison, CO 81230  
Website: [www.GunnisonCounty.org](http://www.GunnisonCounty.org)

October 24, 2017

Jeff Lawrence  
Division Director  
Colorado Department of Public Health & Environment  
4300 Cherry Creek Drive South, A-2  
Denver, CO 80246-1530

Jeff,

I am writing to express my support for the implementation of the FDA Food Code for retail food establishments. While initially we had concerns for our small communities and most especially our small family-owned restaurants, we are now supportive. We explored in our community the opportunity to provide the necessary safe food handling training and found an ideal collaborative opportunity with our local CSU Extension office. In addition, as we learned more about the code we understood the rationale as well as the need to have at least one certified safe food handler in each food establishment.

I appreciate the work of the Environmental Health & Sustainability division at CDPHE. In general there is a high level of support for local public health agency environmental health work. There is consistently technical assistance, education and outreach from the division staff and leadership. In addition, there have been multiple outreaches specific to the FDA retail food code including presentations and discussions at various meetings, email correspondence and discussion with staff members individually. I recognize it's a challenge to find a code that fits all communities but this code appears to be standards based that allows for flexibility and local control

I would be glad to provide additional information if needed. Thank you for your consideration of our input.

In Health,

A handwritten signature in black ink that reads "Joni Reynolds, RN/CNS, MSN". The signature is written in a cursive style.

Joni Reynolds, RN/CNS, MSN  
Executive Director





702 SW 8th Street  
Bentonville, AR 72716  
Phone 123.456.7890  
Fax 123.456.7892  
[www.walmart.com](http://www.walmart.com)

October 26, 2017

Troy Huffman, Program Coordinator  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530

Dear Mr. Huffman:

Wal-Mart Stores, Inc. appreciates the opportunity to comment on the proposed amendment to the Colorado Retail Food Establishment Rules and Regulations.

It is our opinion that the proposed amendments provide greater uniformity with national standards such as the FDA Model Food Code and other recognized public health standards. Thus, we support the regulation amendment as proposed.

Should you have questions concerning our position, please do not hesitate to contact me.

Respectfully,

A handwritten signature in black ink, appearing to read "Kristi Kelley". The signature is fluid and cursive, with a long horizontal stroke at the end.

Kristi Kelley  
Sr. Manager Food Safety  
Wal-Mart Stores, Inc.



# Chaffee County Public Health

448 East 1st Street · Suite 137 · Salida, CO · Phone 719-539-4510 · Fax 719-539-7197

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Troy Huffman, Program Coordinator  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530

October 20, 2017

Dear Mr. Huffman:

Chaffee County Public Health appreciates the opportunity to comment on the proposed amendment to the Colorado Retail Food Establishment Rules and Regulations.

It is our opinion that the proposed amendments provide greater uniformity with national standards such as the FDA Model Food Code and other recognized public health standards. Thus, we support the regulation amendment as proposed.

Should you have questions concerning our position, please do not hesitate to contact me.

Respectfully,

JOANNE SAI  
FOR ANDREA CARLSTROM

Andrea Carlstrom, Public Health Director  
Wano Urbonas, Environmental Health Manager

October 13, 2017

Colorado Board of Health  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South, EDO-A5  
Denver, CO 80246-1530

RE: Colorado Adoption of the 2013 FDA Food Code

Dear Colorado Board of Health members:

Jefferson County Public Health (JCPH) has been a partner in Colorado's food safety programs for several decades. We have always worked closely with our Colorado Department of Public Health and Environment (CDPHE) food safety program leaders to ensure that Colorado has robust and comprehensive food safety programs, which manage and implement regulations for the food manufacturing, milk and retail food industries.

State statute directs CDPHE to establish regulations and ensure uniform statewide administration, implementation and enforcement for the retail food program. Over the years, JCPH has actively participated in updating the *Colorado Retail Food Establishment Rules and Regulations*. These regulation updates have historically used the *FDA Food Code* as a guide or reference point but have never adopted the Code in its entirety. The significant investment of time and resources dedicated to this process by CDPHE, local public health agencies, industry and other partners over the years is difficult to justify for a program that has significant documented resource constraints, especially since a strong national code exists that can be adopted by reference without having an overly significant impact on the retail food safety program as it currently exists.

JCPH supports the adoption of the *2013 FDA Food Code* for the following reasons:


- It is a science-based code vetted through a robust national rule-making process, the Conference for Food Protection, and is nationally supported from federal partners (FDA, CDC and USDA) and by industry. CDPHE and all its local public health agency (LPHA) partners have an active voice in this national rule-making process.
- It brings Colorado into conformity with Standard 1 of the *FDA Voluntary National Retail Food Program Regulatory Standards*, which CDPHE has adopted as the minimum program standards for all retail food establishment regulatory agencies across the state.
- It enhances State and LPHA connections to FDA resources and guidance that are readily available in eight or more languages.
- It aligns Colorado's retail food program with all other state and local retail food programs that use the *2013 FDA Food Code*.
- It eliminates costly and time-consuming database customization required with each revision of Colorado Regulation. Most data systems currently used for this program in Colorado incorporate the *2013 FDA Food Code* in off-the-shelf products.
- It increases eligibility for state and local public health agencies for federal training, grants, and cooperative agreements by utilizing the model code.

- It simplifies the rule-making process, allowing stakeholders much more time to address training needs, data system modifications, communications with industry, impacts of new regulatory requirements, and other implementation logistics.

JCPH fully realizes that, like all change initiatives, the transition to the *FDA Food Code* will include some challenges because the current *Colorado Retail Food Establishment Rules and Regulations* and the *2013 FDA Model Food Code*, while equivalent, are not identical. The *FDA Food Code*'s emphasis on food safety principles and less prescriptive regulatory specifications allow our food safety technical experts to apply risk-based techniques when addressing the diversity and creativity that make Colorado's retail food industry great. We agree with CDPHE's desired policy for the retail food regulatory program and fully believe that this set of regulations will allow us to fully utilize the technical skills of our professional staff and continue to provide a high degree of public health protection to the residents and guests of Colorado.

Thank you for the opportunity to provide input to this process.

Sincerely,



James A. Rada, REHS  
Environmental Health Services Division Director  
Jefferson County Public Health

## Kit Carson County Public Health & Environment

Kelly Alvarez

Environmental Health Specialist

252 S. 14 th St.

P.O. Box 70

Burlington, CO 80807

---

Telephone 719-346-7158

Fax 719-346-8066

Troy Huffman, Program Coordinator  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530

10/25/2017

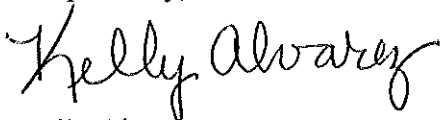
Dear Mr. Huffman:

Kit Carson County Public Health and Environment, which serves Cheyenne, Lincoln and Kit Carson Counties, appreciates the opportunity to comment on the proposed amendment to the Colorado Retail Food Establishment Rules and Regulations.

It is our opinion that the proposed amendments provide greater uniformity with national standards such as the FDA Model Food Code and other recognized public health standards. Thus, we support the regulation amendment as proposed.

Should you have questions concerning our position, please do not hesitate to contact me.

Respectfully,



Kelly Alvarez

Kit Carson County Public Health and Environment



Department of Public Health and Environment

Troy Huffman, Program Coordinator  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530

October 24, 2017

Dear Mr. Huffman:

The San Miguel County Department of Public Health and Environment appreciates the opportunity to comment on the proposed amendment to the Colorado Retail Food Establishment Rules and Regulations.

It is our opinion that the proposed amendments provide greater uniformity with national standards such as the FDA Model Food Code and other recognized public health standards. Thus, we support the regulation amendment as proposed.

Should you have questions concerning our position, please do not hesitate to contact me.

Respectfully,

Chris Smith  
San Miguel County Environmental Health

[chriss@sanmiguelcountyco.go](mailto:chriss@sanmiguelcountyco.go)

(970)728-0447



Yum! Brands, Inc.  
528 N Parkside Dr.  
Rigby, ID 83442  
Tel (502) 874-2422

October 25, 2017

Troy Huffman  
Retail Food Safety Program Manager  
Colorado Department of Public Health & Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246

Greetings Troy,

I am writing on behalf of Yum! Brands, Inc. in support of the Colorado Department of Public Health & Environment adopting the 2013 FDA Food Code used to enforce food safety regulation at retail establishments and restaurants like ours. YUM Brands has over 400 KFC, Pizza Hut and Taco Bell restaurants in Colorado, most of which are owned and operated by local franchisees.

In the interest of public health, I applaud your effort to modernize your food code.

Utilizing the Conference for Food Protection (CFP), the FDA updates its Food Code with input from local, state and federal regulators, as well as academia, consumers, and industry. It is science based, peer reviewed, and updated every four years, so it utilizes ongoing research and addresses current food safety issues. Adopting the 2013 version of the FDA Model Food Code will better ensure your food safety requirements are current, generally agreed upon by all stakeholders, and consistent with other states that maintain an up-to-date food code. It will focus on risks and adherence to food safety principles instead of prescriptive requirements that may become quickly outdated.

The FDA 2013 Food Code includes a requirement that each establishment have at least one Certified Food Protection Manager (CFPM). I am happy to see that you will include this requirement when you adopt the FDA Food Code. CDC and FDA research has shown that restaurants perform better on Health Inspections when the manager-on-duty is a CFPM. Data from our own internal food safety audits support their findings. So having at least one CFPM in a restaurant better ensures safe food is being served in Colorado.

Please let me know if I can be of any assistance in your food code revision efforts.

Sincerely,

Dan Tew  
Yum Brands  
Manager, Food Safety and Regulatory Affairs



700 Columbine St., Sterling, CO 80751 - (970) 522-3741 - (877) 795-0646 - [www.nchd.org](http://www.nchd.org)

To whom it may concern;

In writing this letter, the Northeast Colorado Health Department (NCHD) is expressing our support in the adoption of the 2013 FDA Food Code for the State of Colorado. We believe that the adoption of this new code will greatly benefit our communities in several areas. While certain areas of the current regulations (such as mobile units and temporary events) will need to be examined to determine where we proceed in the future, other areas of the 2013 FDA Food Code have been carefully vetted through the Conference for Food Protection. This process is much more in depth than those processes used in the past. The formal processes used include members of industry, regulatory, academia, consumer and professional organizations allowing for equal input in developing and modifying Food Safety Guidance throughout the United States.

As an enrolled member in FDA's Voluntary National Retail Food Regulatory Program Standards, NCHD strives to provide a more uniform approach to completing retail food inspections. The goal is to reduce complexity, while ensuring a higher level of compliance from our facilities. In adopting the 2013 FDA Food Code, we will gain the ability to use more professional judgement in our varying facilities that may not fit the mold. Change of ownership highly outweighs the number of newly built facilities in our jurisdiction. Asking these facilities to fit the mold of a new facility is often difficult. In most instances, the financial hardships placed on the new owner drives them to abandon their projects in turn allowing for less options to our rural consumers. A more standardized approach will allow us more time to spend in our facilities by reducing the amount of time needed to review new regulations. The added value of access to more training/information in multiple languages will improve the quality of service we provide to our facilities.

NCHD employees value the relationships we have with our food service operators. While we realize that there will be more effort on our end to implement the new changes, we feel that the long-term benefits highly outweigh the legwork needed up front from our staff. We also feel that the Colorado Department of Public Health and Environment (CDPHE) is dedicated to listening to the areas needing addressed in order to continue to provide the level of service we are currently providing. For these reasons, NCHD fully supports CDPHE's vision in implementing the 2013 FDA Food Code across the state of Colorado.

Sincerely,

Melvin Bustos  
Environmental Health Manager



October 25, 2017

Jeff Lawrence, Division Director  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246

RE: Proposed Revisions to the Colorado Retail Food Establishment Rules and Regulations

Dear Mr. Lawrence:

San Juan Basin Public Health has been an active participant throughout CDPHE's stakeholder process regarding proposed revisions to the Colorado Retail Food Establishment Rules and Regulations – specifically, the adoption of the 2013 FDA *Food Code* for the State of Colorado.

As a contract partner with the State of Colorado in the implementation of the Retail Food Establishment program in La Plata, Archuleta, and San Juan counties, San Juan Basin Public Health supports the State's adoption of the 2013 FDA *Food Code* for the following reasons:

- The *Food Code* is a science-based code nationally supported from federal partners (FDA, CDC and USDA) and by industry. Not only is this good business, but also increases our eligibility for federal training in the form of grants and cooperative agreements.
- Adopting the *Food Code* would allow Local Public Health Agencies in Colorado the opportunity to achieve standardization with Standard 1: Regulatory Foundation, which requires public health interventions contained in the *Food Code*.
- There is a wealth of guidance documents developed by the Conference for Food Protection, (e.g. white papers on phases of food incident response, technical guidance for mobile food establishments, and field training guides) however the documents are all based on the FDA *Food Code*.
- Our geographic location close to communities in New Mexico allows food vendors the opportunity to do business in our communities. The inconsistency between the State's regulations creates confusion for those food handlers crossing state lines regarding regulatory requirements. Adoption of the *Food Code* would create consistency with our neighboring state, thus better protecting public health.

San Juan Basin Public Health enthusiastically supports the State of Colorado Board of Health's adoption of the 2013 FDA *Food Code* and sees this as a positive step forward in food safety, both for the communities we serve and for the entire state of Colorado.

Best Regards,

*Liane Jollon*

Liane Jollon  
Executive Director

Troy Huffman, Program Coordinator  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530

October 30, 2017

Dear Mr. Huffman:

The Otero County Health Department appreciates the opportunity to comment on the proposed amendment to the Colorado Retail Food Establishment Rules and Regulations.

It is our opinion that the proposed amendments provide greater uniformity with national standards such as the FDA Model Food Code and other recognized public health standards. By adopting the Food Code, we can move forward with meeting all nine of the FDA's Voluntary National Retail Food Program Standards to make sure we are offering a well-trained and informed inspection staff.

There are many ways to provide uniformity without sacrificing local control or the individual needs of the retail food facilities in local jurisdictions. An example from education is the teaching of multiplication facts. While the goal is for the student to know that  $9 \times 5 = 45$ , there are many approaches to teaching this fact and indeed, individual learning styles need to be considered. In retail food, one goal is to protect the public from unwanted foodborne illnesses. Science has shown that food is safe when held below  $41^{\circ}\text{F}$  and above  $135^{\circ}\text{F}$ . This fact stays the same even though there may be more than one way to ensure that these temperatures are maintained and the customer's safety is protected.

We give our full support of the regulation amendment as proposed.

Should you have questions concerning our position, please do not hesitate to contact me.

Respectfully,



Su Korbitz  
Environmental Services Program Director  
Otero County Health Department  
13 W 3<sup>rd</sup> Street RM 111  
La Junta, CO 81050  
719-383-4728

**Testimony of****Nega Beru, Ph.D.****Director, Office of Food Safety****Center for Food Safety and Applied Nutrition****U.S. Food and Drug Administration****To the**

State of Colorado, Colorado Board of Health,

**November 15, 2017****Amendments to 6 CCR 1010-2, Colorado Retail Food Establishments**

Honorable Members of the Colorado Department of Health and Environment (Environmental Health and Sustainability Division), thank you for the opportunity to submit written testimony in which we will discuss the public health significance and importance of the adoption and implementation of the FDA Food Code, along with stating several cross-cutting benefits to government and industry.

The Public Health Service has determined through several studies that effective foodborne disease prevention requires the application of comprehensive food sanitation measures from production to consumption. FDA's purpose in maintaining an updated model food code is to assist food control jurisdictions at all levels of government by providing them with a scientifically sound, technical, and legal basis for regulating the retail segment of the food industry. The model Food Code provides guidance on food safety, sanitation, and fair equitable advice that can be uniformly adopted for the retail segment of the food industry. The document is the cumulative result of the efforts and recommendations of many individuals, agencies, and organizations with years of experience using earlier model code editions. It embraces the concept that our quality of life, state of health, and the public welfare are directly affected by how we collectively provide and protect our food.

Foodborne illness in the United States is a major cause of personal distress, preventable death, and avoidable economic burden. Despite advances in food safety, foodborne illness remains a common occurrence in the United States. CDC estimates that each year roughly 1 out of 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases. The CDC states that reducing *foodborne illness by just 1% would keep about 500,000 Americans from getting sick each year; reducing foodborne illness by 10% would keep about 5 million from getting sick.*

In 2014, FDA initiated a Retail Food Safety Initiative<sup>1</sup> as part of its prevention-based, farm-to-table food safety strategy to reduce foodborne illness. A goal of FDA's Retail Food Safety Initiative is to "*Encourage widespread, uniform, and complete adoption of the FDA Food Code.*" To address this goal, FDA emphasizes benefits that can be realized when State, territorial, local, and tribal governments adopt the Food Code in its entirety. An important step in this process is engaging all stakeholders. FDA gained insights from the Restaurant Food Safety Partnership and the Retail Food Store Partnership established under the FDA Retail Food Safety Initiative when developing the document entitled, "*Benefits Associated with Complete Adoption and Implementation of the FDA Food Code*".<sup>2</sup>

As you seek to update the Colorado Retail Food Establishments (6 CCR 1010-2) food safety statutes, codes, and ordinances related to food safety, understanding and recognition of these twenty-one benefits by government, and the retail store, foodservice and vending industries should help to ensure complete and widespread Food Code adoption in Colorado.

### **Cross-cutting Benefits for Government and Industry**

1. Promotes uniform national standards for retail food safety to reduce complexity and better ensure compliance.

<sup>1</sup> For more information regarding the FDA Food Safety Initiative visit the link:  
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm230315.htm>

<sup>2</sup> FDA thanks the Restaurant Food Safety Partnership and the Retail Food Store Partnership for their insight in developing this document at:  
<https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm494616.htm>

2. Ensures food safety regulations reflect the most current science available and evolve to reflect new science and knowledge, emerging technologies and to remain current with other federal laws.
3. Created through a coordinated and collaborative process (Conference for Food Protection), the Food Code reflects input from all stakeholders: National, state and local regulators, industry, academia and consumers.
4. Stakeholders can take advantage of scientific and personnel resources expended by FDA and other agencies to ensure the FDA Food Code is complete.
5. Provides effective controls as a means of reducing the risks of foodborne illnesses within retail establishments, thus protecting consumers and industry from potentially devastating health consequences and financial losses.
6. Provides a comprehensive approach to food safety management and provides extensive supporting documents and training.
7. Facilitates and allows for standardization of inspections and inspectors.
8. May result in cost savings related to the conduct of inspections.
9. Reduces complexity and the paperwork burden for industry and government alike.
10. Improves consumers' understanding of food safety expectations.
11. Creates a common/standardized food safety language that can improve communication between regulators and industry operators.
12. Uniformity of using the same Food Code allows comparison of performance across national chains by providing standardized inspection criteria. Thereby an establishment can target resources according to science and risk to improve the public health performance of restaurants.
13. State and local agencies usage of FDA interpretations of Food Code reduces the work load associated with development of interpretations.
14. Creates a common/standardized language between regulators and industry.
15. Fosters a common understanding of risk, risk control/management and food safety between industry and regulators.
16. Reduces industry Food Safety training costs by allowing the utilization of training materials which can be used across all jurisdictions.

## Regulatory Benefits

1. Ensures conformance with *Standard No .1 – Regulatory Foundation* of FDA’s Voluntary National Retail Food Regulatory Program Standards.
2. Avoids errors caused when State and Local jurisdictions adopt only selected sections of the FDA Food Code (cross references may be missed or overlooked or incorrectly referenced).
3. Makes the process for updating laws and regulations at the State and Local level more efficient through elimination of redundant food code creation processes at the state and local regulatory level.
4. Conserves resources by allowing regulatory software providers to develop inspection tools that work at all jurisdictions.
5. Demonstrates food safety commitment and therefore increases eligibility for federal training, grants, cooperative agreements and other resources.

We are writing to you today to strongly encourage you to adopt the FDA Model Food Code as the Colorado Department of Health and Environment (Environmental Health and Sustainability Division) regulations governing food safety at the retail level.

### Recommendation:

Adoption and implementation of all the provisions in the FDA Model Food Code by the Colorado Department of Health and Environment (Environmental Health and Sustainability Division), can increase the safety of food sold at retail, and provide needed protections for all consumers, especially those at high-risk of foodborne illness and its serious consequences. We urge you to adopt the provisions of the FDA Model Food Code in their entirety.

Thank you for consideration of this information and recommendation.

---

October 27, 2017

Colorado Board of Health  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive, South EDO-A5  
Denver, CO 80246-1530

To whom it may concern:

Colorado State University (CSU), Environmental Health Services, Public Health Office, recognizes the benefit of adopting the FDA model Food Code and appreciates the opportunity to comment on the proposed amendment to the Colorado Retail Food Establishment Rules and Regulations. CSU is committed to addressing the critical challenge of improving food safety and promoting the public's health.

CSU fully supports the adoption and it is our opinion that the proposed amendments provide greater uniformity with national standards for retail food safety; they enhance regulatory compliance by reducing complexity in providing a common food safety language between states, jurisdictions, regulators and industry, which results in greater communication. The benefit of the adoption is that it provides a comprehensive preventative approach to food safety; thus, we support the regulation amendment as proposed.

Should you have questions concerning our position, please do not hesitate to contact me.

Sincerely,

**Jeannine Riess** MPH, HHS, CPFS  
Public Health Administrator

Environmental Health Services, *Public Health Office*



Troy Huffman, Retail Food Team Coordinator  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530

10/25/2017

Dear Mr. Huffman:

Chipotle Mexican Grill appreciates the opportunity to comment on the proposed adoption of the 2013 FDA Food Code and the 2015 Supplement to the Food Code as the Colorado Retail Food Establishment Rules and Regulations.

It is our opinion that the proposed adoption provides greater uniformity with national standards and other recognized public health standards. Thus, we support the regulation amendment as proposed.

Should you have questions concerning our position, please do not hesitate to contact me.

Respectfully,

A handwritten signature in black ink that reads "Amanda Spilos". The signature is written in a cursive style with a large loop at the end of the last name.

Amanda Spilos

Chipotle Mexican Grill, Health and Safety Manager





Troy Huffman, Program Coordinator  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530

October 24, 2017

Dear Mr. Huffman:

As a representative of PathTracer Laboratory & Consulting Services, I appreciate the opportunity to comment on the proposed amendment to the Colorado Retail Food Establishment Rules and Regulations.

As a former chairman of the Lincoln/Lancaster County Board of Health it is my opinion that the proposed amendments provide greater uniformity with national standards such as the FDA Model Food Code and other recognized public health standards. I battled the “islands of rules” and to this day, I don’t understand why a county thinks their rules should be different. The goals are the same, safe food.

Should you have questions concerning my position, please do not hesitate to contact me. I have lots of stories.

Respectfully,

*Richard Ross*

Richard Ross  
PathTracer Laboratory & Consulting Services

**Colorado Restaurant Association  
Statement on the  
Adoption of the 2013 FDA Model Food Code**

The Colorado Restaurant Association (CRA) represents nearly half of the more than 11,000 eating and drinking establishments in the State of Colorado who employ more than 275,000 Colorado residents. The CRA supports the Colorado Board of Health adoption of the 2013 FDA Model Food Code as the Colorado Food Code.

We have carefully reviewed a comparison between the current Colorado Food Code and the 2013 FDA Model Food Code (the FDA Code). While there will be minor operational changes for retail food establishments as a result of adopting the FDA Code, we feel that these changes are not overly burdensome and will contribute to increased food safety.

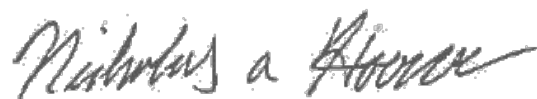
Adopting the FDA Code will allow the Colorado Department of Public Health and Environment (CDPHE), and local health departments, to be better stewards of the money that they receive from the industry. With the FDA Code, Colorado will have access to hundreds of documents and training materials, developed by the FDA, to help the industry and regulators apply the FDA Code. These are resources CDPHE would have to develop on their own if they opted to update the current version of Colorado's code instead.

Moving to the FDA Code will also support the intentions of Colorado House Bill 16-1401, which increased license fees on retail food establishments in exchange for increased consistency in application of the food code and retail inspection program. Businesses that operate in multiple states will be able to harmonize their practices in Colorado with other states that have adopted the FDA Code. Furthermore, CDPHE and local health departments will be able to utilize interpretations, formed by the FDA, instead of having to develop them independently. This will ensure that each local health department, including CDPHE, is applying the code in a more uniform manner, which benefits the industry.

Finally, adopting the FDA Code will make important practical changes to how CDPHE and local health departments interact with their regulated industry. The current food code is very restrictive, forcing establishments to appeal for variances from CDPHE to utilize new and developing practices. Because the FDA Code focuses on principals of food safety, instead of specific restrictive requirements, it allows regulators and industry to adapt to modern practices as they are developed without compromising public health.

Adoption of the FDA Code will help the retail food establishments in the State of Colorado because health departments will be better stewards of their funds, it will increase uniformity between local health departments and other states, and will allow the industry to work as partners with regulators as new practices are developed. The Colorado Restaurant Association asks you to adopt by reference the 2013 FDA Model Food Code as Colorado's food code.

Sonia Riggs, President & CEO



Nick Hoover, Manager of Government Affairs

**HEALTH DEPARTMENT***Serving Crowley & Otero Counties*

**Executive Director**  
Richard Ritter

**Program Directors**  
Aaron Olivieri, Training  
Susan Workman, Nursing  
Jo Jancar, WIC  
John Miller, Business  
Dr. Janell Maier, Epidemiology  
Michael Mustain, Tobacco Control  
Su Korbitz, Environmental  
Cassandra Rogers, Regional Health Connector  
Kristin Carpenter, Communities That Care

**Website:** [www.oterogov.com](http://www.oterogov.com)

**La Junta Office**  
13 West 3<sup>rd</sup> Street, Room 111  
La Junta, CO 81050  
Phone: (719) 383-3040

**Rocky Ford Office**  
811 South 13<sup>th</sup> Street  
Rocky Ford, CO 81067  
Phone: (719) 254-5300

**Ordway Office**  
603 Main, Courthouse Annex  
Ordway, CO 81063  
Phone: (719) 267-5245

Tuesday, October 31, 2017

To Whom It May Concern:

My name is Richard Ritter, and I am the Public Health Director for Crowley and Otero Counties in rural, Southeast Colorado. Please accept this correspondence as a letter of support for the adoption of the 2013 FDA Food Code as our Colorado Retail Food Regulations.

The proper regulation of retail food establishments is quintessential public health, protecting our populations from serious and potentially deadly foodborne pathogens. Su Korbitz, our Environmental Services Program Director, is the person responsible for retail food regulation in our combined jurisdiction of Crowley and Otero Counties. I have spoken to her multiple times about the Colorado adoption of the FDA Food Code, and we are both enthusiastic supporters of this meritorious idea.

The reason we support this initiative includes the following:

- ✓ The Food Code is a science-based code nationally supported from federal partners (FDA, CDC and USDA) and by industry.
- ✓ Incorporation strengthens connections to FDA resources/guidance that are readily available in eight or more languages for both LPHAs and industry.
- ✓ Aligns Colorado's retail food program with all other state and local retail food programs that use the national standard.
- ✓ Eliminates costly and time-consuming customization required with each revision of Colorado Regulation.
- ✓ Increases eligibility for state and local public health agencies for federal training, grants, and cooperative agreements by utilizing the model code.
- ✓ Simplifies the rule-making process, allowing stakeholders much more time to address training needs, data system modifications, communications with industry, impacts of new regulatory requirements, and other implementation logistics.

Without doubt, the most appealing facet of the FDA Food Code to me is the emphasis on food safety principles and less emphasis on prescriptive regulatory specifications, which will allow food safety technical experts to apply risk-based techniques when addressing retail food safety in their own unique jurisdictions. This enlightened approach of "*not one size fits all*" will address the diverse issues in the spectrum of rural to urban LPHA retail food regulation.

If you have any questions, please do not hesitate to contact me at 719-383-3045.

Sincerely,

Richard Ritter, Executive Director  
Otero County Health Department



195 W. 14<sup>th</sup> Street  
Rifle, CO 81650  
(970) 625-5200

2014 Blake Avenue  
Glenwood Springs, CO 81601  
(970) 945-6614

Troy Huffman, Program Coordinator  
Division of Environmental Health and Sustainability  
Colorado Department of Public Health and Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246-1530

October 30<sup>th</sup>, 2017

Dear Mr. Huffman:

As the Garfield County Environmental Health Manager, I support the proposed amendment of the Colorado Retail Food Establishment Rules and Regulations, specifically the adoption of the FDA Model Food Code.

The proposed amendments provide greater uniformity with national standards, other recognized public health standards, aligns with training provided to the regulating community, and is also supported by the regulated industry. We support the regulation amendment as proposed.

Thank you for the opportunity to provide comment.

Respectfully,

A handwritten signature in black ink that reads 'Joshua S. Williams'.

Joshua S. Williams  
Garfield County Environmental Health Manager  
195 W 14<sup>th</sup> St.  
Rifle, CO 81650  
[jwilliams@garfield-county.com](mailto:jwilliams@garfield-county.com)  
970-665-6380



October 31, 2017

Mr. Jeff Lawrence, Division Director  
Environmental Health & Sustainability Division  
Colorado Department of Public Health & Environment  
4300 Cherry Creek Drive South  
Denver, CO 80246

Dear Mr. Lawrence,

We're writing to support the incorporation of the 2013 Food & Drug Administration's (FDA) Model Food Code into the rules that govern retail food establishments in Colorado, and ask that you incorporate this letter into your packet for the Colorado Board of Health's rulemaking hearing scheduled for November 15, 2017.

Adoption of the most recent FDA Food Code represents a successful federal/state/local partnership in improving food safety and signals commitment to the goal of preventing and reducing the incidence of foodborne illness in retail food service establishments in Colorado. The 2013 FDA Model Food Code is an improvement to previous codes in that its performance-based approach allows for uniform implementation (a very important factor for the regulated industry) to be accomplished by having a highly trained staff in accordance with FDA Program Standard 2. Inasmuch as previous, more prescriptive codes are easier to interpret, they do not take into consideration the unique limitations that exist within retail food establishments that require equally unique operational controls to be implemented in order to adequately protect the dining public. By adopting the 2013 FDA Model Food Code, agencies will be more focused on the operational risk factors that cause foodborne illness.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kenneth Nordstrom".

Kenneth Nordstrom, REHS  
President

## **2017 DEHS Board of Health Presentation**

### Slide 1

# ***Colorado Retail Food Program Regulations***

January 2017 Program Overview and Regulation Evaluation

Troy Huffman, Colorado Retail Food Program Manager  
Sean Scott, Deputy Director DEHS



COLORADO  
Division of Environmental  
Health & Sustainability  
Department of Public Health & Environment


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### Slide 2

#### Overview - Program Size

- Approximately 21,000 retail food establishments (RFEs)<sup>1</sup>
  - Restaurants, groceries, convenience stores, food trucks, etc.
- Over 75% of RFEs are licensed as restaurants
  - >2 million meals served per day<sup>2</sup>
  - >\$11.6B in sales in 2016<sup>2</sup>
  - 38% increase in sales from 2010 to 2016<sup>2</sup>
- Local Public Health partners & CDPHE completed approximately 34,000 inspections and compliance assistance activities in FY 2016.

<sup>1</sup> Excludes City and County of Denver  
<sup>2</sup> Source: Colorado Restaurant Association



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### Slide 3

#### Overview - Program Staffing

- CDPHE delegates RFE authority, (e.g., inspection, licensing, and enforcement) to 33 local public health agencies (LPHAs)
  - LPHAs cover inspections and program activities in 59 counties
    - Over 150 LPHA staff work in some way with retail food
- CDPHE-DEHS staff directly service the program to six counties
- Typical workload :
  - 320 inspections per FTE<sup>1</sup>

<sup>1</sup> Based on FDA national program standards

### Slide 4

#### Overview - Program Budget

- Current retail food program funding is \$4.7M provided through annual license fees.
  - Based on FDA National Program Standards, budget would require \$8M annually.
  - Stakeholders review fees every 3 years. In 2015 fees were increased 50% over the next 3 years.
  - CDPHE collects \$43 from each license to fund program administration (approximately 13 percent of license fee)

## Slide 5

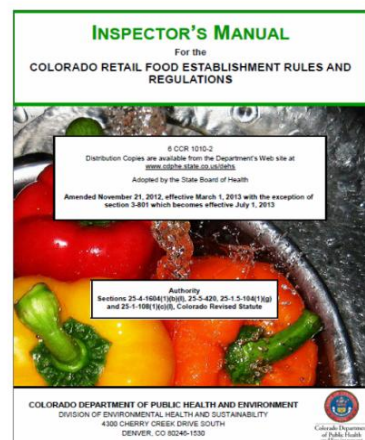
### Overview - Program Budget (cont.)

- Current underfunded program model
  - Strains LPHAs budgets to meet funding needs
  - Possible inequities generated based on different county budgets
- Future program model - preventative approach (FDA Food Code)
- Proactive adoption of the FDA code will allow full and effective use of the existing and future budget without increasing program costs.

## Slide 6

### Retail Food Regulations

- 6 CCR 1010-2 *Colorado Retail Food Establishment Rules and Regulations*
  - Last amended 2013
    - Rule revision pending - 2017
  - Based on 2009 FDA Model Food Code
  - Rule revision process (2010 - 2013)
  - 2013 revised Colorado regulations did not result in the expected outcome





## Slide 7

**Retail Food Regulation 2013 Revisions**

Colorado regulations in relation to the FDA code requirements

- Combined similar elements
- Reworded standard language
- Elaborated deeper into some topics
- Added new requirements



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## Slide 8

**Retail Food Regulation 2013 Revisions**

Unintended consequences...

- Broke connections to FDA resources that are provided at no cost
  - Necessitated developing Colorado-specific support resources (i.e., FDA-offered classroom and online training, inspection forms, handouts, posters, interpretations, materials in multiple languages)
- Omitted requirements
  - Lost some of the public health impact

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## Slide 9

### Retail Food Regulation 2013 Revisions

#### Unintended consequences...(cont.)

- Prescriptive language resulted in an increase in the number of variances requested by RFEs and resolved by the department (over 100 variance requests since 2013)
- Data tracking among other programs and with other states very challenging or impossible and can reduce compatibility of multi-state outbreak response protocol

## Slide 10

### Retail Food Regulation 2013 Revisions

#### **FDA Food Code** requirements for drainboards...

*4-204.119 - Sinks and drainboards of warewashing sinks and machines shall be self-draining.*

*4-301.13 - Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary utensil holding before cleaning and after sanitizing.*



Slide 11

**Retail Food Regulation 2013 Revisions**

**Colorado Regulations** requirements for drainboards:

**4-405 Drainboard and Dishtable Requirements**

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



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Slide 12

**Retail Food Regulation 2013 Revisions**

**Colorado regulation requirements for drainboards:**

**4-405 Drainboard and Dishtable Requirements**

D. ...

1. Drainboards and dishtables installed on the establishment's primary means for warewashing shall be sized in accordance with the following:

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



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Division of Environmental  
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## Slide 13

### Variances

Of 111 variances

- 76 requests where related to **non-critical** violations
- 35 requests where related to **critical** violations
- 42 are not in the Food Code (e.g., commercial freezer, handsink size, etc.)
- 9 discrepancies between CO Code and FDA Code (e.g., # of toilets required, grease trap location, etc.)
- If the FDA code was utilized, 22 critical violation variances would not have been necessary

We believe the FDA Food Code will reduce variance workload requests by over 50%

- The workload benefit will help us best utilize the ~3.7M funding gap and provide a RF landscape for consumers that is based on published code and not on individual variances

## Slide 14

### Public Health Elements **Not** Addressed in the Colorado Regulations

Date Marking


&


Manager Certification

## Slide 15

**Date Marking Potentially Hazardous Ready-to-eat Foods:**  
(controlling the growth of Listeria)

- Why is Date Marking Important?
  - Listeria can grow to dangerous levels when certain foods are held at refrigerated temperatures for extended periods. To assure the food is safe, it must be either consumed or discarded within seven days.
- What foods would require dates?
  - Potentially hazardous
  - Ready-to-eat
  - Refrigerated; and
  - Held more than 24 hours.



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Division of Environmental Health & Sustainability  
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## Slide 16

**Manager Certification:**

- Each State that has adopted the FDA code reported fewer foodborne norovirus outbreaks than did those states electing not to adopt<sup>1</sup>.
- CDC identified key provisions in the FDA code:
  - Prohibiting bare-hand contact
  - **Requiring a Certified Food Program Manager (missing in Colorado Regulations)**
  - Excluding ill staff for  $\geq 24$  h after symptom resolution
- Bogard et al. (2013) found that restaurants with a certified manager **reported better food safety practices**.
- Multiple facilities already require manager certification - not an industry burden



1 Kambhampati, et. 2016

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Division of Environmental Health & Sustainability  
Department of Public Health & Environment

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Slide 17

Proposal being considered:



Incorporate By Reference  
The FDA 2013 Food Code



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Health & Sustainability  
Department of Public Health & Environment


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Slide 18

## 2013 FDA Food Code Implementation

**FDA Food Code** - Science Based

- Robust national rulemaking process
  - Biannual Conference for Food Protection
    - Federal, State, Local, Tribal, Industry, Academia, Consumers all participate
    - HE/EJ - equal opportunity for representation for rural, smaller counties
  - Colorado has an active voice in the national process
    - State voting delegate
    - Colorado LPHA representation
    - Multiple state & local industry members
    - FDA Regional Specialist - Denver Office
    - 16 ongoing advisory committees



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## Slide 19

### 2013 FDA Food Code Implementation

- Streamline rulemaking process
  - National Support - FDA, CDC and USDA
  - Industry Support - State and National level
  - LPHA Support - Most support 100%, some have expressed concerns
  - Resources already available, guidance ready
    - HE/EJ - Operator resources available in 8 languages
- Repair broken connections to free FDA resources
- Reduce the number of variance requests
- Aligns Colorado's RF program with all other state programs that use the national standard.

## Slide 20

### 2013 Retail Food Regulation Implementation

#### Data systems

- Most data systems incorporate the FDA Food Code in off-the-shelf products.
  - No customization required with each revision of Colorado Regulation.
- Facilitates standardization of inspections and inspectors.
- Using the same uniform National Code allows for comparisons.
  - Industry - comparisons with across national chains.
  - Regulatory - national state and local partners.
- Provides a suite of resources for industry and LPHAs to utilize

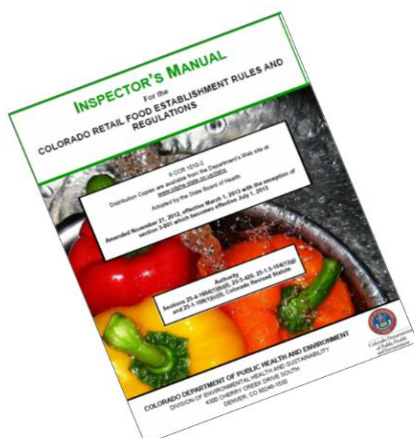
## Slide 21

### Relying on the FDA Food Code

- **Avoids errors** when only selected sections of the FDA Food Code are adopted (references may be missed, overlooked or incorrectly cited).
- **Makes the process more efficient** through elimination of redundant food code.
- **Conserves resources** by allowing software providers to develop inspection tools for jurisdictions more quickly/cheaply.
- **Demonstrates food safety commitment** and therefore increases eligibility for federal training, grants, and cooperative agreements.

## Slide 22

### Questions?





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

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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(1)(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, department policy guidance*  
60 pursuant to Section 25-4-1602(17), C.R.S., or other department-approved methods as  
61 authorized by statute and as appropriate to assure that retail food establishments  
62 comply with the Colorado Food Protection Act, part 16, article 4, 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),  
85 C.R.S.

## 86 87 2.5 License Requirements

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

## 91 92 2.6 Incorporation by Reference

93  
94 A. Throughout these regulations, standards and requirements of outside organizations  
95 have been adopted and incorporated by reference. The material incorporated by  
96 reference cited herein includes only those versions that were in effect on November

97 15, 2017, and no later amendments to the incorporated materials. These regulations  
98 incorporate by reference:  
99

- 100 1. *Food Code, 2013 Recommendations of the United States Public Health*  
101 *Service/Food and Drug Administration* as published by the U.S. Department of  
102 Health and Human Services, Public Health Service, Food and Drug  
103 Administration (*the Code*); and  
104
- 105 2. *Supplement to the 2013 Food Code (2015)*, U.S. Department of Health and  
106 Human Services, Public Health Service, Food and Drug Administration, (*the*  
107 *Supplement*).  
108

109 B. Any provision included or incorporated herein by reference which conflicts with the  
110 Colorado Revised Statutes, including but not limited to Section 25-4-1601, et seq.,  
111 C.R.S. and Section 25-1.5-102, C.R.S., shall be null and void.  
112

113 To align with Section 25-4-1601, et seq., C.R.S., these regulations do not incorporate  
114 by reference:  
115

- 116 1. *Subpart 8-203.10 (Preoperational Inspections) of the Code;*  
117
- 118 2. *Section 8-3 (Permit to Operate) of the Code;*  
119
- 120 3. *Subpart 8-401.10 (Establishing Inspection Interval) of the Code; and*  
121
- 122 4. *Subpart 8-401.20 (Performance- and Risk-Based) of the Code.*  
123

124 C. The Division of Environmental Health and Sustainability shall maintain certified copies  
125 of the complete text of the incorporated materials, which shall be available for public  
126 inspection during regular business hours, and shall provide certified copies of the  
127 materials at cost upon request. For information regarding how the incorporated  
128 materials may be obtained or examined, contact:  
129

130 Division Director  
131 Division of Environmental Health and Sustainability  
132 Colorado Department of Public Health and Environment  
133 4300 Cherry Creek Drive South  
134 Denver, Colorado 80246-1530  
135

136 D. The incorporated materials are available at:  
137

138 [www.colorado.gov/pacific/cdphe/food-regulations/food-code](http://www.colorado.gov/pacific/cdphe/food-regulations/food-code)  
139

## 140 **2.7 Temporary Retail Food Establishments**

  
141

### 142 **A. General**

  
143

144 A temporary retail food establishment shall comply with all requirements of these  
145 rules and regulations except as approved by the Regulatory Authority. A temporary  
146 retail food establishment application, which shall include a list of food items to be

147 sold, shall be submitted to the Regulatory Authority for each event. The application  
148 shall be submitted at least ten working days prior to the event.

149  
150 **B. Operations**

- 151
- 152 1. Approvals will be based upon the nature and extent of the proposed menu,  
153 equipment capacities, setup and the ability to handle and prepare food in a  
154 safe manner and protect against public health hazards.
  - 155
  - 156 2. Temporary retail food establishment operators shall maintain records detailing  
157 the source of all foods being held, stored, offered for sale, sold and  
158 distributed. These records shall be made available to the Regulatory Authority  
159 when requested.
  - 160
  - 161 3. Grease from grease-producing equipment and any wastewater shall not be  
162 discharged onto the ground or into any storm drainage system.
  - 163
  - 164 4. All food shall be maintained at required temperatures during all aspects of the  
165 operation including transportation.
  - 166
  - 167 5. A handwashing station, as required by the Regulatory Authority, shall be  
168 provided within the temporary retail food establishment that meets the  
169 operational needs of the establishment.

170  
171 **C. Commissary**

- 172
- 173 1. The Regulatory Authority's decision whether to require auxiliary support  
174 services such as a commissary or servicing area will be based on the menu,  
175 type of operation, duration of event and availability of on-board equipment and  
176 support services at the event.
  - 177
  - 178 2. The location of the commissary or servicing area shall be adequate to support  
179 operations and the safe handling of food.
- 180

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

~~6 CCR 1010-2  
Adopted by the State Board of Health~~

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



**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**

~~COLORADO DEPARTMENT OF PUBLIC HEALTH  
AND ENVIRONMENT  
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- 503 **CHAPTER 1**
- 504 **PURPOSE AND DEFINITIONS**
- 505 **1-101—Purpose**
- 506 The following rules and regulations shall be applied for the protection of public health.
- 507 The purpose of this Regulation is to safeguard public health and provide to consumers food that is  
508 safe and unadulterated. This Regulation establishes definitions; sets standards for management and  
509 personnel, food operations and equipment and facilities; and provides for food establishment plan  
510 review, license issuance, inspections, employee restriction and enforcement. This Regulation is  
511 intended to be the standard for the Department and its authorized agents and employees, to be applied  
512 uniformly by all parties.
- 513 **1-202—Definitions**
- 514 A. The following terms are defined for the purposes of the rules and regulations.
- 515 1. **“Accredited Program”** means a food protection manager certification program that has  
516 been evaluated and listed by an accrediting agency as conforming to the national standards  
517 for organizations that certify individuals. Accredited Program does not refer to training  
518 functions or educational programs.
- 519 2. **“Adulterated”** means as stated in the Colorado Pure Food and Drug Act, section 25-5-4,  
520 C.R.S.
- 521 3. **“Allergens”** See major food allergens definition 1-202(66).
- 522 4. **“Approved”** means acceptable to the Department, based on determination of conformity  
523 with principles, practices, and generally recognized standards that protect public health.
- 524 5. **“Asterisk (\*)”** means any section or portion thereof denoted with an \* indicates it is a  
525 critical item.
- 526 6. **“Asymptomatic”**:
- 527 a. Means without obvious symptoms; not showing or producing indications of a  
528 disease or other medical condition, such as an individual infected with a pathogen  
529 but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or  
530 jaundice.
- 531 b. Includes not showing symptoms because symptoms have resolved or subsided, or  
532 because symptoms never manifested.
- 533 7. **“ $a_w$ ”** means water activity which is a measure of the free moisture in a food, is the quotient  
534 of the water vapor pressure of the substance divided by the vapor pressure of pure water at  
535 the same temperature, and is indicated by the symbol  $a_w$ .
- 536 8. **“Balut”** means an embryo inside a fertile egg that has been incubated for a period sufficient  
537 for the embryo to reach a specific stage of development after which it is removed from  
538 incubation before hatching.
- 539 9. **“Bulk Foods”** means foods as defined in section 25-4-1302, C.R.S.
- 540 10. **“Catering Operation”** means a retail food establishment that provides a contracted,  
541 prearranged number of meals and/or food products that are prepared at a licensed retail food

- 542 establishment for service and consumed at the same or another prearranged offsite location  
543 and not available for individual purchase.
- 544 11. ~~“Certified Food Protection Manager” means a person in charge that is certified by an~~  
545 ~~accredited program for food protection.~~
- 546 12. ~~“CFR” means Code of Federal Regulations. Citations in this Code to the CFR refer~~  
547 ~~sequentially to the Title, Part, and Section numbers, such as 40 CFR 180.194 refers to Title~~  
548 ~~40, Part 180, Section 194.~~
- 549 13. ~~“Clean In Place (CIP)” means cleaned in place by the circulation or flowing by mechanical~~  
550 ~~means through a piping system of a detergent solution, water rinse, and sanitizing solution~~  
551 ~~onto or over equipment surfaces that require cleaning, such as the method used, in part, to~~  
552 ~~clean and sanitize a frozen dessert machine.~~
- 553 ~~— CIP does not include the cleaning and sanitization of equipment such as band saws, cutting~~  
554 ~~boards, slicers or mixers that are subjected to in place manual cleaning without the use of an~~  
555 ~~automated CIP system.~~
- 556 14. ~~“Commercial Design” means equipment that is certified or classified by an American~~  
557 ~~National Standards Institute (ANSI) accreditation certification program, such as the National~~  
558 ~~Sanitation Foundation (NSF), Underwriters Laboratories (UL) sanitation standards,~~  
559 ~~Environmental Testing Laboratories, Inc. (ETL) sanitation standards, Baking Industry~~  
560 ~~Sanitation Standards Committee (BISSC), or other comparable design criteria as approved~~  
561 ~~by the Department during a standardized equipment review.~~
- 562 15. ~~“Commingle” means:~~
- 563 a. ~~To combine shellstock harvested on different days or from different growing areas~~  
564 ~~as identified on the tag or label, or~~
- 565 b. ~~To combine shucked shellish from containers with different container codes or~~  
566 ~~different shucking dates.~~
- 567 16. ~~“Comminuted” means reduced in size by methods including chopping, flaking, grinding, or~~  
568 ~~mincing. This includes fish or meat products that are reduced in size and restructured or~~  
569 ~~reformulated such as gefilte fish, formed roast beef, gyros, ground beef, and sausage; and a~~  
570 ~~mixture of two or more types of meat which have been reduced in size and combined, such~~  
571 ~~as sausages made from two or more meats.~~
- 572 17. ~~“Commissary” means a facility that is approved by the Department as a base of operation~~  
573 ~~for a temporary retail food establishment, pushcart, or mobile food establishment where~~  
574 ~~food, containers, or supplies are kept, handled, prepared, packaged or stored and is~~  
575 ~~constructed and operated in compliance with the Rules and Regulations.~~
- 576 18. ~~“Conditional Employee” means a potential food employee to whom a job offer is made,~~  
577 ~~conditional on responses to subsequent medical questions or examinations designed to~~  
578 ~~identify potential food employees who may be suffering from a disease that can be~~  
579 ~~transmitted through food and done in compliance with Title 1 of the Americans with~~  
580 ~~Disabilities Act of 1990.~~
- 581 19. ~~“Contamination” means exposure to or contact with a contaminant. Actions that may~~  
582 ~~contaminate or cause contamination include: unsanitary food contact surfaces, coughing,~~  
583 ~~sneezing, spitting, unnecessary handling, flooding, draining, leakage from overhead pipes,~~  
584 ~~and condensation. “Contaminant” means a substance, organism, or entity that might cause~~  
585 ~~disease or threaten public health, and includes soil, dust, insects, rodents, other pests, and~~  
586 ~~poisonous or toxic materials.~~

- 587 20. ~~“Confirmed Disease Outbreak” means a foodborne disease outbreak in which laboratory~~  
588 ~~analysis of appropriate specimens identifies a causative agent and epidemiological analysis~~  
589 ~~implicates the food as the source of the illness.~~
- 590 21. ~~“Corrosion Resistant Materials” means a material that maintains acceptable surface~~  
591 ~~cleanability characteristics under prolonged influence of the food to be contacted, the normal~~  
592 ~~use of cleaning compounds and sanitizing solutions, and other conditions of the use~~  
593 ~~environment.~~
- 594 22. ~~“Critical Control Point” means any point in a food preparation process at which loss of~~  
595 ~~control might result in an unacceptable consumer health risk.~~
- 596 23. ~~“Critical item” means a provision of these rules and regulations that, if in noncompliance, is~~  
597 ~~more likely than other violations to contribute to food contamination, illness, or an~~  
598 ~~environmental health hazard. These are items denoted in these rules and regulations with an~~  
599 ~~asterisk \*.~~
- 600 24. ~~“Critical Limit” means the maximum or minimum value to which a physical, biological, or~~  
601 ~~chemical parameter must be controlled at a critical control point to minimize the risk that the~~  
602 ~~identified food safety hazard may occur.~~
- 603 25. ~~“Cross Connection” means any connection or arrangement, physical or otherwise, between~~  
604 ~~a potable water supply system and any plumbing fixture or any tank, receptor, equipment or~~  
605 ~~device, to which it may be possible for non-potable, used, unclean, polluted or contaminated~~  
606 ~~water, or other substances, to enter any part in such potable water system under any~~  
607 ~~condition.~~
- 608 26. ~~“Cross contamination” means the transfer of harmful bacteria to food from other foods,~~  
609 ~~such as raw or undercooked animal products, to cutting boards, utensils, etc. if they are not~~  
610 ~~handled properly.~~
- 611 27. ~~“Cut Leafy Greens” means fresh leafy greens whose leaves have been cut, shredded, sliced,~~  
612 ~~chopped, or torn. The term “leafy greens” includes iceberg lettuce, romaine lettuce, leaf~~  
613 ~~lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole,~~  
614 ~~endive, spring mix, spinach, cabbage, kale, arugula and chard. The term “leafy greens” does~~  
615 ~~not include herbs such as cilantro or parsley.~~
- 616 28. ~~“Department” means the Colorado Department of Public Health and Environment, and its~~  
617 ~~authorized employees as well as any county or district board of health who have been~~  
618 ~~delegated the powers and duties described in Sections 25-4-1604(1)(a), (c), (d) and (h)~~  
619 ~~C.R.S.~~
- 620 29. ~~“Drinking Water”~~
- 621 a. ~~“Drinking Water” means water that meets criteria as specified in section 25-1.5-2,~~  
622 ~~C.R.S., *Colorado Primary Drinking Water Regulations*~~
- 623 b. ~~“Drinking Water” is traditionally known as “potable water.”~~
- 624 c. ~~“Drinking Water” includes the term “water” except where the term used connotes~~  
625 ~~that the water is not potable, such as “boiler water,” “mop water,” “rainwater,”~~  
626 ~~“wastewater,” and “nondrinking” water.~~
- 627 30. ~~“Dry Storage Area” means a room or area designated for the storage of packaged or~~  
628 ~~containerized bulk food that is not potentially hazardous (time and temperature control for~~  
629 ~~food safety) and dry goods such as single-service items.~~

- 630 31. ~~“Easily Cleanable” means surfaces are readily accessible and fabricated of such materials~~  
631 ~~and finishes that residue can be effectively removed by normal cleaning methods.~~
- 632 32. ~~“Egg” means the shell egg of avian species such as chicken, duck, goose, guinea, quail,~~  
633 ~~ratites or turkey.~~
- 634 ~~“Egg” does not include:~~
- 635 a. ~~A balut;~~
- 636 b. ~~The egg of reptile species such as alligator; or~~
- 637 c. ~~An egg product.~~
- 638 33. ~~“Egg Product”~~
- 639 a. ~~“Egg Product” means all, or a portion of, the contents found inside eggs separated~~  
640 ~~from the shell and pasteurized in a food processing plant, with or without added~~  
641 ~~ingredients, intended for human consumption, such as dried, frozen or liquid eggs~~
- 642 b. ~~“Egg Product” does not include food which contains eggs only in a relatively small~~  
643 ~~proportion such as cake mixes.~~
- 644 34. ~~“Employee” means the licensee, person in charge, food employee, person having~~  
645 ~~supervisory or management duties, person on the payroll, family member, volunteer, person~~  
646 ~~performing work under contractual agreement, and any person working in a food~~  
647 ~~establishment.~~
- 648 35. ~~“Enterohemorrhagic Escherichia coli” means E. coli which cause hemorrhagic colitis,~~  
649 ~~meaning bleeding enterically or bleeding from the intestine. The term is typically used in~~  
650 ~~association with E. coli that have the capacity to produce Shiga toxins and to cause attaching~~  
651 ~~and effacing lesions in the intestine. EHEC is a subset of Shiga toxin producing E. coli~~  
652 ~~(STEC), whose members produce additional virulence factors. Infections with EHEC may~~  
653 ~~be asymptomatic but are classically associated with bloody diarrhea (hemorrhagic colitis)~~  
654 ~~and hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP).~~  
655 ~~Examples of serotypes of EHEC include: E. coli O157:H7; E. coli O157:NM; E. coli~~  
656 ~~O26:H11; E. coli O145:NM; E. coli O103:H2; or E. coli O111:NM. Also see Shiga toxin-~~  
657 ~~producing E. coli.~~
- 658 36. ~~“EPA” means the U.S. Environmental Protection Agency~~
- 659 37. ~~“Equipment” means an article used in the operation of a food establishment, such as, but~~  
660 ~~not limited to a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach in~~  
661 ~~refrigerator, range, scale, sink, slicer, stove, table, temperature measuring device, or~~  
662 ~~warewashing machine.~~
- 663 ~~Equipment does not include items used for handling or storing large quantities of packaged~~  
664 ~~foods received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts,~~  
665 ~~dollies, pallets, racks, and skids.~~
- 666 38. ~~“Exclude” means to prevent a person from working as an employee in a food establishment~~  
667 ~~or entering a food establishment as an employee.~~
- 668 39. ~~“Extensively Remodeled” means any major alteration of an existing configuration in a food~~  
669 ~~establishment which might affect the food operation that results in one or more of the~~  
670 ~~following conditions:~~



- 671 a. ~~Seating capacity, including service provided anywhere on the premises, is increased~~  
 672 ~~by a minimum of 15 seats or 20 percent whichever is greater in either a single~~  
 673 ~~construction project or an incremental series of construction activities;~~
- 674 b. ~~Alterations or revisions involving retail food establishments or related equipment~~  
 675 ~~that require a building or construction permit by local building authorities. Routine~~  
 676 ~~maintenance, repairs or cosmetic changes shall not be defined as extensive~~  
 677 ~~remodeling;~~
- 678 c. ~~Changes or alterations made in the nonpublic areas that result in a reduction or~~  
 679 ~~increase of total space by 25 percent or more; or~~
- 680 d. ~~The facility's capabilities to handle food, equipment, and utensils in a sanitary~~  
 681 ~~manner have been diminished due to a food process or significant menu change that~~  
 682 ~~introduces new risks for foodborne illness.~~
- 683 40. ~~“Fish”~~
- 684 a. ~~“Fish” means fresh or saltwater finfish, crustaceans and other forms of aquatic life~~  
 685 ~~(including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and~~  
 686 ~~the roe of such animals) other than birds or mammals, and all mollusks, if such~~  
 687 ~~animal life is intended for human consumption.~~
- 688 b. ~~“Fish” includes an edible human food product derived in whole or in part from fish,~~  
 689 ~~including fish that have been processed in any manner.~~
- 690 41. ~~“Food” means a raw, cooked, or processed edible substance, ice, beverage, or ingredient~~  
 691 ~~used or intended for use or for sale in whole or in part for human consumption.~~
- 692 42. ~~“Foodborne Disease Outbreak” means an incident in which:~~
- 693 a. ~~Two or more otherwise unrelated persons experience a similar illness after ingestion~~  
 694 ~~of a common food; and~~
- 695 b. ~~Epidemiological analysis implicates the food as the source of the illness.~~
- 696 43. ~~“Foodborne Illness Risk Factor” means the five most significant contributing factors,~~  
 697 ~~behaviors and practices, which have been determined to contribute directly to foodborne~~  
 698 ~~illness within retail food establishments by the Centers for Disease Control and Prevention.~~  
 699 ~~The five categories are:~~
- 700 a. ~~Food from unsafe sources~~
- 701 b. ~~Inadequate cooking~~
- 702 c. ~~Improper holding temperatures~~
- 703 d. ~~Contaminated equipment~~
- 704 e. ~~Poor personal hygiene~~
- 705 44. ~~“Food Contact Surfaces” means those surfaces of equipment and utensils with which food~~  
 706 ~~normally comes in contact, and those surfaces from which food may drain, drip, or splash~~  
 707 ~~back onto surfaces in contact with food. This excludes ventilation hoods.~~
- 708 45. ~~“Food Employee” means an individual who works directly with unpackaged food, food~~  
 709 ~~equipment or utensils, or food contact surfaces. A food employee does not include~~  
 710 ~~employees who are hostesses, servers and/or others who do not directly handle food or clean~~  
 711 ~~equipment and utensils.~~

- 712 46. ~~“Food Preparation” means packaging, processing, assembling, portioning, or any operation~~  
713 ~~that changes the form, flavor, or consistency of food, but does not include trimming of~~  
714 ~~produce for display prior to sale.~~
- 715 47. ~~“Food Processing Establishment” means an establishment in which food is processed,~~  
716 ~~prepared, packaged, and distributed for human consumption and approved by the~~  
717 ~~Department.~~
- 718 48. ~~“Game Animal”~~
- 719 a. ~~“Game Animal” means an animal, the products of which are food, that is not~~  
720 ~~classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR~~  
721 ~~301.2 Definitions, or as poultry, or fish.~~
- 722 b. ~~“Game Animal” includes mammals such as reindeer, elk, deer, antelope, water~~  
723 ~~buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic~~  
724 ~~reptiles such as land snakes.~~
- 725 c. ~~“Game Animal” does not include ratites such as emu, ostrich and rhea~~
- 726 49. ~~“Ground Beef” means meat that is derived from the voluntary striated muscle of beef, with~~  
727 ~~a maximum of thirty percent total fat by weight, with no water, phosphates, extenders, or~~  
728 ~~binders added.~~
- 729 50. ~~“HACCP Plan” means a written document that delineates the formal procedures for~~  
730 ~~following the Hazard Analysis Critical Control Point principles.~~
- 731 51. ~~“Handwashing Sink” means a lavatory, a basin or vessel for washing, a wash basin, or a~~  
732 ~~plumbing fixture especially placed for use in personal hygiene and designed for the washing~~  
733 ~~of the hands.~~
- 734 52. ~~“Hazard” means a biological, chemical, or physical property that might cause an~~  
735 ~~unacceptable consumer health risk.~~
- 736 53. ~~“Health Practitioner” means a physician licensed to practice medicine, or if allowed by~~  
737 ~~law, a nurse practitioner, physician assistant, or similar medical professional.~~
- 738 54. ~~“Hermetically Sealed Container” means a container designed and intended to be secure~~  
739 ~~against the entry of microorganisms and to maintain the commercial sterility of its content~~  
740 ~~after processing.~~
- 741 55. ~~“Highly Susceptible Population” means persons who are more likely than other people in~~  
742 ~~the general population to experience foodborne disease because they are~~  
743 ~~immunocompromised, preschool age children, or older adults; and they obtain food at a~~  
744 ~~facility that provides services such as custodial care, health care, or assisted living, such as a~~  
745 ~~child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional~~  
746 ~~or socialization services such as a senior center.~~
- 747 56. ~~“Hygroscopic” means readily taking up and retaining moisture.~~
- 748 57. ~~“Imminent Health Hazard” means a significant threat or danger to health that is considered~~  
749 ~~to exist when there is evidence sufficient to show that a product, practice, circumstance, or~~  
750 ~~event creates a situation that requires immediate correction or cessation of operation to~~  
751 ~~prevent injury or illness based on:~~
- 752 a. ~~The number of potential injuries or illnesses, and~~
- 753 b. ~~The nature, severity, and duration of the anticipated injury or illness.~~

- 754 58. — ~~“**Injected**” means manipulating meat to which a solution has been introduced into its interior~~  
755 ~~by processes that are referred to as “injecting,” “pump marinating,” or “stitch pumping”.~~
- 756 59. — ~~“**Inspection**” means an inspection of a retail food establishment conducted by the~~  
757 ~~department or a county or district board of health to ensure compliance by such~~  
758 ~~establishment with these rules.~~
- 759 60. — ~~“**Juice**”~~
- 760 a. — ~~“**Juice**” means the aqueous liquid expressed or extracted from one or more fruits or~~  
761 ~~vegetables, purées of the edible portions of one or more fruits or vegetables, or any~~  
762 ~~concentrates of such liquid or purée.~~
- 763 b. — ~~“**Juice**” does not include, for purposes of HACCP, liquids, purées, or concentrates~~  
764 ~~that are not used as beverages or ingredients of beverages.~~
- 765 61. — ~~“**Kitchenware**” means all multi-use utensils other than tableware, used in the storage,~~  
766 ~~preparation, transportation or serving of food.~~
- 767 62. — ~~“**Law**” means applicable local, state, and federal statutes, regulations, and ordinances.~~
- 768 63. — ~~“**License**” means a grant to a license to operate a retail food establishment.~~
- 769 64. — ~~“**Licensee**” means a person that is licensed or who holds a certificate of license and is~~  
770 ~~responsible for the lawful operation of a retail food establishment.~~
- 771 65. — ~~“**Linens**” means fabric items such as cloth hampers, cloth napkins, tablecloths, wiping~~  
772 ~~cloths, and work garments including cloth gloves.~~
- 773 66. — ~~“**Major Food Allergen**”~~
- 774 a. — ~~“**Major Food Allergen**” means: Milk, egg, fish (such as bass, flounder, cod, and~~  
775 ~~including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as~~  
776 ~~almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or a food ingredient~~  
777 ~~that contains protein derived from a food, as specified in this paragraph.~~
- 778 b. — ~~“**Major Food Allergen**” does not include: Any highly refined oil derived from a~~  
779 ~~food specified in paragraph (a) of this definition and any ingredient derived from~~  
780 ~~such highly refined oil; or any ingredient that is exempt under the petition or~~  
781 ~~notification process specified in the Food Allergen Labeling and Consumer~~  
782 ~~Protection Act of 2004 (Public Law 108-282).~~
- 783 67. — ~~“**Meat**” means the flesh of animals used as food including the dressed flesh of cattle, swine,~~  
784 ~~sheep, or goats and other edible animals, except fish, poultry, and wild game animals.~~
- 785 68. — ~~“**Mechanically Tenderized**”~~
- 786 a. — ~~“**Mechanically Tenderized**” means manipulating meat with deep penetration by~~  
787 ~~processes which may be referred to as “blade tenderizing,” “jaccarding,” “pinning,”~~  
788 ~~“needling,” or using blades, pins, needles or any mechanical device.~~
- 789 b. — ~~“**Mechanically Tenderized**” does not include processes by which solutions are~~  
790 ~~injected into meat.~~
- 791 69. — ~~“**mg/L**” means milligrams per liter, which is the metric equivalent of parts per million~~  
792 ~~(ppm).~~
- 793 70. — ~~“**Mobile Retail Food Establishment**” means a retail food establishment that is a wheeled~~  
794 ~~vehicle or trailer that is readily moveable and designed for the service of food from the~~

- 795 interior of the unit that is intended to physically report to and operate from a commissary for  
796 servicing, restocking, and maintenance each operating day.
- 797 71. ~~“Molluscan Shellfish” means any edible species of fresh or frozen oysters, clams, mussels,~~  
798 ~~and scallops or edible portions thereof, except when the scallop product consists only of the~~  
799 ~~shucked adductor muscle.~~
- 800 72. ~~“New Retail Food Establishment” means a facility that makes its initial application as a~~  
801 ~~retail food establishment, a facility that changes its physical location, a newly constructed or~~  
802 ~~extensively remodeled establishment, or when there is a change in the Department of~~  
803 ~~Revenue Sales Tax ID Number.~~
- 804 73. ~~“Nonfood Contact Surfaces” means all surfaces other than food contact surfaces.~~
- 805 74. ~~“Non-Continuous Cooking”:~~
- 806 a. ~~Means the cooking of food in a food establishment using a process in which the~~  
807 ~~initial heating of the food is intentionally halted so that it may be cooled and held for~~  
808 ~~complete cooking at a later time prior to sale or service such as, but not limited to,~~  
809 ~~the par cooking of bacon.~~
- 810 b. ~~Does not include cooking procedures that only involve temporarily interrupting or~~  
811 ~~slowing an otherwise continuous cooking process.~~
- 812 75. ~~“Non-Critical item”:~~
- 813 a. ~~Means a provision in this Code that is not designated as a critical item.~~
- 814 b. ~~Does not include cooking procedures that only involve temporarily interrupting or~~  
815 ~~slowing an otherwise continuous cooking process.~~
- 816 76. ~~“Packaged”~~
- 817 a. ~~Means bottled, canned, cartoned, securely bagged, or securely wrapped, whether~~  
818 ~~packaged in a food establishment or a food processing plant.~~
- 819 b. ~~“Packaged” does not include a wrapper, carry out box, or other nondurable~~  
820 ~~container used to containerize food with the purpose of facilitating food protection~~  
821 ~~during service and receipt of the food by the consumer.~~
- 822 77. ~~“Person” means an association, a corporation, individual, partnership, other legal entity,~~  
823 ~~government, or governmental subdivision or agency.~~
- 824 78. ~~“Person In Charge” means the individual present at a retail food establishment who is~~  
825 ~~responsible for the operation at the time of inspection. If no individual is responsible, then~~  
826 ~~any employed person present is the person in charge.~~
- 827 79. ~~“Personal Care Items” means items or substances that may be poisonous, toxic, or a source~~  
828 ~~of contamination which are used to maintain or enhance a person's health, hygiene, or~~  
829 ~~appearance, such as medicines, first aid supplies, cosmetics, toiletries such as lotion,~~  
830 ~~toothpaste and mouthwash.~~
- 831 80. ~~“pH” means the measure of the degree of acidity or alkalinity of a solution. pH between 0~~  
832 ~~and 7 indicate acidity and pH between 7 and 14 indicate alkalinity. The value for pure~~  
833 ~~distilled water is 7, which is considered neutral.~~
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836 81. ~~“Physical Facilities” means the structure and interior surfaces of a retail food establishment~~  
837 ~~including floors, walls, ceilings, lighting, and premises, including, but not limited to~~  
838 ~~accessories such as soap and towel dispensers and attachments such as light fixtures and~~  
839 ~~heating or air conditioning system vents.~~
- 840 82. ~~“Poisonous or Toxic Materials” means substances not intended for ingestion and are~~  
841 ~~included in four categories:~~
- 842 a. ~~Cleaners and sanitizers, which include cleaning and sanitizing agents and agents~~  
843 ~~such as caustics, acids, drying agents, polishes, and other chemicals;~~
- 844 b. ~~Pesticides, which include substances such as insecticides and rodenticides;~~
- 845 c. ~~Substances necessary for the operation and maintenance of the establishment such as~~  
846 ~~nonfood grade lubricants and personal care items that may be deleterious to health;~~  
847 ~~and~~
- 848 d. ~~Substances that are not necessary for the operation and maintenance of the~~  
849 ~~establishment and are on the premises for retail sale, such as petroleum products and~~  
850 ~~paints.~~
- 851 83. ~~“Potentially Hazardous Food (Time/Temperature Control for Safety Food)”~~
- 852 a. ~~“Potentially Hazardous Food (time/temperature control for safety food)” means a~~  
853 ~~food that requires time/temperature control for safety (TCS) to limit pathogenic~~  
854 ~~microorganism growth or toxin formation.~~
- 855 b. ~~“Potentially Hazardous Food (time/temperature control for safety food)” includes:~~
- 856 (1) ~~A food of animal origin that is raw or heat treated; a food of plant origin~~  
857 ~~that is heat treated or consists of raw seed sprouts, cut melons, cut leafy~~  
858 ~~greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a~~  
859 ~~way so that they are unable to support pathogenic microorganism growth or~~  
860 ~~toxin formation, or garlic in oil mixtures that are not modified in a way so~~  
861 ~~that they are unable to support pathogenic microorganism growth or toxin~~  
862 ~~formation; and~~
- 863 (2) ~~Except as specified in Subparagraph (c)(4) of this definition, a food that~~  
864 ~~because of the interaction of its a<sub>w</sub> and pH values is designated as Product~~  
865 ~~Assessment Required (PA) in Table A or B of this definition.~~

| <b>Table A. Interaction of pH and aw for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged</b> |                         |                      |                      |
|---|-------------------------|----------------------|----------------------|
| <b>aw values</b>  | <b>pH values</b>        |                      |                      |
|   | <b>4.6 or less</b>      | <b>&gt;4.6–5.6</b>   | <b>&gt;5.6</b>       |
| <b>≤0.92</b>  | non-PHF*/non-TCS food** | non-PHF/non-TCS food | non-PHF/non-TCS food |
| <b>&gt;0.92–.95</b>   | non-PHF/non-TCS food    | non-PHF/non-TCS food | PA***                |
| <b>&gt;0.95</b>   | 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

| <b>Table B. Interaction of pH and a<sub>w</sub> for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged</b> |                          |                       |                       |                       |
|--|--------------------------|-----------------------|-----------------------|-----------------------|
| <b>a<sub>w</sub> values</b>  | <b>pH values</b>         |                       |                       |                       |
|  | <b>&lt;4.2</b>           | <b>4.2–4.6</b>        | <b>&gt;4.6–5.0</b>    | <b>≥5.0</b>           |
| <b>&lt;0.88</b>  | non-PHF*/ non-TCS food** | non-PHF/ non-TCS food | non-PHF/ non-TCS food | non-PHF/ non-TCS food |
| <b>0.88–0.90</b>   | non-PHF/ non-TCS food    | non-PHF/ non-TCS food | non-PHF/ non-TCS food | PA***                 |
| <b>&gt;0.90–0.92</b>   | non-PHF/ non-TCS food    | non-PHF/ non-TCS food | PA                    | PA                    |
| <b>&gt;0.92</b>  | 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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- e. ~~"Potentially Hazardous Food (time/temperature control for safety food)" does not include:~~
- ~~(1) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae; and~~
  - ~~(2) A food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution.~~
  - ~~(3) A food that because of its pH or a<sub>w</sub> value, or interaction of a<sub>w</sub> and pH values, is designated as a non-PHF/non-TCS food in Table A or B of this definition;~~
  - ~~(4) A food that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:
 
    - ~~(a) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;~~
    - ~~(b) Extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use, of~~
    - ~~(c) a combination of intrinsic and extrinsic factors; or~~~~
  - ~~(5) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subparagraphs (c)(1)–(4) of~~

- 892   ~~this definition even though the food may contain a pathogenic~~  
893   ~~microorganism or chemical or physical contaminant at a level sufficient to~~  
894   ~~cause illness or injury.~~
- 895         84. ~~“Poultry” means any domesticated bird such as chickens, turkeys, ducks, geese, or guineas~~  
896   ~~or squabs and any migratory waterfowl, game bird, such as pheasant, partridge, quail,~~  
897   ~~grouse, or pigeon.~~
- 898         85. ~~“Premises” means the physical facility, its contents, and the contiguous land or property and~~  
899   ~~its facilities and contents that may impact retail food establishment personnel, facilities, or~~  
900   ~~operations.~~
- 901         86. ~~“Primal Meat Cuts” means a basic major cut into which carcasses and sides of meat are~~  
902   ~~separated, such as a beef round, pork loin, lamb flank, or veal breast.~~
- 903         87. ~~“Private Boarding Houses” means a house at which meals, or meals and lodging, may be~~  
904   ~~obtained for payment.”~~
- 905   ~~“Private Boarding Houses” does not include:~~
- 906   a. ~~Hotels~~
- 907   b. ~~Motels~~
- 908   c. ~~Homeless shelters~~
- 909   d. ~~Youth hostel~~
- 910   e. ~~Other commercial facilities providing lodging and/or meals for the indigent~~  
911   ~~population whether or not there is a charge for such food and/or lodging.~~
- 912         88. ~~“Pushcart” means a retail food establishment that is a non-motorized, unit designed so~~  
913   ~~foods are served from the exterior of the unit, and which is intended to physically report~~  
914   ~~to and operate from a commissary for servicing, restocking and maintenance each~~  
915   ~~operating day.~~
- 916         89. ~~“Ratite” means a flightless bird such as an emu, ostrich, or rhea.~~
- 917         90. ~~“Ready-to-Eat Food” means food that is edible without further washing, cooking, or~~  
918   ~~additional preparation and that is reasonably expected to be consumed in that form.~~  
919   ~~Ready-to-eat food does not include whole, raw fruits and vegetables that are intended for~~  
920   ~~washing by the consumer before consumption~~
- 921         91. ~~“Reconstituted” means dehydrated food products recombined with water or other~~  
922   ~~liquids.~~
- 923         92. ~~“Reduced Oxygen Packaging”~~
- 924   a. ~~“Reduced Oxygen Packaging” means:~~
- 925   (1) ~~The reduction of the amount of oxygen in a package by removing~~  
926   ~~oxygen; displacing oxygen and replacing it with another gas or~~  
927   ~~combination of gases; or otherwise controlling the oxygen content to a~~  
928   ~~level below that normally found in the atmosphere (approximately 21%~~  
929   ~~at sea level); and~~
- 930   (2) ~~A process as specified in section (a)(1) of this definition that involves a~~  
931   ~~food for which the hazards Clostridium botulinum or Listeria~~  
932   ~~monocytogenes require control in the final packaged form.~~
- 933   b. ~~“Reduced Oxygen Packaging” includes:~~

- 934 (1) ~~Vacuum packaging, in which air is removed from a package of food and~~  
 935 ~~the package is hermetically sealed so that a vacuum remains inside the~~  
 936 ~~package;~~
- 937 (2) ~~Modified atmosphere packaging, in which the atmosphere of a package~~  
 938 ~~of food is modified so that its composition is different from air but the~~  
 939 ~~atmosphere may change over time due to the permeability of the~~  
 940 ~~packaging material or the respiration of the food. Modified atmosphere~~  
 941 ~~packaging includes reduction in the proportion of oxygen, total~~  
 942 ~~replacement of oxygen, or an increase in the proportion of other gases~~  
 943 ~~such as carbon dioxide or nitrogen;~~
- 944 (3) ~~Controlled atmosphere packaging, in which the atmosphere of a package~~  
 945 ~~of food is modified so that until the package is opened, its composition is~~  
 946 ~~different from air, and continuous control of that atmosphere is~~  
 947 ~~maintained, such as by using oxygen scavengers or a combination of~~  
 948 ~~total replacement of oxygen, nonrespiring food, and impermeable~~  
 949 ~~packaging material;~~
- 950 (4) ~~Except as specified in section (c), Cook chill packaging, in which cooked~~  
 951 ~~food is hot filled into impermeable bags which have the air expelled and~~  
 952 ~~are then sealed or crimped closed, the bagged food is rapidly chilled and~~  
 953 ~~refrigerated at temperatures that inhibit the growth of psychrotrophic~~  
 954 ~~pathogens; or~~
- 955 (5) ~~Sous vide packaging, in which raw or partially cooked food is vacuum~~  
 956 ~~packaged in an impermeable bag, cooked, rapidly chilled, and~~  
 957 ~~refrigerated at temperatures that inhibit the growth of psychrotrophic~~  
 958 ~~pathogens.~~
- 959 e. ~~"Reduced Oxygen Packaging" does not include:~~
- 960 (1) ~~Placing product in a bag and sealing it immediately prior to or after,~~  
 961 ~~cooking, cooling or reheating the product as long as the product is:~~
- 962 (a) ~~Labeled with the time and date the product is placed in the bag;~~  
 963 ~~and~~
- 964 (b) ~~Removed from the bag within 48 hours of the time the product is~~  
 965 ~~placed in the bag.~~
- 966 93. ~~"Refuse" means solid waste not carried by water through the sewage system.~~
- 967 94. ~~"Re-service" means the transfer of food that is unused and returned by a consumer after~~  
 968 ~~being served or sold and in the possession of the consumer, to another person.~~
- 969 95. ~~"Restrict" means to limit the activities of a food employee so that there is no risk of~~  
 970 ~~transmitting a disease that is transmissible through food and the food employee does not~~  
 971 ~~work with exposed food, clean equipment, utensils, linens, or unwrapped single service~~  
 972 ~~or single use articles.~~
- 973 96. ~~"Retail Food Establishment" means a retail operation that stores, prepares, or packages~~  
 974 ~~food for human consumption or serves or otherwise provides food for human~~  
 975 ~~consumption to consumers directly or indirectly through a delivery service, whether such~~  
 976 ~~food is consumed on or off the premises or whether there is a charge for such food.~~
- 977 ~~"Retail Food Establishment" does not include:~~



- 978 a. ~~Any private home;~~
- 979 b. ~~Private boarding houses;~~
- 980 c. ~~Hospital and health facility patient feeding operations licensed by the Department;~~
- 981 d. ~~Child care centers and other child care facilities licensed by the Department of~~
- 982 ~~Human services;~~
- 983 e. ~~Hunting camps and other outdoor recreation locations where food is prepared in the~~
- 984 ~~field rather than at a fixed base of operation;~~
- 985 f. ~~Food or beverage wholesale manufacturing, processing, or packaging plants, or~~
- 986 ~~portions thereof, that are subject to regulatory controls under state or federal laws or~~
- 987 ~~regulations;~~
- 988 g. ~~Motor vehicles used only for the transport of food;~~
- 989 h. ~~Establishments preparing and serving only hot coffee, hot tea, instant hot beverages,~~
- 990 ~~and nonpotentially hazardous doughnuts or pastries obtained from sources~~
- 991 ~~complying with all laws related to food and food labeling;~~
- 992 i. ~~Establishments that handle only nonpotentially hazardous prepackaged food and~~
- 993 ~~operations serving only commercially prepared, prepackaged foods requiring no~~
- 994 ~~preparation other than the heating of food within its original container or package;~~
- 995 j. ~~Farmers markets and roadside markets that offer only uncut fresh fruit and~~
- 996 ~~vegetables for sale;~~
- 997 k. ~~Automated food merchandising enterprises that supply only prepackaged~~
- 998 ~~nonpotentially hazardous food or drink or food or drink in bottles, cans, or cartons~~
- 999 ~~only, and operations that dispense only chewing gum or salted nuts in their natural~~
- 1000 ~~protective covering;~~
- 1001 l. ~~The donation, preparation, sale, or service of food by a nonprofit or charitable~~
- 1002 ~~organization in conjunction with an event or celebration if such donation,~~
- 1003 ~~preparation, sale, or service of food;~~
- 1004 (1) ~~Does not exceed the duration of the event or celebration or a maximum of~~
- 1005 ~~fifty two days within a calendar year; and~~
- 1006 (2) ~~Takes place in the county in which such nonprofit or charitable organization~~
- 1007 ~~resides or is principally located.~~
- 1008 97. ~~“Risk” means the likelihood that an adverse health effect will occur within a population as a~~
- 1009 ~~result of a hazard in a food.~~
- 1010

- 1011  
1012 98. —“**Safe Materials**” means articles manufactured from or composed of materials that may not  
1013 reasonably be expected to result, directly or indirectly, in their becoming a component or  
1014 otherwise affecting the characteristic of any food. If materials are food additives or color  
1015 additives as defined in section 25-5-402(3) or (12), C.R.S., of the “Colorado Pure Food and  
1016 Drug Law”, as used, they are “safe” only if they are used in conformity with all applicable  
1017 regulations of the U.S. Food and Drug Administration.
- 1018 99. —“**Sanitization**” means the application of cumulative heat or chemicals on cleaned food-  
1019 contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs,  
1020 which is equal to a 99.999% reduction, of representative disease microorganisms of public  
1021 health importance.
- 1022 100. —“**Sealed**” means free of cracks or other openings that allow the entry or passage of  
1023 moisture or debris.
- 1024 101. —“**Self Contained Mobile Retail Food Establishment**” means a licensed mobile retail food  
1025 establishment that is approved to operate without a commissary, and is not connected to  
1026 fixed utilities such as water, sewer and electricity, and is required to report to an approved  
1027 servicing location for sewage disposal and water.
- 1028 102. —“**Service Animal**” means any dog or miniature horse that is individually trained to do work  
1029 or perform tasks for the benefit of an individual with a disability, including a physical,  
1030 sensory, psychiatric, intellectual, or other mental disability. Other species of animals,  
1031 whether wild or domestic, trained or untrained, are not service animals for the purposes of  
1032 this definition. The work or tasks performed by a service animal must be directly related to  
1033 the handler's disability. Examples of work or tasks include, but are not limited to, assisting  
1034 individuals who are blind or have low vision with navigation and other tasks, alerting  
1035 individuals who are deaf or hard of hearing to the presence of people or sounds, providing  
1036 non-violent protection or rescue work, pulling a wheelchair, assisting an individual during a  
1037 seizure, alerting individuals to the presence of allergens, retrieving items such as medicine or  
1038 the telephone, providing physical support and assistance with balance and stability to  
1039 individuals with mobility disabilities, and helping persons with psychiatric and neurological  
1040 disabilities by preventing or interrupting impulsive or destructive behaviors. The crime  
1041 deterrent effects of an animal's presence and the provision of emotional support, well-being,  
1042 comfort, or companionship do not constitute work or tasks for the purposes of this definition.
- 1043 103. —“**Sewage**” means liquid waste containing animal or plant matter in suspension or solution  
1044 and may include liquids containing chemicals in solution.
- 1045 104. —“**Shellstock**” means raw, in-shell, molluscan shellfish.
- 1046 105. —“**Shiga Toxin-Producing *Escherichia coli*” (STEC)** means any *E. coli* capable of  
1047 producing Shiga toxins (also called verocytotoxins or “Shiga like” toxins). Examples of  
1048 serotypes of STEC include both O157 and non-O157 *E. coli*. *Also see* Enterohemorrhagic  
1049 *Escherichia coli*.
- 1050 106. —“**Shucked Shellfish**” means molluscan shellfish that have one or both shells removed.
- 1051 107. —“**Single Service Articles**” means cups, containers, lids, closures, plates, knives, forks,  
1052 spoons, stirrers, paddles, straws, napkins, place mats, doilies, wrapping materials, toothpicks  
1053 and similar articles intended for one-time, one-consumer use and then discarded after use.
- 1054

- 1055  
1056 108. — ~~“Single-Use Articles”~~
- 1057 a. — ~~“Single-Use Articles” means utensils and bulk food containers designed and~~  
1058 ~~constructed to be used once and discarded;~~
- 1059 b. — ~~“Single-Use Articles” includes items such as wax paper, butcher paper, plastic~~  
1060 ~~wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread~~  
1061 ~~wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the~~  
1062 ~~materials, durability, strength, and cleanability specifications under 4-101, and 4-~~  
1063 ~~201 for multiuse utensils.~~
- 1064 109. — ~~“Slacking” means the process of moderating the temperature of a food such as allowing a~~  
1065 ~~food to gradually increase from a temperature of 23°C (-10°F) to 4°C (25°F) in preparation~~  
1066 ~~for deep-fat frying or to facilitate even heat penetration during the cooking of previously~~  
1067 ~~block-frozen food such as shrimp.~~
- 1068 110. — ~~“Smooth” means:~~
- 1069 a. — ~~A food-contact surface having a surface free of pits and inclusions with a~~  
1070 ~~cleanability equal to or exceeding that of (100-grit) number 3 stainless steel;~~
- 1071 b. — ~~A nonfood-contact surface of equipment having a surface equal to that of~~  
1072 ~~commercial grade hot-rolled steel free of visible scale; and~~
- 1073 c. — ~~A floor, wall, or ceiling having an even or level surface with no roughness,~~  
1074 ~~projections, perforations, pits, or inclusions that render it difficult to clean.~~
- 1075 111. — ~~“Tableware” means eating, drinking, and serving utensils for table use, such as forks,~~  
1076 ~~knives, and spoons; including bowls, cups, serving dishes, tumblers and plates.~~
- 1077 112. — ~~“Temperature Measuring Device” means a thermometer, thermocouple, thermistor, or~~  
1078 ~~other device that indicates the temperature of food, air, or water.~~
- 1079 113. — ~~“Temporary Event” means a single community event or celebration that operates for a~~  
1080 ~~period of time of not more than the fourteen (14) consecutive days and may include town~~  
1081 ~~celebrations, fairs, and festivals.~~
- 1082 — ~~Temporary events do not include:~~
- 1083 a. — ~~Regularly scheduled series of events at venues such as sporting arenas, concert halls,~~  
1084 ~~flea markets, or farmers’ markets;~~
- 1085 b. — ~~Events serviced by licensed caterers are not considered temporary events.~~
- 1086 c. — ~~Sporadic promotional events such as grand openings are not considered temporary~~  
1087 ~~events.~~
- 1088 114. — ~~“Temporary Retail Food Establishment” means a food establishment that is limited to~~  
1089 ~~operating at temporary events only.~~
- 1090 115. — ~~“USDA” means the U.S. Department of Agriculture.~~
- 1091 116. — ~~“Utensil” means a food-contact implement or container used in the storage, preparation,~~  
1092 ~~transportation, dispensing, sale or service of food, such as kitchenware or tableware that is~~  
1093 ~~multiuse, single-service, or single-use.~~
- 1094 117. — ~~“Variance” means a written document issued by the Colorado Department of Public Health~~  
1095 ~~and Environment (CDPHE) that authorizes a modification or waiver of one or more~~

- 1096 requirements of this Code if, in the opinion of CDPHE, a health hazard or nuisance will not  
1097 result from the modification or waiver.
- 1098 118. ~~“Warewashing”~~ means the cleaning and sanitizing of utensils and food contact surfaces of  
1099 equipment.
- 1100 119. ~~“Water Activity~~ see a<sub>w</sub> definition in section 1-201(7).
- 1101 120. ~~“Whole Muscle, Intact Beef”~~ means whole muscle beef that is not injected, mechanically  
1102 tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.
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## CHAPTER 2

### MANAGEMENT AND PERSONNEL

#### ~~2-1~~ SUPERVISION

##### ~~2-101~~ Responsibilities

~~The operator shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the retail food establishment during all hours of operation.~~

##### ~~\*2-102~~ Demonstration

~~Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the Department knowledge of foodborne disease prevention, application of the Hazard Analysis Critical Control Point principles, and the requirements of these rules and regulations. The person in charge shall demonstrate this knowledge by:~~

~~A. Complying with these rules and regulations by having no violations of critical items during the current inspection; or~~

~~B. Being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program; or~~

~~C. Responding correctly to the inspector's questions as they relate to the specific food operation. The areas of knowledge include:~~

~~1. Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;~~

~~2. Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;~~

~~3. Describing the symptoms associated with the diseases that are transmissible through food;~~

~~4. Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs and fish;~~

~~5. Stating the required temperatures and times for the safe cooking, refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food (time/temperature control for safety food);~~

~~6. Describing the relationship between the prevention of foodborne illness and the management and control of the following:~~

~~a. Cross contamination;~~

~~b. Hand contact with ready-to-eat foods;~~

~~c. Handwashing, and~~

~~d. Maintaining the food establishment in a clean condition and in good repair;~~

- 1140  
1141 7. — Explaining the relationship between food safety and providing equipment that is:
- 1142 a. — Sufficient in number and capacity, and
- 1143 b. — Properly designed, constructed, located, installed, operated, maintained, and
- 1144 cleaned;
- 1145 8. — Explaining correct procedures for cleaning and sanitizing utensils and food contact
- 1146 surfaces of equipment;
- 1147 9. — Identifying the source of water used and measures taken to ensure that it remains
- 1148 protected from contamination such as providing protection from backflow and
- 1149 precluding the creation of cross connections;
- 1150 10. Identifying poisonous or toxic materials in the food establishment and the procedures
- 1151 necessary to ensure that they are safely stored, dispensed, used, and disposed of
- 1152 according to law;
- 1153 11. Explaining the relationship between maintaining the time and temperature of
- 1154 potentially hazardous food (time/temperature control for safety food);
- 1155 12. Identifying critical control points in the operation from purchasing through sale or
- 1156 service that when not controlled may contribute to the transmission of foodborne
- 1157 illness and explaining steps taken to ensure that the points are controlled in
- 1158 accordance with the requirements of these rules and regulations.
- 1159 13. Explaining the details of how the establishment, person in charge and food employees
- 1160 complies with conditions of any approved variance or any Department approved
- 1161 time as a public health control plan for potentially hazardous food (time/temperature
- 1162 control for safety food) and with any HACCP plan required by the Department.
- 1163 14. Explaining the responsibilities, rights, and authorities assigned by these rules and
- 1164 regulations to the:
- 1165 a. — Food employee
- 1166 b. — Conditional employee
- 1167 c. — Person in charge, and
- 1168 d. — Department
- 1169 15. Explaining how the person in charge, food employees, and conditional employees
- 1170 comply with reporting responsibilities and exclusion or restriction of food
- 1171 employees.
- 1172 16. Describing foods identified as major food allergens and the symptoms that a major food
- 1173 allergen could cause in a sensitive individual who has an allergic reaction.

1174 **\*2-103 — Person in charge**

1175 The person in charge shall educate and monitor employees to ensure that:

- 1176 A. — Employees are effectively cleaning their hands, by routinely monitoring the employees' <sup>2</sup>
- 1177 handwashing;
- 1178 B. — Employees are visibly observing foods as they are received to determine that they are from
- 1179 approved sources, delivered at the required temperatures, protected from contamination,

- 1180 unadulterated, and accurately presented, by routinely monitoring the employees'  
1181 observations and periodically evaluating foods upon their receipt;
- 1182 C.— Employees are properly cooking potentially hazardous food (time/temperature control for  
1183 safety food), being particularly careful in cooking those foods known to cause severe  
1184 foodborne illness and death, such as eggs and comminuted meats, through daily oversight  
1185 of the employees' routine monitoring of the cooking temperatures using appropriate  
1186 temperature measuring devices properly sealed and calibrated as specified in section 4-  
1187 401 of these rules and regulations;
- 1188 D.— Employees are using proper methods to rapidly cool potentially hazardous foods  
1189 (time/temperature control for safety foods) that are not held hot or are not for  
1190 consumption within 4 hours, through daily oversight of the employees' routine  
1191 monitoring of food temperatures during cooling;
- 1192 E.— Employees are properly sanitizing cleaned multiuse equipment and utensils before they are  
1193 reused, through routine monitoring of solution temperature and exposure time for hot  
1194 water sanitizing, and chemical concentration, pH, temperature, and exposure time for  
1195 chemical sanitizing;
- 1196 F.— Consumers are notified that clean tableware is to be used when they return to self-service  
1197 areas such as salad bars and buffets as specified in section 3-411(A);
- 1198 G.— Employees prevent bare hand contact with ready-to-eat food by properly using suitable  
1199 utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment;
- 1200 H.— Employees are properly trained in food safety as it relates to their assigned duties;
- 1201 I.— Food employees and conditional employees are informed of their responsibilities to report  
1202 their illnesses and infections transmissible through food to the person in charge, so that  
1203 the person in charge may exclude or restrict any employees who are ill, have a boil or  
1204 wound, and when to notify the department of illnesses;
- 1205 J.— Employees and other persons such as delivery and maintenance persons and pesticide  
1206 applicators entering the food preparation food storage, and warewashing areas comply  
1207 with this code; and
- 1208 K.— Consumers who order raw or partially cooked ready-to-eat foods of animal origin are  
1209 informed as specified in section 3-801 of these rules and regulations that the food is not  
1210 cooked sufficiently to ensure its safety.

## 1211 ~~2-2~~ — EMPLOYEE HEALTH

### 1212 \*2-201 — Responsibility of Licensee, Person in charge, and Employees

- 1213 A.— The licensee shall require food employees and conditional employees to report to the person  
1214 in charge information about their health and activities as they relate to diseases that are  
1215 transmissible through food. A food employee or conditional employee shall report pertinent  
1216 information in a manner that allows the person in charge to reduce the risk of foodborne  
1217 disease transmission, if the food employee or conditional employee:
- 1218 1.— Has any of the following symptoms:
- 1219 a.— Vomiting;
- 1220 b.— Diarrhea;

- 1221 e. — Jaundice;
- 1222 d. — Sore throat with fever; or
- 1223 e. — A lesion containing pus such as a boil or infected wound that is open and/or
- 1224 draining and is:
- 1225 (1) — On the hands or wrists, unless an impermeable cover such as a finger
- 1226 cot or stall protects the lesion and a single use glove is worn over
- 1227 the impermeable cover;
- 1228 (2) — On exposed portions of the arms, unless the lesion is protected by an
- 1229 impermeable cover; or
- 1230 (3) — On other parts of the body, unless the lesion is covered by a dry,
- 1231 durable, tight fitting bandage.
- 1232 2. — Has an illness diagnosed by a health practitioner due to:
- 1233 a. — Norovirus;
- 1234 b. — Hepatitis A virus;
- 1235 c. — Shigella spp.;
- 1236 d. — Enterohemorrhagic or Shiga Toxin Producing Escherichia coli;
- 1237 e. — Salmonella Typhi; or
- 1238 f. — Other enteric bacterial pathogen such as Salmonella or Campylobacter.
- 1239 3. — Had a previous illness, diagnosed by a health practitioner, within the past three (3)
- 1240 months due to Salmonella Typhi, as determined by a health practitioner.
- 1241 B. — The person in charge shall notify the Department when a food employee is:
- 1242 1. — Jaundiced; or
- 1243 2. — Diagnosed with an illness due to a pathogen as specified in Subparagraphs (A)(2) and
- 1244 (A)(3) of this section.
- 1245 C. — The person in charge shall ensure that a conditional employee who exhibits or reports a
- 1246 symptom, or who reports a diagnosed illness as specified in Subparagraphs (A)(1) (3) of this
- 1247 section, is prohibited from becoming a food employee until the conditional employee meets
- 1248 the criteria for the specific symptoms or diagnosed illness as specified section 2-203.
- 1249 D. — The person in charge shall ensure that a food employee who exhibits or reports a symptom,
- 1250 or who reports a diagnosed illness as specified in subparagraphs (A)(1) (3) of this section is:
- 1251 1. — Excluded as specified in 2-202 (A) (D)(1), (E)(1), (F), (G)(1), and in compliance with
- 1252 the provisions specified under 2-203(A) (F); or
- 1253 2. — Restricted as specified in subparagraphs 2-202 (D)(2), (E)(2), (F), (G)(2), (H), and in
- 1254 compliance with the provisions specified under 2-203 (A) (F).
- 1255 E. — A food employee or conditional employee shall report to the person in charge the
- 1256 information as specified in (A) of this section.
- 1257 F. — A food employee shall:
- 1258 1. — Comply with an exclusion as specified in 2-202 (A) (D)(1), (E)(1), (F), (G)(1); or



1259 2. ~~Comply with a restriction as specified in subparagraphs 2-202 (D)(2), (E)(2), (F),~~  
 1260 ~~(G)(2), (H), and in compliance with the provisions specified under 2-203 (A) (F).~~

1261 **~~\*2-202 Exclusions and Restrictions~~**

1262 ~~The person in charge shall exclude or restrict a food employee from a food establishment in~~  
 1263 ~~accordance with the following:~~

1264 A. ~~Except when the symptom is from a noninfectious condition, exclude a food employee if the~~  
 1265 ~~food employee is:~~

1266 1. ~~Symptomatic with vomiting or diarrhea; or~~

1267 2. ~~Symptomatic with vomiting or diarrhea and diagnosed with an infection from~~  
 1268 ~~Norovirus, Shigella spp., or Enterohemorrhagic or Shiga toxin producing E. coli.~~

1269 B. ~~Exclude a food employee who is:~~

1270 1. ~~Jaundiced and the onset of jaundice occurred within the last seven (7) calendar days,~~  
 1271 ~~unless the food employee provides to the person in charge written medical~~  
 1272 ~~documentation from a health practitioner specifying that the jaundice is not caused~~  
 1273 ~~by hepatitis A virus or other fecal-orally transmitted infection;~~

1274 2. ~~Diagnosed with an infection from hepatitis A virus within fourteen (14) calendar days~~  
 1275 ~~from the onset of any illness symptoms, or within seven (7) calendar days of the~~  
 1276 ~~onset of jaundice; or~~

1277 3. ~~Diagnosed with an infection from hepatitis A virus without developing symptoms.~~

1278 C. ~~Exclude a food employee who is diagnosed with an infection from Salmonella Typhi, or~~  
 1279 ~~reports a previous infection with Salmonella Typhi within the past three (3) months as~~  
 1280 ~~specified under Subparagraph 2-201(A)(3).~~

1281 D. ~~If a food employee is diagnosed with an infection from Shigella spp. and is asymptomatic:~~

1282 1. ~~Exclude the food employee who works in a food establishment serving a highly~~  
 1283 ~~susceptible population; or~~

1284 2. ~~Restrict the food employee who works in a food establishment not serving a highly~~  
 1285 ~~susceptible population.~~

1286 E. ~~If a food employee is diagnosed with an infection from Enterohemorrhagic or Shiga toxin-~~  
 1287 ~~producing E. coli, and is asymptomatic:~~

1288 1. ~~Exclude the food employee who works in a food establishment serving a highly~~  
 1289 ~~susceptible population; or~~

1290 2. ~~Restrict the food employee who works in a food establishment not serving a highly~~  
 1291 ~~susceptible population.~~

1292 F. ~~If a food employee is diagnosed with another bacterial enteric pathogen and is asymptomatic~~  
 1293 ~~consult with the Department to determine the need for exclusion or restriction.~~

1294 G. ~~If a food employee is ill with symptoms of acute onset of sore throat with fever:~~

1295 1. ~~Exclude the food employee who works in a food establishment serving a highly~~  
 1296 ~~susceptible population; or~~

1297 2. ~~Restrict the food employee who works in a food establishment not serving a highly~~  
 1298 ~~susceptible population.~~

1299 H. ~~If a food employee is infected with a skin lesion containing pus such as a boil or infected~~  
 1300 ~~wound that is open or draining and not properly covered as specified in section 2-~~  
 1301 ~~201(A)(1)(e), restrict the food employee.~~

1302 ~~\*2-203 Removal, Adjustment, or Retention of Exclusions and Restrictions~~

1303 The person in charge shall adhere to the following conditions when removing, adjusting, or retaining  
 1304 the exclusion or restriction of a food employee:

1305 A. ~~Reinstate a food employee who was excluded as specified in section 2-202(A)(1) if the~~  
 1306 ~~employee:~~

1307 1. ~~Is asymptomatic for at least 24 hours; or~~

1308 2. ~~Provides to the person in charge written medical documentation from a health~~  
 1309 ~~practitioner that states the symptom is from a noninfectious condition.~~

1310 3. ~~If a food employee was diagnosed with an infection from Norovirus and excluded as~~  
 1311 ~~specified in section 2-202(A)(2), the food employee should not be reinstated until~~  
 1312 ~~the employee has been asymptomatic for at least 48 hours and the person in charge~~  
 1313 ~~obtains approval from the Department.~~

1314 4. ~~If a food employee was diagnosed with an infection from Shigella spp. and excluded as~~  
 1315 ~~specified in section 2-202(A)(2), the food employee should not be reinstated until~~  
 1316 ~~the employee has met parameters listed in the Colorado Communicable Disease~~  
 1317 ~~Manual and the person in charge obtains approval from the Department.~~

1318 5. ~~If a food employee was diagnosed with an infection from Enterohemorrhagic or Shiga~~  
 1319 ~~toxin-producing Escherichia coli and excluded as specified in section 2-202(A)(2),~~  
 1320 ~~the food employee should not be reinstated until the employee has met parameters~~  
 1321 ~~listed in the Colorado Communicable Disease Manual and the person in charge~~  
 1322 ~~obtains approval from the Department.~~

1323 B. ~~Reinstate a food employee who was excluded as specified under Subparagraphs 2-202(B) if~~  
 1324 ~~the employee has met parameters listed in the Colorado Communicable Disease Manual and~~  
 1325 ~~the person in charge obtains approval from the Department.~~

1326 C. ~~Reinstate a food employee who was excluded as specified in 2-202(C). If the employee has~~  
 1327 ~~met parameters listed in the Colorado Communicable Disease Manual and the person in~~  
 1328 ~~charge obtains approval from the Department.~~

1329 D. ~~Reinstate a food employee who was restricted as specified in 2-202(H) if the skin, infected~~  
 1330 ~~wound, cut, or pustular boil is properly covered with one of the following:~~

1331 1. ~~An impermeable cover such as a finger cot or stall and a single use glove over the~~  
 1332 ~~impermeable cover if the infected wound or pustular boil is on the hand, finger, or~~  
 1333 ~~wrist;~~

1334 2. ~~An impermeable cover on the arm if the infected wound or pustular boil is on the arm;~~  
 1335 ~~or~~

1336 3. ~~A dry, durable, tight fitting bandage if the infected wound or pustular boil is on another~~  
 1337 ~~part of the body.~~

1338 E. ~~Reinstate a food employee who was excluded as specified under subparagraphs 2-202(D)(1)~~  
 1339 ~~or who was restricted under Subparagraph 2-202(D)(2). The food employee should not be~~  
 1340 ~~reinstated until the employee has been asymptomatic for at least 48 hours and the person in~~  
 1341 ~~charge obtains approval from the Department.~~

- 1342 F. ~~Reinstate a food employee who was excluded or restricted as specified in Subparagraphs 2-~~  
 1343 ~~202(H)(1) or (2) if the food employee provides to the person in charge written medical~~  
 1344 ~~documentation from a health practitioner stating that the food employee meets one of the~~  
 1345 ~~following conditions:~~
- 1346 1. ~~Has received antibiotic therapy for Streptococcus pyogenes infection for more than 24~~  
 1347 ~~hours;~~
  - 1348 2. ~~Has at least one negative throat specimen culture for Streptococcus pyogenes infection;~~  
 1349 ~~or~~
  - 1350 3. ~~Is otherwise determined by a health practitioner to be free of a Streptococcus pyogenes~~  
 1351 ~~infection.~~

1352 **~~2-204 Discharges from the Eyes, Nose and Mouth~~**

1353 ~~Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges~~  
 1354 ~~from the eyes, nose or mouth may not work with exposed food, clean equipment, utensils, and linens,~~  
 1355 ~~or unwrapped single service or single use articles.~~

1356 **~~2-3 AUTHORIZED PERSONNEL~~**

1357 ~~Only persons necessary to the operation and maintenance of the retail food establishment shall be~~  
 1358 ~~allowed in food preparation, food storage, food equipment storage, and warewashing areas.~~

1359 **~~2-4 PERSONAL CLEANLINESS~~**

1360 **~~\*2-401~~** ~~Food employees shall keep their hands and exposed portions of their arms clean.~~

1361 **~~\*2-402 Cleaning Procedure~~**

- 1362 A. ~~Food employees shall clean their hands and exposed portions of their arms including~~  
 1363 ~~surrogate prosthetic devices for hands or arms with soap and water for at least 20 seconds~~  
 1364 ~~and shall use the following cleaning procedure:~~
- 1365 1. ~~Vigorous friction on the surfaces of the lathered fingers, finger tips, areas~~  
 1366 ~~between the fingers, hands and arms for at least 15 seconds, followed by;~~
  - 1367 2. ~~Thorough rinsing under clean, running warm water; and~~
  - 1368 3. ~~Immediately follow the cleaning procedure with thorough drying of cleaned~~  
 1369 ~~hands and arms with disposable or single use towels or a mechanical hand drying~~  
 1370 ~~device.~~
- 1371 B. ~~Food employees shall pay particular attention to removing soil underneath the~~  
 1372 ~~fingerails during the cleaning procedure.~~
- 1373 C. ~~If approved and capable of removing the types of soils encountered in the food operations~~  
 1374 ~~involved, an automatic handwashing facility installed and operated as per section 5-~~  
 1375 ~~208(I) may be used by food employees to clean their hands.~~

1376 ~~\*2-403—When to Wash~~

1377 ~~Food employees shall clean their hands and exposed portions of their arms immediately before~~  
 1378 ~~engaging in food preparation including working with exposed food, clean equipment and utensils,~~  
 1379 ~~and unwrapped single service and single use articles and:~~

1380 ~~A. Before leaving the restroom, and after returning to food and beverage preparation, food~~  
 1381 ~~storage, equipment storage and warewashing areas from using the restroom;~~

1382 ~~B. After coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or~~  
 1383 ~~drinking;~~

1384 ~~C. When switching between working with raw foods of animal origin and working with ready-~~  
 1385 ~~to eat foods;~~

1386 ~~D. After touching bare human body parts other than clean hands and clean, exposed portions of~~  
 1387 ~~arms;~~

1388 ~~E. During food preparation, as often as necessary to remove soil and contamination and to~~  
 1389 ~~prevent cross contamination when changing tasks;~~

1390 ~~F. Before handling or putting on single use gloves for working with food, and between~~  
 1391 ~~removing soiled gloves and putting on clean gloves;~~

1392 ~~G. After handling soiled equipment or utensils;~~

1393 ~~H. After caring for or handling any animals;~~

1394 ~~I. After engaging in any activities that contaminate the hands; and~~

1395 ~~J. After handling fish in aquariums, shellfish, or crustacea in display tanks.~~

1396 ~~\*2-404—Hand Antiseptics~~

1397 ~~Hand antiseptics may be used in addition to but not in place of proper handwashing.~~

1398 ~~\*2-405—Where to Wash~~

1399 ~~Food employees shall clean their hands in a handsink or approved automatic handwashing facility~~  
 1400 ~~and may not clean their hands in a sink used for food preparation or warewashing, in a dump sink, or~~  
 1401 ~~in a utility sink or a curbed cleaning facility used for the disposal of mop water and similar liquid~~  
 1402 ~~waste.~~

1403 ~~\*2-406—Fingernail Care~~

1404 ~~A. Food employees shall keep their fingernails clean, trimmed, filed and maintained so the~~  
 1405 ~~edges and surfaces are cleanable and not rough.~~

1406 ~~B. Unless wearing intact gloves in good repair, a food employee may not wear fingernail~~  
 1407 ~~polish or artificial fingernails when working with exposed food.~~

1408 ~~2-407—Clothing~~

1409 ~~Employees shall wear clean outer clothing to prevent cross contamination.~~

1410 ~~2-408—Jewelry~~

1411 ~~Except for a plain ring such as a wedding band, while preparing food, food employees may not wear~~  
 1412 ~~jewelry, watches, or medical information bracelets on their wrists and hands or any other area of the~~  
 1413 ~~arm that may interfere with proper handwashing or result in contamination of food.~~

1414 ~~2-5—HYGIENIC PRACTICES~~1415 ~~\*2-501—General~~

1416 ~~Employees shall maintain a high degree of personal cleanliness and shall conform to good hygienic~~  
 1417 ~~practices during all working periods. Proper hygienic practices must be followed by retail food~~  
 1418 ~~employees in performing assigned duties to ensure the safety of the food, prevent the introduction of~~  
 1419 ~~foreign objects into the food, and minimize the possibility of transmitting disease through food.~~

1420 ~~\*2-502—Eating, Drinking, or Using Tobacco~~

1421 ~~A. — Except as specified in paragraph B, employees shall consume food, drink or use tobacco only~~  
 1422 ~~in designated areas. Such designated areas must be located so that eating or tobacco use by~~  
 1423 ~~an employee does not result in contamination of food, equipment, utensils, or other items~~  
 1424 ~~needing protection.~~

1425 ~~B. — An employee may drink from a closed beverage container such as pop top sport bottles when~~  
 1426 ~~teeth or mouth are used to open the top, cups with a lid and a straw, and cups with snap on~~  
 1427 ~~lids with a hole in the top if:~~

1428 ~~1. — The container is clean;~~

1429 ~~2. — It does not contaminate the employee's hands; and~~

1430 ~~3. — It is stored to prevent the contamination of exposed food, clean equipment, utensils,~~  
 1431 ~~linens, unwrapped single service and single use articles.~~

1432 ~~2-503—Hair Restraints~~

1433 ~~A. — Except as provided under paragraph B of this section, food employees engaged in food~~  
 1434 ~~preparation shall wear hair restraints, such as hats, hair coverings, hair or beard nets, or other~~  
 1435 ~~effective means, to effectively keep hair from contacting exposed food, clean equipment,~~  
 1436 ~~utensils, and linens, and unwrapped single service or single use articles.~~

1437 ~~B. — This section does not apply to employees such as counter staff who serve only beverages and~~  
 1438 ~~wrapped or packaged foods, or hosts, bartenders, and wait staff who present a minimal risk~~  
 1439 ~~of contaminating exposed foods, clean equipment, utensils, and linens, and unwrapped~~  
 1440 ~~single service and single use articles.~~

1441

1442

**CHAPTER 3**

1443

**FOOD**1444 **3-1 — CHARACTERISTICS**1445 **\*3-101 — General**

1446 ~~Food shall be safe and unadulterated. Food shall be in sound condition, free from spoilage or~~  
 1447 ~~contamination and shall be safe for human consumption. Food shall not contain unsafe or~~  
 1448 ~~unapproved food or color additives per 21 CFR 170-186. Food shall be obtained from approved~~  
 1449 ~~sources that comply with the applicable laws relating to food and food labeling. Food prepared or~~  
 1450 ~~stored in a private home shall not be used, distributed, or offered for sale.~~

1451 **3-2 — SOURCES AND SPECIFICATIONS**1452 **3-201 — Shellfish and Fish**1453 **\*A. — Molluscan Shellfish**

1454 ~~———— Molluscan Shellfish shall be obtained from sources according to law and the requirements~~  
 1455 ~~specified in the U.S. Department of Health and Human Services, Public Health Service,~~  
 1456 ~~Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control~~  
 1457 ~~of Molluscan Shellfish.~~

1458 **B. — Maintaining Shellstock Identification**

1459 ~~\*1. — Fresh and frozen shucked molluscan shellfish (oysters, clams, mussels or scallops)~~  
 1460 ~~shall be received and/or repacked in non-returnable packages identified with the~~  
 1461 ~~name and address of the original shellstock processor, shucker packer, or repacker,~~  
 1462 ~~and the state shellstock certification number issued according to law. Shucked~~  
 1463 ~~molluscan shellfish shall be kept in the container in which they were received until~~  
 1464 ~~used or sold.~~

1465 ~~———— Each original container of unshucked molluscan shellfish shall be identified by an~~  
 1466 ~~attached tag, to be retained for a period of 90 days after the container is emptied.~~  
 1467 ~~The tag shall be marked with the empty date and, the name and address of the~~  
 1468 ~~original shellfish processor, the kind and quantity of shellfish, and the certification~~  
 1469 ~~number issued by the State or foreign shellfish control agency, where applicable.~~  
 1470 ~~Tags shall be stored in chronological order from the empty date.~~

1471 ~~———— Shellstock from one tagged or labeled container shall not be commingled with~~  
 1472 ~~shellstock from another container before being ordered by the consumer.~~

1473 ~~\*2. — When received by a food establishment, unshucked shellstock shall be reasonably~~  
 1474 ~~free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or~~  
 1475 ~~shellstock with badly broken shells shall be discarded.~~

1476 ~~\*C. — Molluscan shellfish that are recreationally caught may not be received for sale or service.~~

1477 ~~\*D. — Fish that are received for sale or service shall be:~~

1478 ~~1. — Commercially and legally caught or harvested; or~~

- 1479 2. ~~Approved for sale or service.~~
- 1480 \*E. ~~Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label~~  
1481 ~~that identifies the:~~
- 1482 1. ~~Name, address, and certification number of the shucker, packer or repacker of the~~  
1483 ~~molluscan shellfish; and~~
- 1484 2. ~~The "sell by" or "best if used by" date for packages with a capacity of less than 1.89~~  
1485 ~~L (one half gallon) or the date shucked for packages with a capacity of 1.89 L (one~~  
1486 ~~half gallon) or more.~~
- 1487 F. ~~Molluscan Shellfish, Original Container.~~
- 1488 1. ~~Except as specified in (G) (H) of this section, molluscan shellfish may not be~~  
1489 ~~removed from the container in which they are received other than immediately~~  
1490 ~~before sale or preparation for service.~~
- 1491 G. ~~For display purposes, shellstock may be removed from the container in which they are~~  
1492 ~~received, displayed on drained ice, or held in a display container, and a quantity specified by~~  
1493 ~~a consumer may be removed from the display or display container and provided to the~~  
1494 ~~consumer if:~~
- 1495 1. ~~The source of the shellstock on display is identified as specified in section 3-201(A);~~  
1496 ~~and~~
- 1497 2. ~~The shellstock are protected from contamination.~~
- 1498 H. ~~Shucked shellfish may be removed from the container in which they were received and held~~  
1499 ~~in a display container from which individual servings are dispensed upon a consumer's~~  
1500 ~~request if:~~
- 1501 1. ~~The labeling information for the shellfish on display as specified in section 3-201(E)~~  
1502 ~~is retained and correlated to the date when, or dates during which, the shellfish are~~  
1503 ~~sold or served; and~~
- 1504 2. ~~The shellfish are protected from contamination.~~

### 1505 **3-202 Parasite Destruction**

- 1506 \*A. ~~Except as specified in (B) of this section, before service or sale in ready to eat form, raw,~~  
1507 ~~raw marinated, partially cooked, or marinated partially cooked fish shall be:~~
- 1508 1. ~~Frozen and stored at a temperature of 4°F (-20°C) or below for a minimum of 168~~  
1509 ~~hours (7 days) in a freezer;~~
- 1510 2. ~~Frozen at 31°F (-35°C) or below until solid and stored at 31°F (-35°C) or below for~~  
1511 ~~a minimum of 15 hours; or~~
- 1512 3. ~~Frozen at 31°F (-35°C) or below until solid and stored at 4°F (-20°C) or below for~~  
1513 ~~a minimum of 24 hours.~~
- 1514 ~~The freezing temperature and time to which the fish are subjected shall be recorded, retained and~~  
1515 ~~made readily available upon request at the food establishment for 90 calendar days after the time of~~  
1516 ~~service or sale of the fish.~~
- 1517 ~~If the fish are frozen by the retail food establishment and/or supplier, a written agreement or~~  
1518 ~~statement from the supplier stipulating that the fish supplied are frozen to the proper temperature and~~  
1519 ~~for a time specified in this section may substitute for the records required.~~

1520

- 1521  
1522 ~~B. Paragraph (A) of this section does not apply to:~~
- 1523 ~~1. Molluscan shellfish;~~
  - 1524 ~~2. Tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna),~~  
1525 ~~*Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus*~~  
1526 ~~(Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern); or~~
  - 1527 ~~3. Aquacultured fish, such as salmon, that:~~
    - 1528 ~~a. If raised in open water, are raised in net pens, or~~
    - 1529 ~~b. Are raised in land-based operations such as ponds or tanks, and~~
    - 1530 ~~c. Are fed formulated feed, such as pellets, that contains no live parasites~~  
1531 ~~infective to the aquacultured fish.~~
    - 1532 ~~d. If raw, raw marinated, partially cooked, or marinated partially cooked fish~~  
1533 ~~are served or sold in ready to eat form, and the fish are raised and fed as~~  
1534 ~~specified in section 3-202(B)(3)(a)(c), a written agreement or statement~~  
1535 ~~from the supplier or aquaculturist stipulating that the fish were raised and~~  
1536 ~~fed as specified in section 3-202(B)(3)(a)(c) shall be obtained by the~~  
1537 ~~person in charge and retained in the records of the food establishment for 90~~  
1538 ~~calendar days beyond the time of service or sale of the fish.~~
  - 1539 ~~4. Fish eggs that have been removed from the skein and rinsed.~~

### 1540 ~~3-3 SOURCES AND SPECIFICATIONS~~

#### 1541 ~~\*3-301 Package Integrity~~

1542 ~~Food packages shall be in good condition and protect the integrity of the contents so that the~~  
1543 ~~food is not exposed to adulteration or potential contaminants.~~

#### 1544 ~~\*3-302 Hermetically Sealed Food~~

1545 ~~A. The use, distribution, or sale of food from hermetically sealed containers that was not prepared in an~~  
1546 ~~approved food processing establishment or retail food establishment that is approved for this~~  
1547 ~~type of processing, is prohibited.~~

1548 ~~B. Hermetically sealed packages shall be handled so as to maintain product and container integrity.~~  
1549 ~~The “Guide to Can Defects and Basic Components of Double Seam Containers”, November~~  
1550 ~~2011, published by the Association of Food and Drug Officials, shall be used to determine~~  
1551 ~~container integrity. Food items that are spoiled or that are in damaged containers that may~~  
1552 ~~affect the product and those food items that have been returned to, or are being detained by,~~  
1553 ~~the retail food establishment because of spoilage, container damage, or other public health~~  
1554 ~~considerations shall be segregated and held in designated areas pending proper disposition~~  
1555 ~~unless disposed of under the supervision of the Department.~~

#### 1556 ~~\*3-303 Dry Milk and Dry Milk Products~~

1557 ~~Dry milk and milk products used, served or offered for sale shall be made from pasteurized milk and~~  
1558 ~~milk products.~~



1559 ~~\*3-304—Reconstitution of Dry Milk, Dry Milk Products and Non-Dairy Products~~

1560 ~~Dry milk, dry milk products and non dairy creaming, whitening, or whipping agents may be~~  
 1561 ~~reconstituted with potable water on the premises only when they will be stored in sanitized, covered~~  
 1562 ~~containers and cooled to 41°F (7°C) or below within four hours after preparation.~~

1563 ~~Reconstituted dry milk cannot be substituted for use as a Grade A fluid milk product in its final form~~  
 1564 ~~(e.g. for drinking, over cereal, etc.).~~

1565 ~~\*3-305—Fluid Milk, Fluid Milk Products, and Frozen Dessert Mix~~

1566 ~~A. Fluid milk and fluid milk products used, served or offered for sale shall comply with the~~  
 1567 ~~Colorado Grade A Pasteurized Fluid Milk and Milk Products Regulation.~~

1568 ~~B. Only pasteurized mix from an approved licensed dairy plant may be mixed and/or frozen by~~  
 1569 ~~a counter freezer.~~

1570 ~~C. Raw milk supplied to and held by retail food establishments for distribution to shareholders~~  
 1571 ~~shall meet the requirements of section 25-5.5-117 et. seq., C.R.S.~~

1572 ~~1. Only farms or dairies that are properly registered with the Department may~~  
 1573 ~~distribute raw milk.~~

1574 ~~2. Only an owner or shareholder of a cow, goat or dairy herd may distribute raw milk~~  
 1575 ~~from a retail food establishment. Distribution of raw milk by management or~~  
 1576 ~~employees of a retail food establishment that are not owners or shareholder of a~~  
 1577 ~~cow, goat or dairy herd is prohibited.~~

1578 ~~3. Only an owner or shareholder of a cow, goat or dairy herd shall receive raw milk~~  
 1579 ~~from the farm or dairy where the cow or goat is located or from a shareholder of the~~  
 1580 ~~same cow, goat or dairy herd.~~

1581 ~~4. Containers used to hold raw milk shall have a prominent warning statement that the~~  
 1582 ~~milk is not pasteurized, is delivered to the shareholder with the milk or is displayed~~  
 1583 ~~on a label affixed to the milk container.~~

1584 ~~5. Storage of raw milk with other food is prohibited. Raw milk must be stored in a~~  
 1585 ~~separate refrigerator or cooler that is used only for raw milk and must be stored in a~~  
 1586 ~~manner where it cannot be mistaken for pasteurized milk. Display or access of raw~~  
 1587 ~~milk to the public is prohibited.~~

1588 ~~\*3-306—Wild Mushrooms~~

1589 ~~A. Except as specified in paragraph B of this section, mushroom species picked in the wild shall~~  
 1590 ~~be obtained from sources where each mushroom is individually inspected and found to be~~  
 1591 ~~safe by a mushroom identification expert approved by the Department. To be approved by~~  
 1592 ~~the department an individual must:~~

1593 ~~1. Identify which county(ies) and retail food establishments they will supply wild~~  
 1594 ~~mushrooms;~~

1595 ~~2. Provide the genus and species of the wild mushrooms that will be supplied;~~

1596 ~~3. Provide written verification detailing their qualifications that demonstrate their~~  
 1597 ~~ability to identify and pick wild mushrooms that are safe for human consumption~~  
 1598 ~~such as educational degrees, years of experience, membership to any professional~~  
 1599 ~~organizations;~~

- 1600 4. ~~Provide a written letter of reference from a separate individual who can verify the~~  
 1601 ~~picker has the expertise. The person supplying the letter of reference must be a~~  
 1602 ~~recognized mycologist who can attest the picker has the ability to identify the genus~~  
 1603 ~~and species of wild mushrooms they intend to pick;~~
- 1604 5. ~~Maintain records for at least two (2) years identifying the buyers, the type of~~  
 1605 ~~mushroom(s) received and the quantity received, and;~~
- 1606 6. ~~Supply an invoice to the buyer with each shipment that identifies:~~
- 1607 a. ~~The variety of mushroom by common name and genus and species;~~
- 1608 b. ~~The quantity;~~
- 1609 c. ~~The suppliers name, address, and date of packing.~~
- 1610 B. ~~This section does not apply to:~~
- 1611 1. ~~Cultivated wild mushroom species that are grown, harvested, and processed in an~~  
 1612 ~~operation that is regulated by the regulatory agency that has jurisdiction over the~~  
 1613 ~~operation; or~~
- 1614 2. ~~Wild mushroom species if they are in packaged form and are the product of a food~~  
 1615 ~~processing plant that is regulated by the food regulatory agency that has jurisdiction~~  
 1616 ~~over the plant.~~

1617 ~~\*3-307 Meat, Poultry, Game Animals and Exotic Species~~

- 1618 ~~Game animals and exotic species may be received for sale or service provided they are slaughtered~~  
 1619 ~~and processed according to laws governing meat and poultry as determined by the agency that has~~  
 1620 ~~animal health jurisdiction and the agency that conducts the inspection program.~~
- 1621 A. ~~Meat and poultry are required to come from a USDA FSIS inspected facility.~~
- 1622 1. ~~Meats listed in the Federal Meat Inspection Act that require mandatory USDA~~  
 1623 ~~inspection include cattle, swine, sheep, goats, horse, mule, other equine, and any~~  
 1624 ~~others as determined by the USDA.~~
- 1625 2. ~~Poultry listed in the Poultry Products Inspection Act that require Mandatory USDA~~  
 1626 ~~Inspection include chicken, geese, duck, turkey, guineas, emu, ratite, ostrich, squab~~  
 1627 ~~(pigeon), and any others as determined by the USDA.~~
- 1628 B. ~~Game animals indigenous to North America such as reindeer, elk, deer, antelope, water~~  
 1629 ~~buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and any others as~~  
 1630 ~~determined by the USDA shall go through the USDA Voluntary Meat~~**Error! Bookmark not**  
 1631 ~~defined.~~ **defined.** ~~Inspection Program in order to be considered an approved source.~~
- 1632 C. ~~Poultry products that are game animals are required to be inspected under the USDA~~  
 1633 ~~Voluntary Poultry Inspection Program. Species include Quail, pheasant, dove, other game~~  
 1634 ~~birds and any others as determined by the USDA.~~
- 1635 D. ~~Any other game animal that is obtained from a retail food establishment would fall under~~  
 1636 ~~FDA inspection authority. This would include rattlesnake, bear, alligator, and any others as~~  
 1637 ~~determined by the USDA.~~
- 1638 E. ~~Game animals obtained from States that have contracts with the FDA or USDA to conduct~~  
 1639 ~~inspections of game animal food processing establishments are recognized by the~~  
 1640 ~~Department as being an approved regulatory authority and food products received from these~~  
 1641 ~~states are considered an approved source.~~

1642 For additional guidance, refer to the Colorado Department of Public Health and Environment issued  
 1643 interpretative memo titled “Determining Approved Source for Meat, Poultry, Game Animals, and  
 1644 Exotic Animal Species.”

1645 ~~\*3-308—Eggs~~

1646 A. Only clean intact, approved shell eggs meeting applicable grade standards or pasteurized shell,  
 1647 liquid, frozen or dry eggs, or pasteurized dry egg products shall be used or offered for sale.

1648 B. The egg carton must be new, clean and properly labeled to include the supplier’s name and  
 1649 address, egg grade, size and pack date. *FDA Safe Handling Instructions* on the carton are  
 1650 required.

1651 C. Eggs can be offered for sale loose or in a basket, but must have an accompanying card or sign  
 1652 that contains the required labeling information including the wash and process date versus a  
 1653 pack date as indicated on a carton.

1654 D. Pooling of raw shell eggs is allowed only if the eggs are 41°F (5°C) or below when they are  
 1655 cracked and maintained at 41°F (5°C) or below until cooked.

1656 ~~3-309—Ice~~

1657 \*A. Only ice which has been manufactured from drinking water and handled in a sanitary manner  
 1658 shall be used or offered for sale. Ice offered for sale shall be packaged and properly labeled.

1659 B. Ice for human consumption shall be drained.

1660 ~~\*3-310—Ice Used as Exterior Coolant, Prohibited as Ingredient~~

1661 Ice used as a cooling medium for food storage, beverage containers, food containers or food utensils  
 1662 shall not be used or sold for human consumption.

1663 ~~3-311—Storage or Display of Food in Contact With Water or Ice~~

1664 A. Packaged food may be stored in direct contact with drinking water if the packaging,  
 1665 wrapping, or container is not subject to entry of water.

1666 B. Except as specified in C and D of this section, unpackaged food may not be stored in direct  
 1667 contact with undrained ice.

1668 C. Whole raw fruits and whole or cut raw vegetables, such as celery or carrot sticks or cut  
 1669 potatoes; and tofu may be immersed in ice made with drinking water.

1670 D. Raw chicken and raw fish that are received immersed in ice made with drinking water in  
 1671 shipping containers may remain in that condition while in storage awaiting preparation,  
 1672 display, service, or sale.

1673 ~~\*3-312—Juice~~

1674 A. Pre packaged juice shall be obtained pasteurized; in a sterile shelf stable form in a ; or  
 1675 otherwise treated under an approved HACCP plan as specified in 21 CFR section 120.24,  
 1676 (2003) to attain a 5-log reduction of the most resistant microorganism of public health  
 1677 significance.

1678

1679  
 1680 B. — ~~Juice packaged in a retail establishment and sold exclusively and directly to its consumers~~  
 1681 ~~does not have to be processed in conformance with an approved HACCP plan, but if~~  
 1682 ~~packaged shall bear the phrase: “WARNING: This product has not been pasteurized and,~~  
 1683 ~~therefore, may contain harmful bacteria that can cause serious illness in children, the elderly,~~  
 1684 ~~and persons with weakened immune systems” and meet the requirements of the Federal Fair~~  
 1685 ~~Packaging and Labeling Act.~~

1686 ~~**\*3-313 Whole Muscle, Intact Beef Steaks**~~

1687 ~~Whole muscle, intact beef steaks that are intended for consumption in an undercooked form~~  
 1688 ~~without a consumer advisory as specified in section 3-801 shall be:~~

1689 A. — ~~Obtained from a food processing plant that, upon requested by the purchaser, packages the~~  
 1690 ~~steaks and labels them, to indicate that the steaks meet the definition of whole muscle, intact~~  
 1691 ~~beef, or~~

1692 B. — ~~Deemed acceptable by the Department based on other evidence, such as written buyer~~  
 1693 ~~specifications or invoices, that indicates that the steaks meet the definition of whole muscle,~~  
 1694 ~~intact beef; and~~

1695 C. — ~~If individually cut in a food establishment:~~

1696 1. — ~~Cut from a whole muscle intact beef that is labeled by a food processing plant as~~  
 1697 ~~specified in part (A) of this section or identified as specified in part (B) of this~~  
 1698 ~~section;~~

1699 2. — ~~Prepared so they remain intact; and~~

1700 3. — ~~If packaged for undercooking in a food establishment, labeled as specified in part~~  
 1701 ~~(A) of this section or as identified in part (B) of this section.~~

1702 ~~**3-4 PROTECTION FROM CONTAMINATION AFTER RECEIVING**~~

1703 ~~**\*3-401 Preventing Contamination from Hands**~~

1704 A. — ~~Food employees shall wash their hands as specified in section 2-402 of these rules and~~  
 1705 ~~regulations.~~

1706 B. — ~~Food employees shall minimize bare hand and arm contact with exposed food that is not~~  
 1707 ~~in a ready to eat form.~~

1708 C. — ~~Except when washing fruits and vegetables as specified in section 3-408(A) of these~~  
 1709 ~~rules and regulations or except as specified in (D) of this section, food employees may~~  
 1710 ~~not contact exposed, ready to eat food including fruits and vegetables with their bare~~  
 1711 ~~hands and shall use suitable utensils such as deli tissue, spatulas, tongs, single use gloves,~~  
 1712 ~~or dispensing equipment.~~

1713 D. — ~~Food employees not serving a highly susceptible population may contact exposed, ready-~~  
 1714 ~~to eat food with their bare hands if:~~

1715 1. — ~~Written procedures are maintained in the food establishment and made available~~  
 1716 ~~to the Department upon request that include:~~

1717 a. — ~~A listing of the ready to eat food categories that are touched by bare~~  
 1718 ~~hands;~~

- 1719 b. ~~Handwashing facilities are, equipped, maintained, are easily accessible~~  
 1720 ~~and in close proximity to the work station(s) where the bare hand contact~~  
 1721 ~~procedure is conducted as specified in section 5-208 (B)–(J) of these~~  
 1722 ~~rules and regulations;~~
- 1723 c. ~~A written employee health policy that details how the food establishment~~  
 1724 ~~will comply with sections 2-201, 2-202, 2-203, and 2-204 of these rules~~  
 1725 ~~and regulations, including health conditions upon which the food~~  
 1726 ~~employee will not be allowed to work and acknowledgement of their~~  
 1727 ~~responsibilities as specified in sections 2-201 and 2-202;~~
- 1728 d. ~~An employee training program that documents completion of the~~  
 1729 ~~following training areas:~~
- 1730 ~~(1) The risks of contacting the ready-to-eat foods with bare hands;~~  
 1731 ~~(2) Proper handwashing as specified in section 2-401 and 2-402;~~  
 1732 ~~(3) When to wash their hands as specified in section 2-403;~~  
 1733 ~~(4) Where to wash their hands as specified in section 2-405;~~  
 1734 ~~(5) Proper fingernail maintenance as specified in section 2-406 (A);~~  
 1735 ~~(6) Prohibition of jewelry as specified in section 2-408; and~~  
 1736 ~~(7) Good hygienic practices as related to section 2-501 and section 2-~~  
 1737 ~~502.~~
- 1738 2. ~~Hands are washed prior to food preparation and as necessary to prevent cross~~  
 1739 ~~contamination as specified in section 2-401, 2-402, 2-403 and 2-405 by food~~  
 1740 ~~employees during all hours of operation when the specific ready-to-eat foods are~~  
 1741 ~~prepared.~~
- 1742 3. ~~In addition to the requirements specified in section 2-403 “When to Wash”, food~~  
 1743 ~~employees contacting ready-to-eat foods with bare hands utilize two or more of~~  
 1744 ~~the following control measures to provide additional safeguards to hazards~~  
 1745 ~~associated with bare hand contact:~~
- 1746 a. ~~Double handwashing;~~
- 1747 b. ~~Nail brushes;~~
- 1748 c. ~~A hand antiseptic after handwashing as specified in section 2-404;~~
- 1749 d. ~~Incentive programs that encourage food employees not to work when~~  
 1750 ~~they are ill with a communicable disease that can be transmitted by foods~~  
 1751 ~~as specified in section 2-201; or~~
- 1752 e. ~~Other control measures approved by the Department.~~
- 1753 4. ~~Corrective actions are immediately taken when subparagraphs D (1)–(3) of this~~  
 1754 ~~section are not followed. Accompanying monitoring, corrective actions, and~~  
 1755 ~~appropriate documentation are required.~~
- 1756 E. ~~If a food establishment is found to be in non-compliance with the requirements listed in~~  
 1757 ~~subparagraphs D (1)–(4) and a civil penalty has been issued in accordance with C.R.S.,~~  
 1758 ~~§25-4-1611, as a result of this non-compliance, or if a confirmed foodborne illness is~~  
 1759 ~~associated with bare hand contact and ill employees, the Department may suspend or~~

1760 ~~revoke the food establishment's allowance for food employees to contact ready-to-eat~~  
 1761 ~~foods with their bare hands.~~

1762 F. ~~— If the allowance for a food establishment to contact ready-to-eat foods with bare hands is~~  
 1763 ~~voluntarily discontinued by the food establishment, suspended or revoked as provided for~~  
 1764 ~~in subparagraph E, a food establishment may not reinstate bare hand contact with ready-~~  
 1765 ~~to-eat foods without prior written approval from the Department.~~

### 1766 ~~3-402—Glove Use~~

1767 ~~\*A. — If used, single-use gloves shall be used for only one task, such as working with ready-to-~~  
 1768 ~~eat food, or with raw animal food. Single-use gloves shall be used for no other purpose,~~  
 1769 ~~and discarded when damaged, when interruptions occur in the operation, or when the task~~  
 1770 ~~is completed.~~

1771 ~~B. — Except as specified in (C) slash-resistant gloves that are used to protect the hands during~~  
 1772 ~~operations requiring cutting shall be used in direct contact only with food that is~~  
 1773 ~~subsequently cooked as specified in part 3-5 such as frozen food or a primal cut of meat.~~

1774 ~~C. — Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently~~  
 1775 ~~cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer~~  
 1776 ~~surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent~~  
 1777 ~~glove, or a single-use glove.~~

1778 ~~D. — Cloth gloves may not be used in direct contact with food unless the food is subsequently~~  
 1779 ~~cooked as required under section 3-5 such as frozen food or a primal cut of meat.~~

### 1780 ~~\*3-403—Preventing Contamination When Tasting~~

1781 ~~A food employee may not use a utensil more than once to taste food that is to be sold or served.~~

### 1782 ~~\*3-404—General~~

1783 ~~At all times, including while being stored, prepared, displayed, dispensed, packaged, or transported,~~  
 1784 ~~food shall be protected from cross-contamination between foods and from potential contamination by~~  
 1785 ~~insects, insecticides, rodents, rodenticides, other toxins, probe-type price tags or probe-type~~  
 1786 ~~identification tags, unclean equipment and utensils, unnecessary handling, flooding, draining,~~  
 1787 ~~overhead leakage or condensation, or other agents of public health significance. Hanging primal cuts~~  
 1788 ~~and quarters or sides of meat, and uncut raw fruits and vegetables do not need to be over-wrapped or~~  
 1789 ~~covered. Foods in original individual packages must be over-wrapped or covered if the package has~~  
 1790 ~~been torn or broken. During transportation, including transportation to another location for service or~~  
 1791 ~~catering operations, food shall meet the requirements of these rules and regulations relating to food~~  
 1792 ~~protection, food storage and temperature maintenance of potentially hazardous foods~~  
 1793 ~~(time/temperature control for safety foods).~~

### 1794 ~~\*3-405—Cross-Contamination Control~~

1795 ~~Each time there is a change in processing between raw beef, raw pork, other raw meats, raw poultry,~~  
 1796 ~~raw fish and molluscan shellfish or from raw to ready-to-eat foods, food contact surfaces and utensils~~  
 1797 ~~shall be cleaned and sanitized as specified in 4-403 and 4-404. Salads and other ready-to-eat foods~~  
 1798 ~~may also be prepared simultaneously in areas that are separated by a barrier or open space from areas~~  
 1799 ~~used for processing potentially hazardous raw products.~~

1800 ~~3-406 — Packaged and Unpackaged Food — Separation, Packaging, and Segregation~~

1801 A. — ~~Food shall be protected from cross contamination by separating raw animal foods during~~  
 1802 ~~storage, preparation, holding, and display from:~~

1803 ~~\*1. — Raw ready to eat food including other raw animal food such as fish for sushi or~~  
 1804 ~~molluscan shellfish, or other raw ready to eat food such as fruits and vegetables;~~  
 1805 ~~and~~

1806 ~~\*2. — Cooked ready to eat food;~~

1807 B. — ~~Frozen, commercially processed and packaged raw animal food may be~~  
 1808 ~~stored or displayed with or above frozen, commercially processed and packaged, ready to~~  
 1809 ~~eat food.~~

1810 ~~\*3-407 — Pasteurized Eggs, Substitute for Shell Eggs for Certain Recipes~~

1811 ~~Pasteurized eggs or egg products shall be substituted for raw eggs in the preparation of foods such as~~  
 1812 ~~Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, meringue, eggnog, ice cream, and egg-~~  
 1813 ~~fortified beverages that are not cooked as specified in section 3-502 (D). This section does not apply~~  
 1814 ~~if there is a Consumer Advisory in place as specified in Section 3-801 excepts as prohibited by~~  
 1815 ~~Section 3-702(C).~~

1816 ~~3-408 — Washing Fruits and Vegetables/Additives/Sulfites~~

1817 A. — ~~Except as specified in (B)–(D) of this section and except for whole, raw fruits and vegetables~~  
 1818 ~~that are intended for washing by the consumer before consumption, raw fruits and vegetables~~  
 1819 ~~shall be thoroughly washed in running drinking water to remove soil and other contaminants~~  
 1820 ~~before being cut, combined with other ingredients, cooked, served, or offered for human~~  
 1821 ~~consumption in ready to eat form. Commercially, prewashed raw fruits and vegetables that~~  
 1822 ~~are prepackaged to prevent contamination do not require further washing prior to use.~~

1823 B. — ~~Fruits and vegetables from which rinds, peels, husks, or shells are not removed~~  
 1824 ~~before preparation require washing.~~

1825 C. — ~~Chemicals for washing fruits and vegetables, criteria.~~

1826 ~~\*1. — Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the~~  
 1827 ~~requirements specified in 21 CFR 173.315, “Chemicals used in washing or to assist~~  
 1828 ~~in the peeling of fruits and vegetables”.~~

1829 ~~2. — Ozone as an antimicrobial agent used in the treatment, storage, and processing of~~  
 1830 ~~fruits and vegetables in a food establishment shall meet the requirements specified in~~  
 1831 ~~21 CFR 173.368.~~

1832 ~~\*D. — Application of sulfiting agents to fresh fruits and vegetables intended for raw consumption or~~  
 1833 ~~to a food considered to be a good source of vitamin B<sub>12</sub>, such as poultry, crab meat (except~~  
 1834 ~~canned), mixed nuts, whole grains, whole grain flours, enriched bakery products is~~  
 1835 ~~prohibited.~~

1836 E. — ~~New or extensively remodeled establishments with food items that require washing shall~~  
 1837 ~~have a food preparation sink. The food preparation sink must be supplied with both hot and~~  
 1838 ~~cold running water, must be indirectly drained to sewer and must be equipped with an~~  
 1839 ~~approved eighteen inch (18") [(46 centimeters (cm))] drain board or an alternate drain table or~~  
 1840 ~~work space approved by the Department. If a garbage disposal is to be installed at the food~~

1841 preparation sink, it shall be located in the drain board of the sink and must be plumbed in  
1842 accordance with section 5-205.

1843 F. ~~— In establishments licensed prior to the effective date of these regulations, where vegetable~~  
1844 ~~preparation is limited to a few items and in limited quantity, and either single-service~~  
1845 ~~tableware or a mechanical dishwasher is used, the three-compartment warewashing sink~~  
1846 ~~may be used for food preparation if the sink is indirectly drained and the sink and drain~~  
1847 ~~boards are cleaned and sanitized between changes in use.~~

1848 G. ~~— A food preparation sink may only be used for washing food, cooling, thawing and other food~~  
1849 ~~preparation activities.~~

### 1850 ~~3-409~~ **In-Use Utensils, Between-Use Storage**

1851 A. ~~— To avoid unnecessary manual contact with the food, suitable dispensing utensils and single-~~  
1852 ~~service articles shall be used by employees and consumers. Consumer display and self-~~  
1853 ~~service of bulk food shall meet the requirements of section 25-4-1301 et seq., C.R.S., (See~~  
1854 ~~Appendix H). Except as specified in 5 and 6, dispensing utensils shall be:~~

- 1855 1. ~~— Stored in the food with the dispensing utensil handle extended out of the food; or~~
- 1856 2. ~~— Stored on a clean and sanitized surface, if washed and sanitized in accordance with~~  
1857 ~~section 4-407(C); or~~
- 1858 3. ~~— Stored in continuously flowing drinking water such as in a dipper well; or~~
- 1859 4. ~~— Stored at temperatures of 135°F (57°C) and above, or 41°F (5°C) and below.~~
- 1860 5. ~~— Utensils may not be stored in cracks and crevices between equipment.~~
- 1861 6. ~~— In-use utensils may not be stored in sanitizing or cleaning solutions.~~

1862 B. ~~— Ice for human consumption shall be dispensed only by employees with scoops, tongs, or~~  
1863 ~~other ice dispensing utensils, or through automatic self-service, ice dispensing equipment.~~  
1864 ~~Ice dispensing utensils shall be stored on a clean surface or in the ice with the dispensing~~  
1865 ~~utensil's handle extended out of the ice. Between uses, ice transfer receptacles shall be~~  
1866 ~~stored in a way that protects them from contamination.~~

### 1867 ~~3-410~~ **Wiping Cloths**

1868 A. ~~— Cloths used for wiping food spills on food contact surfaces shall be cleaned and rinsed~~  
1869 ~~frequently in one of the sanitizing solutions permitted in Appendix F of these rules and~~  
1870 ~~regulations and used for no other purpose. These cloths shall be held between uses in a~~  
1871 ~~clean, chemical sanitizer solution at the proper concentration.~~

1872 B. ~~— Cloths used for cleaning nonfood contact surfaces shall be clean and rinsed as specified in~~  
1873 ~~paragraph A of this section and used for no other purpose. These cloths shall be held~~  
1874 ~~between uses in a clean, chemical sanitizer solution at the proper concentration.~~

1875 C. ~~— Cloths that are used with raw foods of animal origin shall be kept separate from cloths used~~  
1876 ~~for other purposes. Cloths used with raw foods of animal origin shall be kept in a separate~~  
1877 ~~sanitizing solution.~~

1878 D. ~~— Dry, single-use disposable towels are permitted for wiping food spills in lieu of wiping~~  
1879 ~~cloths if discarded after each use.~~

1880 E. ~~— Cloths used for wiping food spills on tableware, such as plates and bowls being served to the~~  
1881 ~~consumer, shall be clean, dry, and used for no other purpose. —~~



- 1882 F. ~~Sponges shall not be used in contact with food contact surfaces.~~
- 1883 G. ~~Wet wiping cloths shall be laundered daily.~~
- 1884 H. ~~Dry wiping cloths shall be laundered as necessary to prevent contamination of food and~~  
1885 ~~clean serving utensils.~~

1886 **3-411 — Re-Use of Tableware**

- 1887 A. ~~Except as specified in B, re-use of soiled tableware is prohibited.~~
- 1888 B. ~~Beverage cups and glasses may be refilled where filling equipment is designed to prevent~~  
1889 ~~cross-contamination provided that the actuating lever or mechanism and filling device of~~  
1890 ~~beverage dispensing equipment is designed to prevent contact with the lip contact surface of~~  
1891 ~~glasses or cups that are being refilled.~~

1892 **3-412 — Refilling Returnables**

- 1893 A. ~~A take-home or personal food container shall not be refilled at a retail food establishment~~  
1894 ~~with a potentially hazardous food (time/temperature control for safety food).~~
- 1895 B. ~~Returnables refilled with food that is not potentially hazardous shall be clean.~~
- 1896 C. ~~Personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee~~  
1897 ~~cups, and promotional beverage glasses, may be refilled by employees or the consumer if~~  
1898 ~~refilling is a contamination-free process.~~

1899 **3-413 — Food Storage**

- 1900 A. ~~Containers of food shall be stored a minimum of six inches (6") [15 centimeters (cm)] above~~  
1901 ~~the floor or stored on dollies, skids, racks, or open-ended pallets, provided such equipment is~~  
1902 ~~easily movable, either by hand or with the use of pallet moving equipment that is on the~~  
1903 ~~premises and used. Such storage areas shall be kept clean.~~
- 1904 B. ~~Pressurized beverage containers, cased food in waterproof containers such as bottles or cans,~~  
1905 ~~milk containers in plastic crates, and waterproof, easily moveable, covered containers may be~~  
1906 ~~stored on a floor that is clean and not exposed to floor moisture.~~
- 1907 C. ~~Packaged food, once the container is opened in the retail food establishment prior to use or~~  
1908 ~~retail sale, shall be kept covered. Food, whether raw or prepared, if removed from the~~  
1909 ~~container in which it was originally packaged, shall be stored in a clean, covered container,~~  
1910 ~~except during necessary periods of preparation or cooling. Foods uncovered during~~  
1911 ~~preparation or cooling must be protected from contamination.~~
- 1912 ~~Primal cuts, quarters or sides of meat, or processed meats, such as country hams, slab bacon,~~  
1913 ~~and smoked or cured sausages, may be hung uncovered or placed on clean, sanitized metal~~  
1914 ~~racks in such a manner as to preclude contamination of any food products in storage.~~

1915 **3-414 — Food Storage, Prohibited Areas**

- 1916 Food may not be stored:
- 1917 A. ~~In locker areas unless the food is completely packaged;~~
- 1918 B. ~~In toilet rooms and their vestibules;~~
- 1919 C. ~~In dressing rooms;~~

- 1920 D. ~~— In rooms designated for garbage, recycling or composting collection;~~
- 1921 E. ~~— In mechanical rooms;~~
- 1922 F. ~~— Under sewer lines that are not shielded to intercept potential drips;~~
- 1923 G. ~~— Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on~~
- 1924 ~~which water has condensed;~~
- 1925 H. ~~— Under open stairwells;~~
- 1926 I. ~~— Under other sources of contamination; or~~
- 1927 J. ~~— In a private home.~~

1928 **3-415 — Food Display**

- 1929 A. ~~— Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling,~~
- 1930 ~~peeling, or washing by the consumer before consumption, food on display shall be protected~~
- 1931 ~~from contamination by the use of packaging; food shields at counters, service lines, or salad~~
- 1932 ~~bars; display cases; or other effective means of protection.~~
- 1933 B. ~~— French style, hearth baked or hard crusted loaves and rolls may be considered properly~~
- 1934 ~~wrapped if contained in an open end bag of sufficient size to enclose the loaves or rolls.~~
- 1935 C. ~~— Bulk food that is available for consumer self dispensing shall meet the requirements of~~
- 1936 ~~section 25-4-1301 et seq., C.R.S., (See Appendix H).~~

1937 **3-416 — Condiments, Protection**

- 1938 A. ~~— Condiments shall be protected from contamination by being kept in protective dispensers, in~~
- 1939 ~~food displays that meet the requirements of section 3-311 (A) and are provided with the~~
- 1940 ~~proper utensils, in original containers that are designed for dispensing, or in individual~~
- 1941 ~~packages or portions.~~
- 1942 B. ~~— Adding additional product before the container is emptied, cleaned and sanitized is~~
- 1943 ~~prohibited.~~

1944 **\*3-417 — Consumer Self-Service Operations**

- 1945 A. ~~— Unpackaged or unwrapped raw animal food, such as beef, lamb, pork, poultry and fish shall~~
- 1946 ~~not be offered for consumer self service. This does not apply to consumer self service of~~
- 1947 ~~ready to eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish, or~~
- 1948 ~~to ready to cook individual portions for immediate cooking and consumption on the~~
- 1949 ~~premises such as consumer cooked meats or consumer selected ingredients for Mongolian~~
- 1950 ~~barbecue.~~
- 1951 B. ~~— Consumer self service operations such as buffets and salad bars shall be monitored by food~~
- 1952 ~~employees trained in safe operating procedures.~~

1953 **\*3-418 — Reservice**

- 1954 ~~Once served to a consumer, portions of leftover food shall not be served again except that packaged~~
- 1955 ~~food, other than potentially hazardous food (time/temperature control for safety food), that is still in~~
- 1956 ~~an unopened package and is still in sound condition, may be re-served.~~

1957

1958

1959 **3-5 — DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN**

1960 **\*3-501 — Temperature**

1961 A. — The temperature of potentially hazardous foods (time/temperature control for safety foods)  
 1962 shall be 41°F (5°C) or below or 135°F (57°C) or above, at all times, except during necessary  
 1963 periods of preparation or as otherwise provided in this code.

1964 B. — Equipment for cooling, heating and holding food, cold and hot, shall be sufficient in number  
 1965 and capacity to provide required food temperatures.

1966 C. — Fluid milk and milk products, molluscan shellstock, and shell eggs may be received at their  
 1967 respective temperatures according to laws governing their distribution.

1968 D. — A food that is labeled frozen and shipped frozen by a food processing plant shall be received  
 1969 and stored frozen.

1970 E. — Upon receipt, potentially hazardous food (time/temperature control for safety food) shall be  
 1971 free of evidence of previous temperature abuse.

1972 **\*3-502 — Cooking Potentially Hazardous Foods (Time/Temperature Control For Safety Foods)**

1973 Potentially hazardous foods (time/temperature control for safety foods) processed within the retail  
 1974 food establishment shall be cooked to a uniform internal temperature of 135°F (57°C), except that:

1975 A. — Poultry, stuffed ratite, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, or stuffing  
 1976 containing fish, meat or poultry shall be cooked to a minimum internal temperature of at  
 1977 least 165°F (74°C) for 15 seconds.

1978 B. — Whole meat roasts including beef, corned beef, lamb, pork, and cured pork roasts such as  
 1979 ham shall be cooked:

1980 1. — In an oven that is preheated to the temperature specified for the roast's weight in the  
 1981 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 <sup>†</sup> | 250°F (121°C) OR LESS                  | 250°F (121°C) OR LESS  |

<sup>†</sup>RELATIVE HUMIDITY GREATER THAN 90% FOR AT LEAST 1 HOUR AS MEASURED IN THE COOKING CHAMBER OR EXIT OF THE OVEN; OR IN A MOISTURE IMPERMEABLE BAG THAT PROVIDES 100% HUMIDITY.

1982

1983 and

1984

1985  
1986  
1987

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<br>°F °C | TIME <sup>†</sup> IN<br>MINUTES | TEMPERATURE<br>°F °C | TIME <sup>†</sup> IN<br>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                               | -                    | -                               |

<sup>†</sup> ~~HOLDING TIME MAY INCLUDE POST-OVEN HEAT RISE.~~

1988

1989  
1990

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

1991  
1992

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

1993  
1994

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

1995  
1996

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.

1997  
1998

- 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.

1999  
2000

- 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).

2001  
2002  
2003

- 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.

2004  
2005

- 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.

2006  
2007  
2008

- 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.

2009

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

2010  
2011

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

- 2012 2. ~~Covered to retain surface moisture~~
- 2013 3. ~~Heated to a temperature of at least 165°F (74°C) in all parts of the food; an~~
- 2014 4. ~~Allowed to stand covered for 2 minutes after cooking to obtain temperature~~
- 2015 ~~equilibrium.~~
- 2016 J. ~~Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of~~
- 2017 ~~135°F (57°C).~~
- 2018 K. ~~Unless otherwise ordered by the immediate consumer and the consumer is informed as~~
- 2019 ~~specified in sections 1(a)–(c) below:~~
- 2020 1. ~~A raw animal food such as raw egg, raw fish, raw marinated fish, raw molluscan~~
- 2021 ~~shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft~~
- 2022 ~~cooked eggs, or rare meat other than whole muscle, intact beef steaks as specified in~~
- 2023 ~~(c) of this section, may be served or offered for sale upon consumer request or~~
- 2024 ~~selection in a ready-to-eat form if:~~
- 2025 a. ~~As specified in section 3-702(A)–(C) of these rules and regulations, the food~~
- 2026 ~~establishment serves a population that is not a highly susceptible~~
- 2027 ~~population;~~
- 2028 b. ~~The food, if served or offered for service by consumer selection from a~~
- 2029 ~~children's menu, does not contain comminuted meat; and~~
- 2030 c. ~~The consumer is informed as specified in part 3-8 "*Consumer Advisory*"~~
- 2031 ~~that to ensure its safety, the food should be cooked as specified in section 3-~~
- 2032 ~~502(A)–(K) of this section.~~

2033 **~~\*3-503 Non-Continuous Cooking of Raw Animal Foods~~**

- 2034 A. ~~Raw animal foods that are cooked using a non-continuous cooking process shall be:~~
- 2035 1. ~~Subject to an initial heating process that is no longer than sixty minutes in~~
- 2036 ~~duration;~~
- 2037 2. ~~Immediately after initial heating, cooled according to the time and temperature~~
- 2038 ~~parameters specified for cooked potentially hazardous food (time/temperature~~
- 2039 ~~control for safety food) in section 3-603(A) of these rules and regulations;~~
- 2040 3. ~~After cooling, held frozen or cold, as specified for potentially hazardous food~~
- 2041 ~~(time/temperature control for safety food) in section 3-501(A) of these rules and~~
- 2042 ~~regulations;~~
- 2043 4. ~~Prior to sale or service, cooked using a process that heats all parts of the food to a~~
- 2044 ~~temperature of at least 165°F (74°C) for 15 seconds;~~
- 2045 5. ~~Cooled according to the time and temperature parameters specified for cooked~~
- 2046 ~~potentially hazardous food (time/temperature control for safety food) in section~~
- 2047 ~~3-603(A)–(C) if not either hot held as specified in section 3-501(A), served~~
- 2048 ~~immediately, or held using time as a public health control as specified in section~~
- 2049 ~~3-605(A)–(B) after complete cooking; and~~
- 2050 6. ~~Prepared and stored according to written procedures approved by the Department~~
- 2051 ~~that:~~
- 2052 a. ~~Are maintained in the food establishment and are available to the~~
- 2053 ~~Department upon request;~~

- 2054 b. Describe how the requirements specified in (1) (5) of this Section are to  
 2055 be monitored and documented by the licensee and the corrective actions  
 2056 to be taken if the requirements are not met;
- 2057 e. Describe how the foods, after initial heating, but prior to complete  
 2058 cooking, are to be marked or otherwise identified as foods that must be  
 2059 cooked as specified in (4) of this section prior to being offered for sale or  
 2060 service; and
- 2061 d. Describe how the foods, after initial heating but prior to cooking as  
 2062 specified in section (4) of this section, are to be separated from ready-to-  
 2063 eat foods as specified in section 3-406.

2064 **\*3-504—Reheating**

- 2065 A. Except as specified in paragraphs (B) and (C) of this section, potentially hazardous foods  
 2066 (time/temperature control for safety foods) that have been cooked and then refrigerated shall  
 2067 be rapidly reheated within two hours to a uniform internal temperature of 165°F (74°C) or  
 2068 higher before being placed in hot food storage holding units which shall maintain product  
 2069 temperature at 135°F (57°C) or above at all times. Food warmers and other hot food holding  
 2070 units shall not be used to reheat potentially hazardous foods (time/temperature control for  
 2071 safety foods) unless the equipment is specifically designed for that purpose.
- 2072 B. Except as specified in paragraph (C) of this section, food reheated in a microwave oven shall  
 2073 be heated to a uniform internal temperature of at least 165°F (74°C) and the food is rotated  
 2074 or stirred, covered, and allowed to stand covered for 2 minutes after reheating.
- 2075 C. Ready to eat food taken from a commercially processed, hermetically sealed container, or  
 2076 from an intact package from a food processing plant that is inspected by the food Department  
 2077 that has jurisdiction over the plant, shall be heated within two hours to a uniform internal  
 2078 temperature of at least 135°F (60°C) for hot holding.

2079 **\*3-505—Preparation for Immediate Service**

- 2080 Cooked and refrigerated food that is prepared for immediate service in response to an individual  
 2081 consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

2082 **3-6—LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC**  
 2083 **HEALTH CONCERN**

2084 **3-601—Thawing**

- 2085 Except as specified in subparagraph (D) of this section, potentially hazardous foods  
 2086 (time/temperature control for safety foods) shall be thawed:
- 2087 \*A. Under refrigeration that maintain the food temperature at 41°F (5°C) or less; or
- 2088 B. Completely submerged and with packaging removed under running water:
- 2089 1. At a water temperature of 70°F (21°C) or below,
- 2090 2. With sufficient water velocity to agitate and float off loose particles in an overflow,  
 2091 and

- 2092                   \*3. — For a period of time that does not allow thawed portions of ready-to-eat food to rise  
2093                   above 41°F (5°C), or
- 2094                   \*4. — For a period of time that does not allow thawed portions of a raw animal food  
2095                   requiring cooking as specified in section 3-502 to be above 41°F (5°C), for more  
2096                   than 4 hours including:
- 2097                   a. — The time the food is exposed to the running water and the time needed for  
2098                   preparation for cooking, or
- 2099                   b. — The time it takes under refrigeration to lower the food temperature to 41°F  
2100                   (5°C);
- 2101                   C. — As part of a cooking process if the food that is frozen is:
- 2102                   1. — Cooked as specified in section 3-502, or
- 2103                   2. — Thawed in a microwave oven and immediately transferred to conventional cooking  
2104                   equipment, with no interruption in the process; or
- 2105                   D. — Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for  
2106                   immediate service in response to an individual consumer's order.

2107   **3-602 — Slacking**

- 2108                   A. — Frozen potentially hazardous food (time/temperature control for safety food) that is slacked  
2109                   to moderate the temperature shall be held:
- 2110                   \*1. — Under refrigeration that maintains the food temperature at 41°F (5°C) or less, or  
2111                   2. — At any temperature if the food remains frozen.

2112   **\*3-603 — Cooling**

- 2113                   A. — Cooked potentially hazardous foods (time/temperature control for safety foods) shall be  
2114                   cooled from 135°F (57°C) to 41°F (5°C), or below, in 6 hours, provided that the food is  
2115                   cooled from 135°F (57°C) to 70°F (21°C) within the first 2 hours.
- 2116                   B. — Potentially hazardous foods (time/temperature control for safety foods) that has been  
2117                   prepared from ingredients at ambient temperature, such as reconstituted milk and canned  
2118                   products, shall be cooled to 41°F (5°C), or below, within 4 hours.
- 2119                   C. — Fluid milk and milk products, shell eggs, and molluscan shellstock received in compliance  
2120                   with laws regulating the respective food during shipment from the supplier shall be cooled to  
2121                   41°F (5°C) or below within 4 hours. —

2122   **3-604 — Cooling Methods**

- 2123                   A. — Cooling shall be accomplished as required in section 3-603, by using one or more of the  
2124                   following methods based on the type of food being cooled:
- 2125                   1. — Placing the food in shallow pans;
- 2126                   2. — Separating the food into smaller or thinner portions;
- 2127                   3. — Using rapid cooling equipment;
- 2128                   4. — Stirring the food in a container placed in an ice water bath;

- 2129 5. ~~Using containers that facilitate heat transfer;~~
- 2130 6. ~~Adding ice as an ingredient; or~~
- 2131 7. ~~Other effective methods that meet the requirements of section 3-603 of these rules~~
- 2132 ~~and regulations.~~
- 2133 B. ~~When using food containers to cool food, food shall be:~~
- 2134 1. ~~Arranged in the container to provide maximum heat transfer through the container~~
- 2135 ~~walls; and~~
- 2136 2. ~~Loosely covered, or uncovered if protected from overhead contamination during the~~
- 2137 ~~cooling period to facilitate heat transfer from the surface of the food.~~

2138 **~~3-605 Time as a Public Health Control~~**

- 2139 \*A. ~~Except as specified in paragraph (D) of this section, if time without temperature control is~~
- 2140 ~~used as the public health control for a working supply of potentially hazardous food~~
- 2141 ~~(time/temperature control for safety food) before cooking, or for ready to eat potentially~~
- 2142 ~~hazardous food (time/temperature control for safety food) that is displayed or held for sale or~~
- 2143 ~~service:~~
- 2144 1. ~~Written procedures shall be prepared in advance, maintained in the food~~
- 2145 ~~establishment and made available to the Department upon request that specify:~~
- 2146 a. ~~Methods of compliance with subparagraphs (B)(1)-(3) or (C)(1)-(5) of this~~
- 2147 ~~section; and~~
- 2148 b. ~~Methods of compliance in section 3-501 of these rules and regulations for~~
- 2149 ~~food that is prepared, cooked, and refrigerated before time is used as a~~
- 2150 ~~public health control.~~
- 2151 \*B. ~~If time temperature control is used as the public health control up to a maximum of 4 hours:~~
- 2152 1. ~~The food shall have an initial temperature of 41°F (5°C) or less when removed from~~
- 2153 ~~cold holding temperature control, or 135°F (57°C) or greater when removed from~~
- 2154 ~~hot holding temperature control;~~
- 2155 2. ~~The food shall be marked or otherwise identified to indicate the time that is 4 hours~~
- 2156 ~~past the point in time when the food is removed from temperature control;~~
- 2157 3. ~~The food shall be cooked and served, served at any temperature if ready to eat, or~~
- 2158 ~~discarded, within 4 hours from the point in time when the food is removed from~~
- 2159 ~~temperature control; and~~
- 2160 4. ~~The food in unmarked containers or packages, or marked to exceed a 4 hour limit~~
- 2161 ~~shall be discarded.~~
- 2162 \*C. ~~If time without temperature control is used as the public health control up to a maximum of 6~~
- 2163 ~~hours:~~
- 2164 1. ~~The food shall have an initial temperature of 41°F (5°C) or less when removed from~~
- 2165 ~~temperature control and the food temperature may not exceed 70°F (21°C) within a~~
- 2166 ~~maximum time period of 6 hours;~~
- 2167 2. ~~The food shall be monitored to ensure the warmest portion of the food does not~~
- 2168 ~~exceed 70°F (21°C) during the 6 hour period, unless an ambient air temperature is~~



- 2169 ~~maintained that ensures the food does not exceed 70°F (21°C) during the 6 hour~~  
 2170 ~~holding period;~~
- 2171 3. ~~The food shall be marked or otherwise identified to indicate:~~
- 2172 a. ~~The time when the food is removed from 41°F (5°C) or less cold holding~~  
 2173 ~~temperature control, and~~
- 2174 b. ~~The time that is 6 hours past the point in time when the food is removed~~  
 2175 ~~from cold holding temperature control;~~
- 2176 4. ~~The food shall be:~~
- 2177 a. ~~Discarded if the temperature of the food exceeds 70°F (21°C), or~~
- 2178 b. ~~Cooked and served, served at any temperature if ready to eat, or discarded~~  
 2179 ~~within a maximum of 6 hours from the point in time when the food is removed from~~  
 2180 ~~41°F (5°C) or less cold holding temperature control; and~~
- 2181 5. ~~The food in unmarked containers or packages, or marked with a time that exceeds~~  
 2182 ~~the 6 hour limit shall be discarded.~~
- 2183 D. ~~A food establishment that serves a highly susceptible population may not use time as~~  
 2184 ~~specified in section (A), (B) or (C) of this section as the public health control for raw eggs.~~

2185 ~~\*3-606 Specialized Processing Methods~~

- 2186 A. ~~Unless otherwise approved by the Department, a retail food establishment shall develop a~~  
 2187 ~~HACCP plan and except in (4) of this section, obtain written approval from the Department~~  
 2188 ~~prior to engaging in any of the following:~~
- 2189 1. ~~Smoking food as a method of food preservation rather than as a method of flavor~~  
 2190 ~~enhancement;~~
- 2191 2. ~~Curing food;~~
- 2192 3. ~~Using food additives or adding components to alter the pH or Water Activity:~~
- 2193 a. ~~As a method of food preservation rather than as a method of flavor~~  
 2194 ~~enhancement, or~~
- 2195 b. ~~To render a food so that it is not potentially hazardous.~~
- 2196 4. ~~Packaging food using a reduced oxygen packaging method except as specified in~~  
 2197 ~~section 3-607 where a barrier to clostridium botulinum in addition to refrigeration~~  
 2198 ~~exists;~~
- 2199 5. ~~Operating a molluscan shellfish life support system display tank used to store or~~  
 2200 ~~display shellfish that are offered for human consumption;~~
- 2201 6. ~~Custom processing animals that are for personal use as food and not for sale or~~  
 2202 ~~service in a food establishment;~~
- 2203 7. ~~Sprouting seeds or beans;~~
- 2204 8. ~~Other specialized processing methods.~~
- 2205

2206

2207 ~~\*3-607~~ **Reduced Oxygen Packaging**

2208 A. ~~— A retail food establishment that packages potentially hazardous food (time/temperature~~  
 2209 ~~control for safety food) using a reduced oxygen packaging method shall control the growth~~  
 2210 ~~and toxin formation of Clostridium botulinum and the growth of Listeria monocytogenes and~~  
 2211 ~~have a HACCP plan that contains the information specified under Appendix G and that:~~

2212 1. ~~— Identifies the food to be packaged;~~

2213 2. ~~— Except as specified in (B)–(D) of this section, requires that the packaged food shall~~  
 2214 ~~be maintained at 41°F (5°C) or less and meet at least one of the following criteria:~~

2215 a. ~~— Has an a<sub>w</sub> of 0.91 or less;~~

2216 b. ~~— Has a pH of 4.6 or less;~~

2217 c. ~~— Is a meat or poultry product cured at a food processing plant regulated by~~  
 2218 ~~the U.S. Department of Agriculture (USDA) using substances specified in 9~~  
 2219 ~~CFR 424.21, use of food ingredients and sources of radiation, and is~~  
 2220 ~~received in an intact package; or~~

2221 d. ~~— Is a food with a high level of competing organisms such as raw meat or raw~~  
 2222 ~~poultry or raw vegetables.~~

2223 3. ~~— Describes how the package shall be prominently and conspicuously labeled on the~~  
 2224 ~~principal display panel in bold type on a contrasting background, with instructions~~  
 2225 ~~to:~~

2226 a. ~~— Maintain the food at 41°F (5°C) or below, and~~

2227 b. ~~— Discard the food if within fourteen (14) calendar days of its packaging it is~~  
 2228 ~~not served for on-premises consumption, or consumed if served or sold for~~  
 2229 ~~off-premises consumption;~~

2230 4. ~~— Limits the refrigerated shelf life to no more than fourteen (14) calendar days from~~  
 2231 ~~packaging to consumption, except the time the product is maintained frozen, or the~~  
 2232 ~~original manufacturer's "sell by" or "use by" date, whichever occurs first;~~

2233 5. ~~— Includes operational procedures that:~~

2234 a. ~~— Prohibit contacting ready-to-eat food with bare hands as specified in section~~  
 2235 ~~3-302 of these rules and regulations;~~

2236 b. ~~— Identify a designated work area and the method by which:~~

2237 (1) ~~— Physical barriers or methods of separation of raw foods and ready-~~  
 2238 ~~to-eat foods minimize cross-contamination, and~~

2239 (2) ~~— Access to the processing equipment is limited to responsible trained~~  
 2240 ~~personnel familiar with the potential hazards of the operation, and~~

2241 c. ~~— Delineate cleaning and sanitization procedures for food-contact surfaces;~~  
 2242 ~~and~~

2243

- 2244  
2245 6. ~~Describes the training program that ensures that the individual responsible for the~~  
2246 ~~reduced oxygen packaging operation understands the:~~
- 2247 a. ~~Concepts required for a safe operation;~~  
2248 b. ~~Equipment and facilities, and~~  
2249 c. ~~Procedures specified under Subparagraph (A)(5) of this section and~~  
2250 ~~Appendix G.~~
- 2251 B. ~~Except for fish that is frozen before, during, and after packaging, a food establishment may~~  
2252 ~~not package fish using a reduced oxygen packaging method.~~
- 2253 C. ~~Except as specified in (B) of this section, a food establishment that packages potentially~~  
2254 ~~hazardous food (time/temperature control for safety food) food using a cook chill or sous~~  
2255 ~~vide process shall:~~
- 2256 1. ~~Implement a HACCP plan that contains the information as specified in Appendix G;~~  
2257 2. ~~Ensure the food is:~~
- 2258 a. ~~Prepared and consumed on the premises, or prepared and consumed off the~~  
2259 ~~premises but within the same business entity with no distribution or sale of~~  
2260 ~~the packaged product to another business entity or the consumer;~~
- 2261 b. ~~Cooked to heat all parts of the food to a temperature and for a time as~~  
2262 ~~specified in section 3-502;~~
- 2263 c. ~~Protected from contamination before and after cooking as specified in~~  
2264 ~~section 3-401 through 3-406;~~
- 2265 d. ~~Placed in a package with an oxygen barrier and sealed before cooking, or~~  
2266 ~~placed in a package and sealed immediately after cooking and before~~  
2267 ~~reaching a temperature below 57°C (135°F);~~
- 2268 e. ~~Cooled to 41°F (5°C) in the sealed package or bag as specified in section 3-~~  
2269 ~~503 and:~~
- 2270 (1) ~~Cooled to 34°F (1°C) within 48 hours of reaching 41°F (5°C) and held~~  
2271 ~~at that temperature until consumed or discarded within thirty (30)~~  
2272 ~~days after the date of packaging;~~
- 2273 (2) ~~Held at 41°F (5°C) or less for no more than 7 days, at which time the~~  
2274 ~~food must be consumed or discarded; or~~
- 2275 (3) ~~Held frozen with no shelf life restriction while frozen until consumed~~  
2276 ~~or used.~~
- 2277 f. ~~Held in a refrigeration unit that is equipped with an electronic system that~~  
2278 ~~continuously monitors time and temperature and is visually examined for~~  
2279 ~~proper operation twice daily;~~
- 2280 g. ~~If transported off site to a satellite location of the same business entity,~~  
2281 ~~equipped with verifiable electronic monitoring devices to ensure that times~~  
2282 ~~and temperatures are monitored during transportation; and~~
- 2283 h. ~~Labeled with the product name and the date packaged; and~~

- 2284 3. ~~Maintain the records required to confirm that cooling and cold holding refrigeration~~  
 2285 ~~time/temperature parameters are met as part of the HACCP plan and:~~
- 2286 a. ~~Make such records available to the Department upon request, and~~  
 2287 b. ~~Hold such records for at least 6 months; and~~
- 2288 4. ~~Implement written operational procedures as specified in (A)(5) of this section and a~~  
 2289 ~~training program as specified in (A)(6) of this section.~~
- 2290 D. ~~A food establishment that packages cheese using a reduced oxygen packaging method shall:~~
- 2291 1. ~~Limit the cheeses packaged to those that are commercially manufactured in a food~~  
 2292 ~~processing plant with no ingredients added in the food establishment and that meet~~  
 2293 ~~the Standards of Identity as specified in 21 CFR 133.150 Hard cheeses, 21 CFR~~  
 2294 ~~133.169 Pasteurized process cheese or 21 CFR 133.187 Semisoft cheeses;~~
- 2295 2. ~~Have a HACCP plan that contains the information specified under appendix G and~~  
 2296 ~~as specified in (A)(1), (A)(3)(a), (A)(5) and (A)(6) of this section;~~
- 2297 3. ~~Labels the package on the principal display panel with a "use by" date that does not~~  
 2298 ~~exceed thirty (30) days from its packaging or the original manufacturer's "sell by" or~~  
 2299 ~~"use by" date, whichever occurs first; and~~
- 2300 4. ~~Discards the reduced oxygen packaged cheese if it is not sold for off premises~~  
 2301 ~~consumption or consumed within thirty (30) calendar days of its packaging.~~
- 2302 E. ~~When applying a reduced oxygen packaging process, retail food establishments shall notify~~  
 2303 ~~the Department in advance and indicate the method proposed (i.e. cook chill, sous vide).~~

2304 **3-608 — Breeding Mixtures**

- 2305 A. ~~Containers of dry breeding mixtures (containing flour, cornmeal, spices, etc.) into which raw~~  
 2306 ~~animal foods such as poultry and fish are repeatedly dipped, may be used for a total period of~~  
 2307 ~~up to 7 days and stored at room temperature, provided that:~~
- 2308 1. ~~Containers are stored covered in a clean dry area overnight and/or when not in use~~  
 2309 ~~as specified in sections 3-413 and 3-414;~~
- 2310 2. ~~The breeding mixture is sifted at a minimum of every 4 hours to remove excess~~  
 2311 ~~moisture and doughballs while in use; and~~
- 2312 3. ~~Containers are completely emptied, cleaned and sanitized, and the breeding mixtures~~  
 2313 ~~discarded at intervals of no greater than 7 days.~~
- 2314 B. ~~If this procedure is used, the person in charge must have a system in place to indicate the~~  
 2315 ~~date the breeding must be discarded.~~
- 2316

2317

2318 **3-7 — ON-PREMISES LABELING**2319 **3-701 — Labeling**

2320 A. ~~When voluntary code date information appears on a retail food establishment or~~  
 2321 ~~manufacturers' label, it shall not be concealed or altered.~~

2322 B. ~~Bulk food available for consumer self dispensing shall be prominently labeled according to~~  
 2323 ~~section 25-4-1301 et seq., C.R.S., (See Appendix H).~~

2324 C. ~~If an unpackaged non-bulk food product is manufactured on-site and sold at the site where it~~  
 2325 ~~was manufactured or sold over the counter at a different site, no labeling is required.~~  
 2326 ~~However, an ingredient label shall be made available upon request.~~

2327 ~~— If a packed food product is manufactured and sold on or off site for customer self service, it~~  
 2328 ~~must be labeled in accordance with section 25-5-401 et seq., C.R.S. and all labeling~~  
 2329 ~~regulations authorized therein.~~

2330 D. ~~A food ingredient, such as flour, sugar, salt, spices, dried herbs, potato flakes, baking~~  
 2331 ~~powder, cooking oil or vinegar, that is not stored in the original package and is not readily~~  
 2332 ~~identifiable on sight, shall be stored in a container identifying it by a common name.~~

2333 **3-702 — Special Requirements for Highly Susceptible Populations**

2334 A. ~~Ready to Eat, Potentially Hazardous Food (Time/Temperature Control for Safety Food)~~  
 2335 ~~served in facilities providing food to highly susceptible populations shall adhere to the~~  
 2336 ~~following date marking requirements:~~

2337 \*1. ~~Except when packaging food using a reduced oxygen packaging method as specified~~  
 2338 ~~in section 3-607 of these rules and regulations, and except as specified in (4) and (5)~~  
 2339 ~~of this section, refrigerated, ready to eat, potentially hazardous food~~  
 2340 ~~(time/temperature control for safety food) prepared and held in a food establishment~~  
 2341 ~~for more than 24 hours shall be clearly marked to indicate the date or day by which~~  
 2342 ~~the food shall be consumed on the premises, sold, or discarded when held at a~~  
 2343 ~~temperature of 41°F (5°C) or less for a maximum of 7 days.~~

2344 \*2. ~~Except as specified in (4) (6) of this section, refrigerated, ready to eat, potentially~~  
 2345 ~~hazardous food (time/temperature control for safety food) prepared and packaged by~~  
 2346 ~~a food processing plant shall be clearly marked, at the time the original container is~~  
 2347 ~~opened in a food establishment and if the food is held for more than 24 hours, to~~  
 2348 ~~indicate the date or day by which the food shall be consumed on the premises, sold,~~  
 2349 ~~or discarded, based on the temperature and time combinations specified in (1) of this~~  
 2350 ~~section and:~~

2351 a. ~~The day the original container is opened in the food establishment shall be~~  
 2352 ~~counted as Day 1; and~~

2353 b. ~~The day or date marked by the food establishment may not exceed a~~  
 2354 ~~manufacturer's use-by date if the manufacturer determined the use-by date~~  
 2355 ~~based on food safety.~~

2356 \*3. ~~A refrigerated, ready to eat, potentially hazardous food (time/temperature control~~  
 2357 ~~for safety food) ingredient or a portion of a refrigerated, ready to eat, potentially~~

- 2358 ~~hazardous food (time/temperature control for safety food) that is subsequently~~  
 2359 ~~combined with additional ingredients or portions of food shall retain the date~~  
 2360 ~~marking of the earliest prepared or first prepared ingredient.~~
- 2361 4. ~~A date marking system that meets the criteria stated in (1) and (2) of this section~~  
 2362 ~~may include:~~
- 2363 a. ~~Using a method approved by the Department for refrigerated, ready to eat~~  
 2364 ~~potentially hazardous food (time/temperature control for safety food) that is~~  
 2365 ~~frequently rewrapped, such as lunchmeat or a roast, or for which date~~  
 2366 ~~marking is impractical, such as soft serve mix or milk in a dispensing~~  
 2367 ~~machine~~
- 2368 b. ~~Marking the date or day of preparation, with a procedure to discard the food~~  
 2369 ~~on or before the last date or day by which the food must be consumed on the~~  
 2370 ~~premises, sold, or discarded as specified in (a) of this section;~~
- 2371 c. ~~Marking the date or day the original container is opened in a food~~  
 2372 ~~establishment, with a procedure to discard the food on or before the last date~~  
 2373 ~~or day by which the food must be consumed on the premises, sold, or~~  
 2374 ~~discarded as specified in (b) of this section; or~~
- 2375 d. ~~Using calendar dates, days of the week, color coded marks, or other~~  
 2376 ~~effective marking methods, provided that the marking system is disclosed to~~  
 2377 ~~the Department upon request.~~
- 2378 5. ~~Paragraphs (1) and (2) of this section do not apply to individual meal portions served~~  
 2379 ~~or repackaged for sale from a bulk container upon a consumer's request.~~
- 2380 6. ~~Paragraph (2) of this section does not apply to the following foods prepared and~~  
 2381 ~~packaged by a food processing plant inspected by a Department:~~
- 2382 a. ~~Deli salads, such as ham salad, seafood salad, chicken salad, egg salad,~~  
 2383 ~~pasta salad, potato salad, and macaroni salad, manufactured in accordance~~  
 2384 ~~with 21 CFR 110 Current good manufacturing practice in manufacturing,~~  
 2385 ~~packing, or holding human food;~~
- 2386 b. ~~Hard cheeses containing not more than 39% moisture as defined in 21 CFR~~  
 2387 ~~133 Cheeses and related cheese products, such as cheddar, gruyere,~~  
 2388 ~~parmesan and reggiano, and romano;~~
- 2389 c. ~~Semi-soft cheeses containing more than 39% moisture, but not more than~~  
 2390 ~~50% moisture, as defined in 21 CFR 133 Cheeses and related cheese~~  
 2391 ~~products, such as blue, edam, gorgonzola, gouda, and monterey jack;~~
- 2392 d. ~~Cultured dairy products as defined in 21 CFR 131 Milk and cream, such as~~  
 2393 ~~yogurt, sour cream, and buttermilk;~~
- 2394 e. ~~Preserved fish products, such as pickled herring and dried or salted cod, and~~  
 2395 ~~other acidified fish products defined in 21 CFR 114 Acidified foods;~~
- 2396 f. ~~Shelf stable, dry fermented sausages, such as pepperoni and Genoa salami~~  
 2397 ~~that are not labeled "Keep Refrigerated" as specified in 9 CFR 317~~  
 2398 ~~Labeling, marking devices, and containers, and which retain the original~~  
 2399 ~~casing on the product; and~~

- 2400 g. — Shelf stable salt-cured products such as prosciutto and Parma (ham) that are  
 2401 not labeled "Keep Refrigerated" as specified in 9 CFR 317 Labeling,  
 2402 marking devices, and containers.
- 2403 \*B. — A food establishment that packages potentially hazardous food (time/temperature control for  
 2404 safety food) that will be served in facilities providing food to highly susceptible populations  
 2405 using a reduced-oxygen packaging method as specified in section 3-607 shall have a HACCP  
 2406 plan that contains the information specified under appendix G and that is provided to the  
 2407 Department for review and approval prior to implementation.
- 2408 \*C. — The following foods may not be served or offered for sale in a ready-to-eat form to persons  
 2409 in a highly susceptible population:
- 2410 1. — Raw animal foods such as raw fish, raw marinated fish, raw molluscan shellfish, and  
 2411 steak tartare;
- 2412 2. — A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked  
 2413 eggs that are made from raw shell eggs and meringue;
- 2414 3. — Raw seed sprouts;
- 2415 4. — Juice that is not pasteurized or treated under an HACCP plan as specified in  
 2416 Appendix G of these rules and regulations, or contains a warning label as specified  
 2417 in Section 3-312(B) of these rules and regulations;
- 2418 \*D. — Food may not be re-served to or from highly susceptible populations under the following  
 2419 conditions:
- 2420 1. — Any food served to patients or clients who are under contact precautions in medical  
 2421 isolation or quarantine, or protective environment isolation may not be re-served to  
 2422 others outside.
- 2423 2. — Packages of food from any patients, clients, or other consumers should not be re-  
 2424 served to persons in protective environment isolation.

2425 **3-8 — CONSUMER ADVISORY (Section Effective July 1, 2013)**

2426 **\*3-801 — Consumption of Animal Foods That Are Raw, Undercooked, or Not Otherwise Processed**  
 2427 **— to Eliminate Pathogens**

- 2428 A. — Except as specified in 3-502(C) and Subparagraph 3-502(K)(1) and in 3-702(A)-(D), if an  
 2429 animal food such as beef, eggs, fish, lamb, milk, pork, poultry, or shellfish is served or sold  
 2430 raw, undercooked, or without otherwise being processed to eliminate pathogens, either in  
 2431 ready-to-eat form or as an ingredient in another ready-to-eat food, the licensee shall inform  
 2432 consumers of the significantly increased risk of consuming such foods by way of a disclosure  
 2433 and reminder, as specified in (B) and (C) of this section using brochures, deli case or menu  
 2434 advisories, label statements, table tents, placards, or other effective written means.
- 2435 B. — Disclosure shall include:
- 2436 1. — A description of the animal-derived foods, such as "oysters on the half shell (raw  
 2437 oysters)," "undercooked eggs," and "hamburgers (can be cooked to order)," or

- 2438 2. ~~Identification of the animal derived foods by asterisking them to a footnote that~~  
2439 ~~states that the items are served raw or undercooked, or contain (or may contain) raw~~  
2440 ~~or undercooked ingredients.~~
- 2441 C. ~~Reminder shall include asterisking the animal derived foods requiring disclosure to a~~  
2442 ~~footnote that states:~~
- 2443 1. ~~Regarding the safety of these items, written information is available upon request;~~
- 2444 2. ~~Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may~~  
2445 ~~increase your risk of foodborne illness; or~~
- 2446 3. ~~Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may~~  
2447 ~~increase your risk of foodborne illness, especially if you have certain medical~~  
2448 ~~conditions.~~
- 2449



2450

**CHAPTER 4**

2451

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

2452

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

2453

**~~4-101 — General~~**

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

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**~~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:~~

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~~A. — Smooth;~~

2475

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

2476

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

2477

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

2478

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

2479

~~1. — Without being disassembled,~~

2480

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

2481

~~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.~~

2482

2483

2484 **4-202—Use Limitations**

2485 A. ~~Cast iron may only be used as a cooking surface which can include use in the service of food~~  
 2486 ~~when used in an uninterrupted process from cooking through service.~~

2487 \*B. ~~Ceramic, china, crystal utensils, and decorative utensils, such as hand-painted ceramic or~~  
 2488 ~~china, that are used in contact with food shall be lead free or contain levels of lead not~~  
 2489 ~~exceeding the limits of the following utensil categories:~~

2490

| 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               |

2491

2492 \*C. ~~Copper and copper alloys, such as brass, may not be used in contact with food that has a pH~~  
 2493 ~~below 6 (e.g. vinegar, fruit juice, wine, carbonated beverage, etc.).~~

2494 ~~—Copper and copper alloys may be used in contact with beer brewing ingredients that have a~~  
 2495 ~~pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such~~  
 2496 ~~as a brewpub or microbrewery.~~

2497 D. ~~Enamelware shall not be used for storage or preparation of acidic foods (e.g. vinegar, tomato~~  
 2498 ~~based sauces, juices, etc.).~~

2499 \*E. ~~Galvanized metal may not be used to fabricate food contact surfaces of equipment that is~~  
 2500 ~~used for beverages, moist food, or hygroscopic food.~~

2501 F. ~~Linens and napkins may not be used in contact with food unless they are used to line a~~  
 2502 ~~container for the service of foods and the linens and napkins are replaced each time the~~  
 2503 ~~container is refilled for a new consumer.~~

2504 G. ~~Clean cloth gloves may be used in direct contact with food that will be subsequently cooked~~  
 2505 ~~as required as specified in part 3-5 of these rules and regulations, such as frozen food or a~~  
 2506 ~~primal cut of meat.~~

2507 H. ~~Pewter alloys containing lead in excess of 0.05% may not be used as a food contact surface.~~

2508 I. ~~Solder and flux containing lead in excess of 0.2%, and cadmium, antimony, bismuth, or~~  
 2509 ~~other toxic chemicals may not be used on surfaces that contact food.~~

2510 J. ~~Except as specified in paragraphs 1, 2, and 3 of this section, wood and wicker may not be~~  
 2511 ~~used as a food contact surface.~~

2512 1. ~~Hard maple or an equivalently hard, close-grained, nonabsorbent wood, provided it~~  
 2513 ~~is not cracked, pitted or uncleanable, may be used for:~~

- 2514 a. ~~Cutting boards, cutting blocks, bakers' tables, bagel boards, and utensils~~  
 2515 ~~such as rolling pins, doughnut dowels, salad bowls, pizza paddles, and~~  
 2516 ~~chopsticks; and~~
- 2517 b. ~~Wooden paddles used in confectionery operations for pressure scraping~~  
 2518 ~~kettles when manually preparing confections at a temperature of 230°F~~  
 2519 ~~(110°C) or above.~~
- 2520 2. ~~Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the~~  
 2521 ~~original wood or wicker containers until the fruits, vegetables, or nuts are used.~~
- 2522 3. ~~If the nature of the food requires removal of rinds, peels, husks, or shells before~~  
 2523 ~~consumption, the whole, uncut, raw food may be kept in:~~
- 2524 a. ~~Untreated wood or wicker containers; or~~
- 2525 b. ~~Treated wood containers if the containers are treated with a preservative~~  
 2526 ~~that meets the requirements specified by the Department in Preservatives for~~  
 2527 ~~Wood, 21 CFR section 178.3800, (2008).~~
- 2528 K. ~~Cutting surfaces that are scratched and scored must be resurfaced so as to be easily cleaned,~~  
 2529 ~~or be discarded when these surfaces can no longer be effectively cleaned and sanitized.~~
- 2530 L. ~~Wrapping of utensils or equipment handles with absorbent or difficult to clean material, such~~  
 2531 ~~as string, wire or tape shall not be allowed.~~
- 2532 M. ~~Newspaper, cloth, paper, oil cloth, cardboard, towels and other nonfood grade surfaces, such~~  
 2533 ~~as grocery bags or retail store bags, are not approved food contact surfaces. This does not~~  
 2534 ~~preclude the use of grocery bags for retail customers.~~

#### 2535 ~~4-203 — Nonfood Contact Surfaces~~

- 2536 ~~Nonfood contact surfaces shall be constructed of approved materials, in good repair, and be easily~~  
 2537 ~~maintained in a clean and sanitary condition.~~
- 2538 A. ~~In new or extensively remodeled retail food establishments, wood interior construction in~~  
 2539 ~~walk-in cooler and freezer units shall be prohibited.~~
- 2540 B. ~~Unfinished wood is not acceptable in food preparation, equipment or warewashing, or food~~  
 2541 ~~storage areas other than those areas used solely as dry food storage areas.~~
- 2542 C. ~~Surfaces of equipment or other areas, which are exposed to splash, food debris or which~~  
 2543 ~~otherwise require frequent cleaning, shall be designed and fabricated to be smooth, durable,~~  
 2544 ~~nonabsorbent, washable, free of unnecessary ledges, projections, or crevices, and readily~~  
 2545 ~~accessible for cleaning.~~
- 2546 D. ~~Wicker and wicker like materials, in good repair can be used for service and display of~~  
 2547 ~~prepackaged food. Service of bread or rolls in wicker or wicker like materials is permissible~~  
 2548 ~~if lined with dry linens or napkins, which are replaced each time the container is refilled for a~~  
 2549 ~~new customer.~~
- 2550 E. ~~Newspapers, cloth, paper, cardboard, towels, contact paper, foil, oil cloth, or similar~~  
 2551 ~~materials shall not be used as liners for shelves, drawers, or drain boards.~~

#### 2552 ~~4-204 — Clean In Place (CIP) Equipment~~

- 2553 A. ~~CIP equipment shall meet the characteristics of food contact surfaces and shall be designed~~  
 2554 ~~and constructed so that:~~

- 2555                   \*1. ~~Cleaning and sanitizing solutions circulate throughout a fixed system and contact all~~  
 2556                   ~~interior food contact surfaces; and~~
- 2557                   2. ~~The system is self draining or capable of being completely drained of cleaning and~~  
 2558                   ~~sanitizing solutions.~~
- 2559                B. ~~CIP equipment that is not designed to be disassembled for cleaning shall be designed with~~  
 2560                   ~~inspection access points to ensure that all interior food contact surfaces throughout the fixed~~  
 2561                   ~~system are being effectively cleaned.~~

2562   **4-205 — “V” Threads, Use Limitation**

- 2563                   ~~“V” type threads may not be used on food contact surfaces, except for hot oil cooking or filtering~~  
 2564                   ~~equipment.~~

2565   **4-206 — Hot Oil Filtering Equipment**

- 2566                   ~~Hot oil filtering equipment shall meet the characteristics specified under food contact surfaces as~~  
 2567                   ~~specified in section 4-201 or CIP equipment as specified in section 4-204 and shall be readily~~  
 2568                   ~~accessible for filter replacement and cleaning of the filter.~~

2569   **4-207 — Bearings and Gear Boxes, Leakproof**

- 2570                   ~~Equipment containing bearings and gears requiring lubricants not made of safe materials shall be~~  
 2571                   ~~designed, constructed and maintained to ensure that the lubricant cannot leak, drip, or be forced into~~  
 2572                   ~~food or onto food contact surfaces. Equipment designed to receive lubrication of bearings and gears~~  
 2573                   ~~on or within food contact surfaces shall be lubricated with materials meeting the requirements of~~  
 2574                   ~~Lubricants, 21 CFR section 178.3570, (2008). (see Appendix E)~~

2575   **4-208 — Beverage Tubing, Separation**

- 2576                   ~~Beverage tubing and cold plate beverage cooling devices shall not be installed in contact with stored~~  
 2577                   ~~ice. This section does not apply to cold plates that are constructed integrally with an ice storage bin.~~

2578   **4-209 — Ice Units, Separation of Drains**

- 2579                   ~~Liquid waste drain lines may not pass through an ice machine or ice storage bin.~~

2580   **4-210 — Condenser Unit, Separation**

- 2581                   ~~If a condenser unit is an integral component of equipment, the condenser unit shall be separated from~~  
 2582                   ~~the food and food storage space by a dustproof barrier.~~

2583   **\*4-211 — Molluscan Shellfish Tanks**

- 2584                   A. ~~Except as specified in B of this section, molluscan shellfish life support system display tanks~~  
 2585                   ~~may not be used to store or display shellfish that are offered for human consumption and~~  
 2586                   ~~shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for~~  
 2587                   ~~display only.~~

- 2588                   B. ~~Molluscan shellfish life support system display tanks that are used to store or display~~  
 2589                   ~~shellfish that are offered for human consumption shall be operated and maintained in~~  
 2590                   ~~accordance with an approval granted by the department or an approved HACCP plan that:~~

- 2591 1. ~~Is submitted by the licensee and approved as specified in section 11-403; and~~
- 2592 2. ~~Ensures that:~~
- 2593 a. ~~Water used with fish other than molluscan shellfish does not flow into the~~
- 2594 ~~molluscan tank,~~
- 2595 b. ~~The safety and quality of the shellfish as they were received are not~~
- 2596 ~~compromised by the use of the tank, and~~
- 2597 c. ~~The identity of the source of the shell stock is retained as specified in~~
- 2598 ~~section 3-201(B).~~

2599 **4-212 — Ventilation and Ventilation Hood Systems**

- 2600 ~~All rooms shall have sufficient ventilation to keep them free of excessive heat, steam, condensation,~~
- 2601 ~~vapors, obnoxious odors, smoke, and fumes. Ventilation systems shall comply with applicable~~
- 2602 ~~building department and fire prevention bureau requirements, and when vented to the outside shall~~
- 2603 ~~not create an unsightly, harmful, or unlawful discharge. Ventilation systems shall comply with 2006~~
- 2604 ~~International Mechanical Code (IMC). When local building and/or fire departments have adopted~~
- 2605 ~~codes equivalent or more stringent than the above, those codes shall apply.~~
- 2606 ~~A. Ventilation Hood Systems. Ventilation systems shall be sufficient in number, capacity, and~~
- 2607 ~~designed and constructed according to 2006 International Mechanical Code, chapter 5,~~
- 2608 ~~sections 507 and 508. Ventilation systems and devices shall be designed to prevent grease or~~
- 2609 ~~condensation from collecting on walls and ceilings, and from dripping into food or onto~~
- 2610 ~~food contact surfaces. Hood filters or other grease extracting equipment shall be easily~~
- 2611 ~~removable for cleaning and replacement when not designed for in place cleaning. Hood~~
- 2612 ~~filters shall remain in place whenever the system is in operation.~~
- 2613 ~~B. Equipment from which aerosols, obnoxious odors, noxious fumes, or vapors may originate~~
- 2614 ~~shall be effectively vented to the outside air or vented through an approved ventilation~~
- 2615 ~~system:~~
- 2616 1. ~~Type I hoods shall be installed where cooking~~
- 2617 ~~appliances produce grease or smoke such as occurs with grills, fryers, broilers,~~
- 2618 ~~ranges and woks.~~
- 2619 2. ~~Type II hoods shall be installed where cooking or~~
- 2620 ~~dish washing appliances produce heat, steam or products of combustion but do not~~
- 2621 ~~produce grease or smoke. This includes steamers, pasta cookers and high~~
- 2622 ~~temperature sanitizing dish washing machines. This does not apply to under-~~
- 2623 ~~counter type commercial dishwashing machines.~~
- 2624 3. ~~Intake and exhaust ducts shall be maintained to~~
- 2625 ~~prevent the entrance of dust, dirt, and other contaminating materials.~~
- 2626 4. ~~In new or extensively remodeled retail food~~
- 2627 ~~establishments, restrooms shall be mechanically vented to the outside.~~
- 2628 ~~C. Except for mobile retail food establishments, make up air must be filtered and mechanically~~
- 2629 ~~introduced into the establishment at a volume equal to or greater than what is exhausted.~~
- 2630 ~~D. Fire prevention, extinguishing equipment and lighting systems shall be installed in a~~
- 2631 ~~ventilation system or hood so as to not create a cleaning problem.~~

2632 **4-3 — LOCATION AND INSTALLATION**

2633 **4-301 — Equipment, and Storage Cabinets, Contamination Prevention**

2634 A. ~~The storage of cleaned and sanitized equipment, utensils, laundered linens, laundered~~  
 2635 ~~clothing and single service and single use articles may not be located:~~

2636 1. ~~In locker areas;~~

2637 2. ~~In toilet rooms and their vestibules;~~

2638 3. ~~In dressing rooms;~~

2639 4. ~~In garbage, recycling, or composting rooms;~~

2640 5. ~~In mechanical rooms;~~

2641 6. ~~Under water and sewer lines that are not shielded to intercept potential drips;~~

2642 7. ~~Under leaking automatic fire sprinkler heads, or under lines on which water has~~  
 2643 ~~condensed;~~

2644 8. ~~In a private home;~~

2645 9. ~~Under open stairwells; or~~

2646 10. ~~Under other sources of contamination.~~

2647 B. ~~A storage cabinet used for linens or completely packaged single service or single use articles~~  
 2648 ~~may be stored in a locker area.~~

2649 **4-302 — Fixed Equipment, Spacing or Sealing**

2650 ~~Equipment, including ice makers and ice storage equipment, shall not be located under sewer lines~~  
 2651 ~~that are not shielded to intercept potential drips or under leaking water lines, including leaking~~  
 2652 ~~automatic fire sprinkler heads, or under lines on which water has condensed.~~

2653 A. ~~Table Mounted Equipment~~

2654 1. ~~Table mounted equipment shall be installed to facilitate the cleaning of the~~  
 2655 ~~equipment and the adjacent areas.~~

2656 2. ~~Equipment that is mounted on tables or counters, unless portable, shall be sealed to~~  
 2657 ~~the table or counter, or elevated on legs to provide at least a 4 inch (10 cm)~~  
 2658 ~~clearance between the table or counter, except that if no part of the table under the~~  
 2659 ~~equipment is more than 18 inches (46 cm) from cleaning access, the clearance space~~  
 2660 ~~shall be three (3) inches (8 cm) or more; or if no part of the table under the~~  
 2661 ~~equipment is more than three (3) inches (8 cm) from cleaning access, the clearance~~  
 2662 ~~space shall be two (2) inches (5 cm) or more.~~

2663 3. ~~Equipment is portable within the meaning of this section if:~~

2664 a. ~~It is small and light enough to be moved easily by one person; or~~

2665 b. ~~Is equipped with a mechanical means of safely tilting the unit for cleaning;~~  
 2666 ~~and~~

2667 c. ~~It is table mounted, such as powered mixers, grinders, slicers, tenderizers,~~  
 2668 ~~and similar equipment; and~~

- 2669 d. ~~It has no utility connection, has a utility connection that disconnects~~  
 2670 ~~quickly, or has a flexible utility connection line of sufficient length to~~  
 2671 ~~permit the equipment to be moved for easy cleaning.~~
- 2672 ~~B. Floor Mounted Equipment~~
- 2673 1. ~~Floor mounted equipment, unless easily moveable, shall be:~~
- 2674 a. ~~Sealed to the floor; or~~
- 2675 b. ~~Elevated on sanitary legs to provide at least a 6 inch (15 cm) clearance~~  
 2676 ~~between the floor and equipment, except that equipment may be elevated to~~  
 2677 ~~provide at least a 4 inch (10 cm) clearance between the floor and equipment~~  
 2678 ~~if the floor under the equipment is no more than six (6) inches (15 cm) from~~  
 2679 ~~cleaning access;~~
- 2680 c. ~~Display shelving units, display refrigeration units, and display freezer units~~  
 2681 ~~are exempt from the provisions of Paragraph 1, a and b of this section if~~  
 2682 ~~they are installed so that the floor beneath the units can be cleaned.~~
- 2683 2. ~~Equipment is easily moveable if:~~
- 2684 a. ~~It is mounted on commercially designed wheels or casters; and~~
- 2685 b. ~~It has no utility connection, or has a utility connection that disconnects~~  
 2686 ~~quickly, or has a flexible utility line of sufficient length to permit the~~  
 2687 ~~equipment to be moved for cleaning.~~
- 2688 3. ~~Grease Use Equipment. Grease use equipment, in which fats and oils are utilized as~~  
 2689 ~~the heat transfer agent or which is used in preparation of foods that produce grease,~~  
 2690 ~~shall be installed to facilitate cleaning around and beneath the equipment by means~~  
 2691 ~~of:~~
- 2692 a. ~~Rollers or casters with a utility connection that disconnects quickly, or has a~~  
 2693 ~~flexible utility line of sufficient design and length to permit the equipment~~  
 2694 ~~to be moved for easy cleaning; or~~
- 2695 b. ~~Mounted on 6 inch (15.24 cm) sanitary legs; or~~
- 2696 c. ~~Cantilever mounted to the wall at least 6 inches (15.24 cm) above the floor.~~
- 2697 ~~C. Space Between Adjoining Units~~
- 2698 1. ~~The space between adjoining units, and between or above a unit and the adjacent~~  
 2699 ~~wall or ceiling, shall be closed unless exposed to seepage, in which event it shall be~~  
 2700 ~~sealed; or sufficient space shall be provided to facilitate easy cleaning between,~~  
 2701 ~~behind, and beside or above all such equipment. (See Figure 1 and Figure 2)~~
- 2702 2. ~~Space required between or behind walls or equipment shall be based on the~~  
 2703 ~~following distances: (See Figure 1 and Figure 2)~~
- 2704 a. ~~When distance "A" is 2 feet (0.61 M) or less, distance "B" must be at least 6~~  
 2705 ~~inches (15 cm).~~
- 2706 b. ~~When distance "A" is over 2 feet (0.61 M) but less than 6 feet (1.8 M),~~  
 2707 ~~distance "B" must be at least 12 inches (30 cm).~~
- 2708 c. ~~When distance "A" is 6 feet (1.8 M) or more, then distance "B" must be at~~  
 2709 ~~least 18 inches (46 cm).~~

2710 3. ~~When rollers or casters are installed on equipment, the space requirements between~~  
 2711 ~~adjoining units may not apply.~~

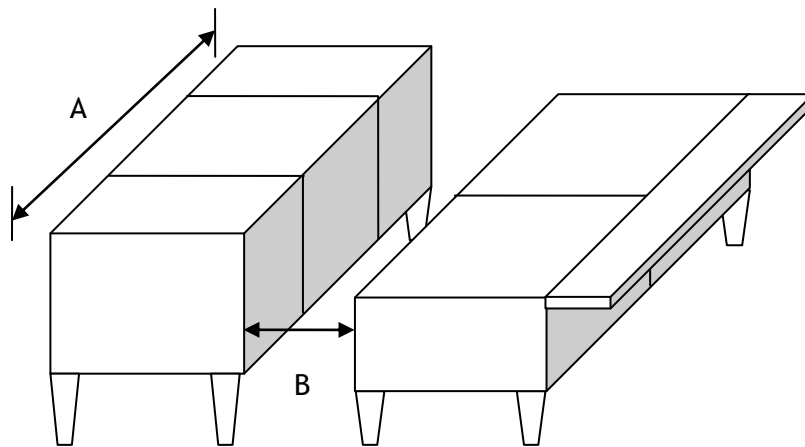


FIGURE 1

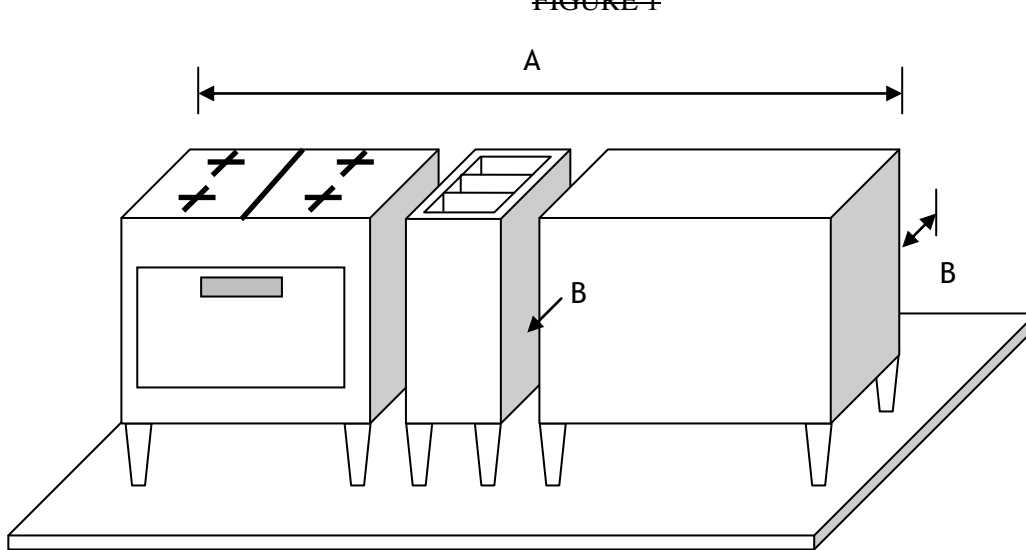


FIGURE 2

2739 ~~D. Aisles and Working Spaces. Aisles and working spaces between units of equipment and~~  
 2740 ~~between equipment and walls shall be unobstructed and of sufficient width to permit~~  
 2741 ~~employees to perform their duties readily without contamination of food or food contact~~  
 2742 ~~surfaces by clothing or personal contact. All easily moveable storage equipment such as~~  
 2743 ~~dollies, skids, racks, and open ended pallets shall be positioned to provide accessibility to~~  
 2744 ~~working areas.~~

2745 ~~E. Kick Plates, Removable. Kick plates shall be designed so that the areas behind them are~~  
 2746 ~~accessible for inspection and cleaning by being:~~



- 2747 1. ~~Removable by one of the methods specified in section 4-201(E)(1-3) of these rules~~  
 2748 ~~and regulations or capable of being rotated open; and~~  
 2749 2. ~~Removable or capable of being rotated open without unlocking equipment doors.~~

2750 ~~4-4 EQUIPMENT AND UTENSIL CLEANING AND SANITIZATION TESTING~~  
 2751 ~~DEVICES~~

2752 ~~4-401 Temperature Measuring Devices~~

2753 ~~Temperature measuring devices shall be provided and used. Surfaces of food temperature measuring~~  
 2754 ~~devices that come in contact with food shall be cleaned and sanitized before use or storage.~~

2755 ~~\*A. Temperature measuring devices shall be available, used, capable of reading both hot and cold~~  
 2756 ~~temperatures, and shall have a numerical scale that includes the range of (0°-220°F), printed~~  
 2757 ~~record, or digital readout in increments no greater than 2°F (1°C). Temperature measuring~~  
 2758 ~~devices shall be used to determine required food temperature(s) and shall be accurate to ±2°F~~  
 2759 ~~(1°C).~~

2760 ~~\*B. A temperature measuring device with a suitable small diameter probe that is capable of~~  
 2761 ~~measuring the temperature of thin masses shall be provided and readily accessible to~~  
 2762 ~~accurately measure the temperature in thin foods such as meat patties and fish fillets, if this~~  
 2763 ~~type of food is prepared.~~

2764 ~~C. Ambient air and warewashing temperature measuring devices shall have a numerical scale,~~  
 2765 ~~printed record, or digital readout in increments no greater than 2°F or 1°C and shall be~~  
 2766 ~~accurate to ±3°F (2°C).~~

2767 ~~D. Each mechanically refrigerated and each hot food storage unit storing potentially hazardous~~  
 2768 ~~food (time/temperature control for safety food) shall be provided with a numerically scaled~~  
 2769 ~~indicating temperature measuring device. Temperature measuring devices used to measure~~  
 2770 ~~the air temperature of cold holding units shall be conspicuously located in the upper one-~~  
 2771 ~~third of the unit. Temperature measuring devices used to measure the air temperature of hot~~  
 2772 ~~food storage units shall be conspicuously located in the lower one-third of the unit.~~

2773 ~~E. Temperature measuring devices shall be checked and calibrated as necessary to ensure their~~  
 2774 ~~accuracy.~~

2775 ~~F. Where it is impractical to install temperature measuring devices on equipment, such as heat~~  
 2776 ~~lamps, calorod units, or insulated food transport carriers, a temperature measuring device, as~~  
 2777 ~~required in part A of this section, shall be available and used to check internal food~~  
 2778 ~~temperature.~~

2779 ~~4-402 Testing Devices~~

2780 ~~A. An appropriate test kit or other device designed to accurately measure the concentration in~~  
 2781 ~~parts per million (mg/L) of the sanitizing solution shall be available and used.~~

2782 ~~B. Where chemicals are used to wash fruits and vegetables in the establishment, the chemicals~~  
 2783 ~~shall be prepared and used in accordance with the manufacture's labeled instructions.~~

2784 ~~C. Where heat sanitization is used in mechanical warewashing machines, an accurate machine~~  
 2785 ~~or water line mounted temperature gauge must be present. In the event a mounted~~  
 2786 ~~temperature gauge is not present, an appropriate irreversible registering temperature~~

2787 indicator, such as a maximum read temperature, measuring device or heat sensitive tape shall  
2788 be available and used to verify proper sanitization.

2789 **4-403—Manual Cleaning and Sanitization**

2790 In new or extensively remodeled retail food establishments, equipment and utensil washing facilities  
2791 in accordance with section (A) of this section shall be provided for washing, rinsing, and sanitizing  
2792 equipment and utensils.

2793 A. — Except as specified in paragraph (C) of this section, a sink with at least three compartments  
2794 shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.  
2795 Each compartment of the sink shall be supplied with hot and cold drinking running water.

2796 B. — Sink compartments shall be self draining and large enough to accommodate immersion of  
2797 the largest equipment and utensils. If equipment or utensils are too large for the sink  
2798 compartments, a warewashing machine or alternative equipment as specified in paragraph  
2799 (C) of this section shall be used.

2800 C. — Alternative manual warewashing equipment may be used when there are special cleaning  
2801 needs or constraints and the Department has approved the use of the alternative equipment.  
2802 Alternative manual warewashing equipment may include:

2803 1. — High pressure detergent sprayers;

2804 2. — Low or line pressure spray detergent foamers;

2805 3. — Other task specific cleaning equipment;

2806 4. — Brushes or other implements;

2807 5. — Two compartment sinks as specified in paragraph D of this section.

2808 6. — Mechanical cleaning and sanitization as specified in Sections 4-404, 4-405 and 4-  
2809 406.

2810 D. — A two compartment sink may be used in an existing retail food establishment only if:

2811 1. — The Department has approved its use; and

2812 2. — The nature of warewashing is limited to batch operations such as between cutting  
2813 one type of raw meat and another or cleanup at the end of a shift, where the number  
2814 of items cleaned is limited, and where the cleaning and sanitizing solutions are made  
2815 up immediately before use and drained immediately after use. \*If a detergent  
2816 sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is not  
2817 a distinct water rinse between the washing and sanitizing steps, then the detergent  
2818 sanitizer shall be approved and used according to the manufacturer's specifications.

2819 3. — A two compartment sink may not be used for warewashing operations such as where  
2820 cleaning and sanitizing solutions are used for a continuous or intermittent flow of  
2821 kitchenware or tableware in an ongoing warewashing process.

2822 E. — In manual warewashing operations, a temperature measuring device shall be provided and  
2823 readily accessible for frequently measuring the washing and sanitizing temperatures. The  
2824 temperature of the wash solution shall be maintained at not less than 110°F (43°C) unless a  
2825 different temperature is specified on the cleaning agent manufacturer's label instructions.

2826 F. — Equipment and utensils shall be pre-flushed or pre-scraped, and when necessary, pre-soaked  
2827 to remove gross food particles and soil.

- 2828 ~~G. When a three compartment sink is utilized for warewashing or when equipment such as~~  
2829 ~~slicers, grinders, kettles, and mixers are cleaned and sanitized in place, the operation shall be~~  
2830 ~~conducted in the following sequence:~~
- 2831 ~~1. The sinks or equipment used for warewashing shall be cleaned and sanitized before~~  
2832 ~~use; and~~
  - 2833 ~~2. Equipment and utensils shall be thoroughly cleaned in the first compartment with a~~  
2834 ~~clean detergent solution that is mixed in accordance with the manufacturer's label~~  
2835 ~~and a temperature of at least 110°F (43°F).~~
  - 2836 ~~3. Equipment and utensils shall be rinsed free of detergent and abrasive with clean~~  
2837 ~~water in the second compartment; and~~
  - 2838 ~~\*4. Equipment and utensils shall be sanitized in the third compartment according to one~~  
2839 ~~of the methods included in section 4-403(I)(1-4).~~
- 2840 ~~\*H. When pressure spray methods are utilized for cleaning and sanitizing, the equipment and~~  
2841 ~~utensils shall be thoroughly flushed with a detergent sanitizer solution until the article is free~~  
2842 ~~of food particles and soil. The detergent sanitizer shall be used in accordance with the~~  
2843 ~~manufacturer's instructions and shall be of the type that does not require a potable water rinse~~  
2844 ~~when used according to those instructions.~~
- 2845 ~~\*I. The food contact surfaces of all equipment and utensils shall be sanitized by:~~
- 2846 ~~1. Immersion for at least ½ minute in clean, hot water of a temperature of at least~~  
2847 ~~170°F (77°C); or~~
  - 2848 ~~2. Immersion for at least 1 minute in a clean solution containing a minimum of 50 parts~~  
2849 ~~per million (mg/L) and no more than 200 parts per million (mg/L) of available~~  
2850 ~~chlorine as a hypochlorite and having a temperature of at least 75°F (24°C); or~~
  - 2851 ~~3. Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per~~  
2852 ~~million (mg/L) of available iodine, having a pH range not higher than 5.0, unless~~  
2853 ~~otherwise certified to be effective by the manufacturer, and at a temperature of at~~  
2854 ~~least 68°F (20°C); or~~
  - 2855 ~~4. Immersion in a clean solution containing a quaternary ammonia product at a~~  
2856 ~~minimum of 75°F (24°C) or any other chemical sanitizing agent allowed under~~  
2857 ~~Sanitizers, 40 CFR 180.940 (2005).~~
  - 2858 ~~5. Treatment with steam that is free from materials or additives other than those~~  
2859 ~~specified in 21 CFR section 173.310, (2003) in the case of equipment too large to~~  
2860 ~~sanitize by immersion, but in which steam can be confined; or~~
  - 2861 ~~6. Rinsing, spraying, or swabbing with a chemical sanitizing solution containing at~~  
2862 ~~least the strength required for that particular sanitizing solution in section 4-~~  
2863 ~~403(I)(2-4) for equipment too large to sanitize by immersion.~~
  - 2864 ~~7. If a chemical not specified in paragraphs (2) (4) of this section is used, the licensee~~  
2865 ~~shall demonstrate to the Department that the solution achieves sanitization and the~~  
2866 ~~use of the solution shall be approved; or~~
  - 2867 ~~8. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium~~  
2868 ~~compound is used, it shall be registered with EPA and applied in accordance with~~  
2869 ~~the EPA registered label use instructions.~~
- 2870 ~~\*J. When hot water is used for sanitizing, the following equipment shall be provided and used:~~

- 2871 1. ~~An integral heating device or fixture installed in, on, or under the sanitizing~~  
 2872 ~~compartment of the sink which is capable of maintaining the water at a temperature~~  
 2873 ~~of at least 170°F (77°C); and~~
- 2874 2. ~~A numerically scaled indicating temperature measuring device, accurate to ±3°F~~  
 2875 ~~(±2°C), located convenient to the sink for frequent checks of water temperature; and~~
- 2876 3. ~~Utensil racks, baskets, or other appropriate means to permit complete immersion of~~  
 2877 ~~utensils and equipment in the hot water.~~
- 2878 \*K. ~~Chemicals used for sanitization, shall not have concentrations higher than the maximum~~  
 2879 ~~permitted under Sanitizers, 40 CFR 180.940 (2005).~~

#### 2880 **4-404 Mechanical Cleaning and Sanitization**

- 2881 A. ~~Cleaning and sanitizing may be done by spray type, immersion warewashing, or by any~~  
 2882 ~~other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes~~  
 2883 ~~equipment and utensils. These machines and devices shall be properly installed and~~  
 2884 ~~maintained in good repair. Machines and devices shall be operated in accordance with~~  
 2885 ~~manufacturer's instructions. Utensils and equipment placed in the machine shall be exposed~~  
 2886 ~~to all warewashing cycles. Automatic detergent dispensers, wetting agent dispensers, and~~  
 2887 ~~liquid sanitizer injectors shall be properly installed and maintained.~~
- 2888 B. ~~The pressure of final rinse water supplied to spray type warewashing machines shall not be~~  
 2889 ~~less than 15 pounds per square inch (1.05 kg per sq cm) nor more than 25 pounds per square~~  
 2890 ~~inch (1.76 kg per sq cm) measured in the water line immediately upstream from the final~~  
 2891 ~~rinse control valve. A 1/4 inch (6.4 millimeters) Iron Pipe Size (IPS) valve shall be provided~~  
 2892 ~~immediately upstream from the final control valve to permit checking the flow pressure of~~  
 2893 ~~the final rinse water. In all new installations, a pressure gauge shall be provided for use with~~  
 2894 ~~the IPS valve. This section does not apply to a machine that uses only a pumped sanitizing~~  
 2895 ~~rinse.~~
- 2896 C. ~~Machine or water line mounted numerically scaled indicating temperature monitoring~~  
 2897 ~~device, accurate to ± 3°F (± 2°C), shall be provided to indicate the temperature of the water~~  
 2898 ~~in each tank of the machine and the temperature of the final rinse water as it enters the~~  
 2899 ~~manifold.~~
- 2900 D. ~~Rinse water tanks shall be protected by baffles, curtains, or other effective means to~~  
 2901 ~~minimize the entry of wash water into the rinse water. Conveyors in warewashing machines~~  
 2902 ~~shall be accurately timed to ensure proper exposure times in wash and rinse cycles in~~  
 2903 ~~accordance with manufacturer's specifications attached to the machines.~~
- 2904 E. ~~Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove~~  
 2905 ~~gross food particles and soil prior to being washed in a warewashing machine unless a pre-~~  
 2906 ~~wash cycle is a part of the warewashing machine operation. Equipment and utensils shall be~~  
 2907 ~~placed in racks, trays, or baskets, or on conveyors, in a way that exposes food contact~~  
 2908 ~~surfaces to the unobstructed application of detergent wash and clean rinse waters, and that~~  
 2909 ~~permits free draining.~~
- 2910 F. ~~Chemical sanitizing warewashing machines (single tank, stationary tank, door type~~  
 2911 ~~machines, and spray type glass washers) may be used provided that:~~
- 2912 1. ~~The temperature of the wash water shall not be less than 120°F (49°C);~~
- 2913 2. ~~The wash water shall be kept clean; and~~

- 2914 3. ~~Chemicals added for washing and sanitization purposes shall be automatically~~  
 2915 ~~dispensed; and~~
- 2916 \*4. ~~Utensils and equipment shall be exposed to the final chemical sanitizing rinse in~~  
 2917 ~~accordance with the manufacturer's specifications for time and concentration; and~~
- 2918 \*5. ~~The chemical sanitizing rinse water temperature shall not be less than 75°F (24°C)~~  
 2919 ~~nor less than the temperature specified by the machine's manufacturer; and~~
- 2920 \*6. ~~Chemical sanitizers shall meet the requirements specified 40 CFR 180.940 (2005)~~  
 2921 ~~and be applied in accordance with the EPA registered label use instructions.~~
- 2922 \*G. ~~Hot water sanitizing warewashing machines may be used, provided that wash water and~~  
 2923 ~~pumped rinse water is kept clean and the wash solution temperature is maintained at not less~~  
 2924 ~~than the temperatures stated in this section 4-404(G)(1-5).~~
- 2925 Achieving a utensil and/or equipment surface temperature of 160°F (71°C) is an acceptable  
 2926 means of testing the sanitization process of a hot water sanitizing warewashing machine.
- 2927 1. ~~Single tank, stationary rack, dual temperature machines:~~  
 2928 ~~Wash temperature 150°F (66°C)~~
- 2929 2. ~~Single tank, stationary rack, single temperature machine:~~  
 2930 ~~Wash temperature 165°F (74°C)~~
- 2931 3. ~~Single tank, conveyor machine:~~  
 2932 ~~Wash temperature 160°F (72°C)~~
- 2933 4. ~~Multi tank, conveyor machine:~~  
 2934 ~~Wash temperature 150°F (66°C)~~  
 2935 ~~Pumped rinse temperature 160°F (72°C)~~
- 2936 5. ~~Single tank, pot, pan, and utensil washer (either stationary or moving rack):~~  
 2937 ~~Wash temperature 140°F (60°C)~~
- 2938 \*H. ~~Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures~~
- 2939 ~~In mechanical warewashing machines the temperature of the fresh hot water sanitizing rinse~~  
 2940 ~~as it enters the manifold may not be more than 194°F (90°C), or less than:~~
- 2941 1. ~~For a stationary rack, single temperature machine, 165°F (74°C); or~~  
 2942 2. ~~For all other machines 180°F (82°C).~~
- 2943 I. ~~All warewashing machines shall be thoroughly cleaned daily and as needed to maintain them~~  
 2944 ~~in a satisfactory operating condition.~~
- 2945 J. ~~A warewashing machine shall be provided with an easily accessible and readable data plate~~  
 2946 ~~affixed to the machine which includes:~~
- 2947 1. ~~Temperatures required for washing, rinsing, and sanitizing;~~
- 2948 2. ~~Pressure required for the fresh water sanitizing rinse unless the machine is designed~~  
 2949 ~~to use only a pumped sanitizing rinse;~~
- 2950 3. ~~Conveyor speed required for conveyor machines or cycle time required for~~  
 2951 ~~stationary rack machines; and~~

- 2952 4. Required type and concentration of sanitizing solutions.
- 2953 K. After being cleaned and sanitized, equipment and utensils shall not be rinsed before air
- 2954 drying or use unless:
  - 2955 1. The rinse is applied directly from a drinking water supply by a warewashing
  - 2956 machine that is maintained and operated as specified in sections 4-404; and
  - 2957 2. The rinse is applied only after the equipment and utensils have been sanitized by the
  - 2958 application of hot water or by the application of a chemical sanitizer solution whose
  - 2959 EPA registered label use instructions call for rinsing off the sanitizer after it is
  - 2960 applied in a commercial warewashing machine.

2961 **4-405 Drainboard and Dishtable Requirements**

- 2962 A. Drainboards and dishtables shall be self draining and shall have a minimum pitch of 1/8 inch
- 2963 (3.2mm) per foot (304.8mm). Drainage shall be directed to warewashing sink bowls, pre-
- 2964 rinse sinks, scuppers or warewashing machines.
- 2965 B. Drainboards and dishtables shall be supported as needed to prevent sagging and shall have
- 2966 edges turned up at least 1/2 inch (12.7 mm).
- 2967 C. When provided on warewashing sinks, drainboards shall be integrally welded to the sink
- 2968 bowl(s).
- 2969 D. Drainboards and dishtables shall be large enough to accommodate for the staging of soiled
- 2970 equipment, dishes, glasses, mugs, kitchenware, tableware and utensils so they may be
- 2971 adequately pre scraped and pre flushed prior to warewashing and large enough to
- 2972 accommodate the air drying of sanitized items that may accumulate during hours of
- 2973 operation. Drainboard and dishtable's length shall be measured from right to left.
  - 2974 1. Drainboards and dishtables installed on the establishment's primary means for
  - 2975 warewashing shall be sized in accordance with the following:

| 2976 FACILITY TYPE     | SOILED DRAINBOARDS | CLEAN DRAINBOARDS |
|------------------------|--------------------|-------------------|
| 2977 Single Service    | Twenty four (24)   | Twenty four (24)  |
| 2978                   | Inches (64 cm)     | Inches (64 cm)    |
| 2979                   |                    |                   |
| 2980 Multi use Service | Thirty six (36)    | Thirty six (36)   |
| 2981 With Manual       | Inches (91 cm)     | Inches (91 cm)    |
| 2982 Warewashing       |                    |                   |
| 2983                   |                    |                   |
| 2984 Multi use Service | Forty eight (48)   | Forty eight (48)  |
| 2985 With Mechanical   | Inches (122 cm)    | Inches (122 cm)   |
| 2986 Warewashing       |                    |                   |
| 2987                   |                    |                   |

- 2988 2. Bar sinks shall be equipped with an eighteen (18") inch (46 cm) drainboard for
- 2989 staging soiled tableware, utensils, glasses and mugs and an eighteen (18") inch (46
- 2990 cm) drainboard for air drying sanitized items.
- 2991 3. Under counter warewashing machines shall be provided with drainboards or
- 2992 dishtables that are large enough to accommodate staging of soiled equipment,
- 2993 dishes, glasses, mugs, kitchenware, tableware and utensils and large enough for air
- 2994 drying of sanitized items. A common drainboard, dishtable or the open door of the
- 2995 warewashing machine may be utilized.

- 2996 4. ~~Multi tank conveyor warewashing machines equipped with both, a powered pre-~~  
 2997 ~~wash unit and a powered blower dryer unit shall be equipped with dishtables sized~~  
 2998 ~~in accordance with the warewashing machine's manufacture.~~
- 2999 5. ~~Alternate equipment or methods, such as wall mounted drainboards, wire shelving~~  
 3000 ~~or bus carts, may be provided for staging of soiled equipment, dishes, glasses, mugs,~~  
 3001 ~~and utensils for pre scraping and pre flushing prior to warewashing and to~~  
 3002 ~~accommodate air drying of sanitized items may be utilized if approved by the~~  
 3003 ~~Department. Alternate equipment shall not be located or constructed in a manner~~  
 3004 ~~that interferes with the proper use of the warewashing facilities.~~
- 3005 E. ~~Except for under counter warewashing machines, prerinse sprayers or other approved means~~  
 3006 ~~shall be provided and used for pre scraping and pre flushing of soiled equipment, dishes and~~  
 3007 ~~utensils when a warewashing machine is installed.~~
- 3008 F. ~~Scuppers when installed shall transverse the entire flat section of the drainboard or dishtable~~  
 3009 ~~to prevent soiled water and debris from draining into the warewashing sink bowl or~~  
 3010 ~~warewashing machine. Scuppers shall be equipped with a readily removable strainers or~~  
 3011 ~~strainer baskets.~~

#### 3012 **4-406 — Drying**

- 3013 ~~Unless used immediately after sanitization, all equipment and utensils shall be air dried. Towel~~  
 3014 ~~drying shall not be permitted. Utensils that have been air dried may be polished with cloths which~~  
 3015 ~~are maintained clean and dry.~~

#### 3016 **4-407 — Food Contact Surfaces of Equipment and Utensils**

- 3017 A. ~~Equipment food contact surfaces and utensils shall be clean to sight and touch.~~
- 3018 \*B. ~~Utensils and food contact surfaces of equipment shall be cleaned and sanitized:~~
- 3019 1. ~~Before each use with a different type of raw animal food, such as beef, fish, lamb,~~  
 3020 ~~pork, or poultry;~~
- 3021 2. ~~Each time there is a change from working with raw animal foods to working with~~  
 3022 ~~ready to eat foods;~~
- 3023 3. ~~Between uses with raw fruits or vegetables and with potentially hazardous food~~  
 3024 ~~(time/temperature control for safety food);~~
- 3025 4. ~~At any time during the operation when contamination may have occurred; and~~
- 3026 5. ~~After final use each working day.~~
- 3027 \*C. ~~Where equipment and utensils are used for the preparation of potentially hazardous food~~  
 3028 ~~(time/temperature control for safety food) on a continuous or production line basis, utensils~~  
 3029 ~~and the food contact surfaces of equipment shall be cleaned and sanitized at intervals not to~~  
 3030 ~~exceed four (4) hours.~~
- 3031 D. ~~Surfaces of utensils and equipment contacting potentially hazardous food (time/temperature~~  
 3032 ~~control for safety food) may be cleaned less frequently than every 4 hours if:~~
- 3033 1. ~~Utensils and equipment such as skillets, omelet pans and woks used on a production~~  
 3034 ~~line basis in continuous use for the heating/cooking of potentially hazardous foods~~  
 3035 ~~(time/temperature control for safety foods) shall be cleaned and sanitized after final~~  
 3036 ~~use each working day and at least every 24 hours;~~

- 3037 2. ~~Containers in serving situations such as salad bars, delis, and cafeteria lines holding~~  
 3038 ~~ready to eat potentially hazardous food (time/temperature control for safety food)~~  
 3039 ~~that is maintained at the temperature specified in chapter 3 and are intermittently~~  
 3040 ~~combined with the additional supplies of the same food that is at the required~~  
 3041 ~~temperature, and the containers are cleaned and sanitized at least every 24 hours;~~
- 3042 3. ~~Utensils and equipment used to prepare food in a refrigerated room or area that is~~  
 3043 ~~maintained at one of the temperatures in Figure 3 shall be cleaned and sanitized at~~  
 3044 ~~the frequency that corresponds to the ambient temperatures;~~
- 3045

| <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                  |

3046 **FIGURE 3**

- 3047 4. ~~The food contact surfaces of cooking and baking utensils and equipment, such as~~  
 3048 ~~grills, woks, hot sandwich presses, waffle irons, as well as baking equipment and the~~  
 3049 ~~cavities and door seals of microwave ovens shall be cleaned at least every 24 hours~~  
 3050 ~~and shall be kept free of encrusted grease deposits and other accumulated soil. This~~  
 3051 ~~shall not apply to hot oil cooking equipment and hot oil filtering systems.~~

3052 **4-408 — Nonfood-Contact Surfaces**

- 3053 ~~Nonfood contact surfaces of equipment, including transport vehicles, shall be cleaned as often as~~  
 3054 ~~necessary to keep the equipment free from the accumulation of dust, dirt, food particles, and other~~  
 3055 ~~debris.~~

3056 **4-409 — Dry Equipment Cleaning Methods**

- 3057 ~~Dry equipment cleaning methods, such as brushing, scraping, and vacuuming shall contact only~~  
 3058 ~~surfaces that are soiled with dry food residues that are not potentially hazardous; this cleaning~~  
 3059 ~~equipment shall not be used for any other purpose.~~

3060 **4-5 — LAUNDRY FACILITIES**

3061 **4-501 — Laundry Facilities**

- 3062 A. ~~If provided, laundry facilities shall be restricted to the washing and drying of linens and work~~  
 3063 ~~clothes used in the operation. If such items are laundered on the premises, an electric or gas~~  
 3064 ~~clothes dryer shall be provided and used, except that it is not necessary to provide a clothes~~  
 3065 ~~dryer provided that:~~
- 3066 1. ~~On premise laundering is limited to wiping cloths intended to be used moist, and~~
- 3067 2. ~~The laundered wiping cloths are stored in an approved sanitizing solution; or~~



- 3068 3. ~~The laundered wiping cloths are air dried in a laundry room or other approved~~  
3069 ~~locations.~~
- 3070 B. ~~Laundry facilities shall not be located in food preparation areas. If located in food storage~~  
3071 ~~areas, it shall be operated in a manner that prevents the contamination of food, equipment,~~  
3072 ~~utensils, linens, single service and single use articles and wiping cloths.~~
- 3073 C. ~~Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry~~  
3074 ~~bags. Soiled linens shall be stored and transported to prevent contamination of food, clean~~  
3075 ~~equipment, clean utensils, single service and single use articles.~~

## 3076 ~~4-6~~ ~~EQUIPMENT AND UTENSIL HANDLING AND STORAGE~~

### 3077 ~~4-601~~ ~~Equipment and Utensil Storage~~

- 3078 A. ~~Cleaned and sanitized equipment and utensils shall be handled in a way that protects them~~  
3079 ~~from contamination. Spoons, knives, and forks shall be touched only by their handles.~~  
3080 ~~Cups, glasses, bowls, plates, and similar items shall be handled without contact with inside~~  
3081 ~~surfaces or surfaces that contact the user's mouth.~~
- 3082 B. ~~Cleaned and sanitized utensils and equipment shall be stored at least 6 inches (15.24 cm)~~  
3083 ~~above the floor in a clean, dry location in a way that protects them from contamination by~~  
3084 ~~splash, dust, and other means. The food contact surfaces of fixed equipment shall also be~~  
3085 ~~protected from contamination. Equipment and utensils shall not be placed under sewer lines~~  
3086 ~~or water lines that are not protected to intercept potential drips, including leaking automatic~~  
3087 ~~fire protection sprinkler heads, or under lines on which water has condensed.~~
- 3088 C. ~~Utensils shall be air dried, in accordance with section 4-406, before being stored or shall be~~  
3089 ~~stored in a self-draining position.~~
- 3090 D. ~~Glasses and cups shall be stored inverted. Other stored tableware shall be covered or~~  
3091 ~~inverted, wherever practical. Facilities for the storage of knives, forks and spoons shall be~~  
3092 ~~designed and used to present the handle to the employee or consumer. Unless pre-wrapped,~~  
3093 ~~holders for knives, forks and spoons at self-service locations shall protect these articles from~~  
3094 ~~contamination and present the handle of the utensil to the consumer.~~

### 3095 ~~4-602~~ ~~Single-Service and Single-Use Articles~~

- 3096 A. ~~Single service articles shall be stored at least 6 inches (15.24 cm) above the floor in closed~~  
3097 ~~cartons or containers which protect them from contamination. They shall not be placed~~  
3098 ~~under exposed sewer lines or water lines, except for automatic fire protection sprinkler heads~~  
3099 ~~that may be required by law.~~
- 3100 B. ~~Single service articles shall be handled and dispensed in a manner that prevents~~  
3101 ~~contamination of surfaces which may come in contact with food or with the mouth of the~~  
3102 ~~user.~~
- 3103 C. ~~Single service knives, forks, and spoons packaged in bulk shall be inserted into holders or be~~  
3104 ~~wrapped prior to dispensing by employees who have washed their hands immediately prior~~  
3105 ~~to sorting or wrapping the utensils. Holders shall be provided to protect these items from~~  
3106 ~~contamination and present the handle of the utensil to the consumer.~~
- 3107 D. ~~Single service and single use articles may not be reused.~~
- 3108 E. ~~Mollusk and crustacea shells may not be used more than once as serving containers.~~

3109 ~~4-603~~ **Preset Tableware**

3110 Tableware may be preset if:

3111 A. ~~Except as specified in paragraph (B) of this section, tableware that is preset shall be~~  
3112 ~~protected from contamination by being wrapped, covered or inverted;~~

3113 B. ~~Preset tableware may be exposed if unused settings are removed when a consumer is seated~~  
3114 ~~and cleaned and sanitized before further use.~~

3115

3116

**CHAPTER 5**

3117

**~~WATER, PLUMBING, AND WASTE~~**3118 **~~5-1 — WATER SUPPLY~~**3119 **~~\*5-101 — General~~**

3120 A. ~~Adequate, uncontaminated, safe drinking water for the needs of the retail food establishment~~  
3121 ~~shall be provided from a source constructed, maintained, and operated according to the~~  
3122 ~~*Colorado Primary Drinking Water Regulations* and regulations adopted pursuant to Title 25-~~  
3123 ~~1.5-203 C.R.S., or~~

3124

3125 1. ~~If the retail food establishment does not meet the definition of a public water~~  
3126 ~~system pursuant to the *Colorado Primary Drinking Water Regulations*,~~  
3127 ~~promulgated pursuant to 25-1.5-101, and 25-1.5-203, C.R.S., the retail food~~  
3128 ~~establishment shall provide:~~

3129

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

3130

b. ~~Bacteriological samples at a minimum of once per quarter or at a~~  
3131 ~~frequency determined by the department; and~~

3132

c. ~~A DPD colorimetric drinking water test kit capable of testing free~~  
3133 ~~chlorine at an accuracy of 0.1 mg/Liter; and~~

3134

d. ~~Free chlorine shall range from a trace amount to 4 mg/Liter (0.2 to 1.2~~  
3135 ~~mg/Liter recommended) at any fixture; and~~

3136

e. ~~Most recent required water sample reports shall be retained on file at the~~  
3137 ~~retail food establishment and shall be available for review by the~~  
3138 ~~department when requested; and~~

3139

2. ~~Retail food establishments with water supplies determined to be surface water or~~  
3140 ~~determined to be under the direct influence of surface water shall be required to~~  
3141 ~~filter their water to 1µm (micron) absolute using National Sanitation Foundation~~  
3142 ~~approved equipment and maintain a residual disinfectant concentration to ensure~~  
3143 ~~inactivation and/or removal of giardia and other parasitic cysts and viruses.~~

3144 **~~\*5-102 — System Flushing and Disinfection~~**

3145 ~~A drinking water system shall be flushed and disinfected before being placed in service after~~  
3146 ~~construction, repair, or modification and after an emergency situation, such as a flood, that may~~  
3147 ~~introduce contaminants to the system.~~

3148 **~~\*5-103 — Bottled Drinking Water~~**

3149 ~~Bottled drinking water used or sold in a retail food establishment shall be obtained from approved~~  
3150 ~~sources in accordance with Processing and Bottling of Bottled Drinking Water, 21 CFR section 129,~~  
3151 ~~(2009).~~

3152

3153

**3154 ~~\*5-104—Transportation~~**

3155 ~~All drinking water not provided directly by pipe to the retail food establishment from the source shall~~  
3156 ~~be transported in a bulk water transport system and shall be delivered to a closed water system. Both~~  
3157 ~~of these systems shall be constructed and operated according to law and operated as approved by the~~  
3158 ~~Department.~~

**3159 ~~\*5-105—Emergency Alternative Water Supply~~**

3160 ~~A.—— Establishments intending to operate when there is a temporary interruption of water service~~  
3161 ~~or an upset in the supply of treated drinking water, with approval by the Department prior to~~  
3162 ~~implementation, the establishment may continue operation if the temporary water supply~~  
3163 ~~meets the requirements of sections 5-101, 5-102, 5-103, 5-104 and 5-105 and drinking water~~  
3164 ~~is made available through:~~

3165

3166

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

3167

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

3168

3. ~~—— An enclosed vehicular drinking water tank;~~

3169

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

3170

5. ~~—— Piping, tubing, or hoses connected to an adjacent approved source.~~**3171 ~~\*5-106—Non-Drinking Water~~**

3172 ~~A non-drinking water system is permitted for air conditioning, non-food equipment cooling,~~  
3173 ~~landscape irrigation and fire protection, and shall be installed according to law. Non-drinking water~~  
3174 ~~shall not directly or indirectly contact food or equipment or utensils that contact food. The piping of~~  
3175 ~~any non-drinking water system shall be identified so that it is readily distinguishable from piping that~~  
3176 ~~carries drinking water.~~

**3177 ~~\*5-107—Pressure and Temperature~~**

3178 ~~A.—— Water under pressure of at least 15 pounds per square inch (psi) (1.05 kg per sq. cm) at the~~  
3179 ~~required temperature shall be provided to all fixtures and equipment that use water.~~

3180

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

**3181 ~~\*5-108—Hot Water~~**

3182 ~~Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands~~  
3183 ~~throughout the retail food establishment. (see Appendix C)~~

**3184 ~~\*5-109—Steam~~**

3185 ~~Steam used in contact with food or food contact surfaces shall be free from any unsafe materials or~~  
3186 ~~additives not listed in Specific Usage Additives, 21 CFR section 173.310, (2003). (see Appendix D)~~

3187

3188

3189 **5-2 — PLUMBING SYSTEM**3190 **5-201 — General**

3191 Plumbing shall be sized, installed, and maintained in accordance with applicable state and local  
 3192 plumbing codes, ordinances, regulations, and standards. Plumbing shall be designed and constructed  
 3193 according to the 2009 International Plumbing Code. Where local building departments have adopted  
 3194 codes equivalent to or more stringent than the above, those codes shall apply. The Department shall  
 3195 work in collaboration with the local building and/or fire department with regard to enforcement and  
 3196 compliance activities. Plumbing fixtures shall be easily cleanable and kept clean.

3197 **\*5-202 — Backflow**3198 **\*A. — General**

3199 The drinking water system shall be constructed to prevent backflow. There shall be no unprotected  
 3200 cross-connections between the drinking water supply and any non-drinking water supply, or any  
 3201 sources of contamination. Devices or assemblies installed shall meet the appropriate application for  
 3202 the hazard of the cross-connection to prevent backflow of a solid, liquid or gas contaminant into the  
 3203 drinking water supply system at each point of use within the retail food establishment.

3204 **\*B. — Backflow prevention devices and installation requirements**

3205 1. — An air gap between the water supply inlet and the flood level rim of the plumbing  
 3206 fixture, equipment, or nonfood equipment shall be at least twice the diameter of the  
 3207 water supply inlet and may not be less than one (1) inch (25 mm).

3208 2. — An atmospheric vacuum breaker shall be located on the discharge side of the last  
 3209 valve and not less than six (6) inches (154.4 mm) above the flood rim of plumbing  
 3210 fixture or equipment. A shutoff valve downstream of the atmospheric vacuum  
 3211 breaker is prohibited.

3212 3. — Backsiphonage and backflow prevention devices shall meet American Society of  
 3213 Sanitary Engineering (A.S.S.E.) standards for construction, installation,  
 3214 maintenance, inspection and testing for that specific application and type of device.

3215 **C. — Applications**

3216 \*1. — Inlets to tanks, vats, garbage disposals, troughs, fixtures, warewashing machines and  
 3217 other equipment with submerged inlets shall be protected by an approved backflow  
 3218 prevention device or with an approved air gap at the inlet.

3219 **\*2. — Carbonated Beverage Dispensers**

3220 — The drinking water supply connection to carbonated beverage dispensers shall be  
 3221 protected against backflow by at least one of the following:

3222 a. — An approved air gap; or

3223 b. — A dual check valve constructed of a material not affected by carbon dioxide  
 3224 with an intermediate vent installed upstream of the carbonator and  
 3225 downstream of any copper and copper alloy piping or fixture; or

- 3226 e. ~~A reduced pressure zone backflow prevention assembly constructed of~~  
 3227 ~~material impervious to attack by carbon dioxide, and installed upstream of~~  
 3228 ~~the carbonator and downstream of any copper and copper alloy piping or~~  
 3229 ~~fixture.~~
- 3230 3. ~~Non-Carbonated Beverage Dispensers~~
- 3231 The drinking water supply connection to non-carbonated beverage dispensers shall  
 3232 be protected against backflow by at least one of the following:
- 3233 a. ~~An approved air gap; or~~
- 3234 b. ~~A dual check valve constructed of a material not affected by carbon dioxide~~  
 3235 ~~with an intermediate vent installed downstream of any copper and copper~~  
 3236 ~~alloy piping or fixture.~~
- 3237 \*4. ~~Hose bibs, sillcocks, and threaded faucets where a hose can be attached shall be~~  
 3238 ~~equipped with a proper backflow prevention device in accordance with 5-202 (B) (2)~~  
 3239 ~~and (3). This paragraph shall not apply to water heater and boiler drain valves that~~  
 3240 ~~are provided with hose connection threads and that are intended only for tank or~~  
 3241 ~~vessel draining, or to water supply valves intended for connection of clothes~~  
 3242 ~~washing machines where backflow prevention is otherwise provided or is integral~~  
 3243 ~~with the machine.~~
- 3244 5. ~~In all new or extensively remodeled facilities, a dedicated hot and cold water supply~~  
 3245 ~~shall be provided for chemical dispensing towers.~~

#### 3246 **5-203 — Conditioning Device, Design**

- 3247 Water filters, screens, and other water conditioning devices installed on water lines shall be made of  
 3248 safe materials and designed and located to facilitate disassembly for periodic servicing and cleaning.  
 3249 A water filter element shall be of the replaceable type.

#### 3250 **5-204 — Grease Trap / Grease Interceptor**

- 3251 If required by the local building, water or sanitation authority, when possible, a grease trap, grease  
 3252 interceptor, or solids interceptor should be located outside the establishment. When installed inside  
 3253 the establishment, a grease trap, grease interceptor, or solids interceptor shall be located away from  
 3254 the food preparation area and be easily accessible for cleaning.

#### 3255 **5-205 — Food Waste Grinders/Garbage Disposals**

- 3256 A. ~~In new or extensively remodeled retail food establishments, food waste grinders or garbage~~  
 3257 ~~disposals, if provided, shall be installed in the soiled drainboard of the warewashing sink,~~  
 3258 ~~food preparation sink, or warewashing machine. The installation will be approved under the~~  
 3259 ~~following conditions:~~
- 3260 1. ~~The disposal shall be directly connected to the sanitary sewer unless otherwise required~~  
 3261 ~~by law; or~~
- 3262 2. ~~When installed in the drainboard of a food preparation sink, the drainboard shall be~~  
 3263 ~~equipped with an indirectly drained scupper/scrap basket or similar device to~~  
 3264 ~~prevent contamination of food contact surfaces. A second approved eighteen inch~~  
 3265 ~~(18") (46 cm) self-draining drain board or alternate approved methods shall be~~  
 3266 ~~provided to prevent contamination of food.~~

3267 B. ~~Food waste grinders or garbage disposals may be installed in the basin of the sink if the sink~~  
3268 ~~is used solely for the disposal of food wastes.~~

3269 ~~\*5-206 Drainage Of Equipment.~~

3270 A. ~~Warewashing machines, refrigerators, walk in refrigerators, freezers, walk in freezers,~~  
3271 ~~warewashing sinks, food/vegetable preparation sinks, steam kettles, potato peelers, ice bins,~~  
3272 ~~containers of ice for use in food and beverages, ice machines, and similar types of equipment~~  
3273 ~~in which food, portable equipment or utensils are placed shall be indirectly connected to the~~  
3274 ~~waste line and shall drain into an approved receptor of such size, shape, and capacity to~~  
3275 ~~prevent splashing or flooding. The receptor shall be readily accessible for cleaning and~~  
3276 ~~inspection.~~

3277 B. ~~Warewashing sinks and dishmachines installed prior to the effective date of these Regulations~~  
3278 ~~may be directly connected to the plumbing waste system provided there is a floor drain or~~  
3279 ~~floor sink installed within five (5) feet (1.5 M) immediately downstream of the sink waste~~  
3280 ~~line, and the fixture shall be connected on the sewer side of the floor drain or floor sink, and~~  
3281 ~~no other fixtures are connected to the waste line. The fixture and floor drain shall be trapped~~  
3282 ~~and vented as required by the 2009 International Plumbing Code or where local building~~  
3283 ~~departments have adopted codes equivalent or more stringent than the above, those codes~~  
3284 ~~shall apply (see Figure 4).~~

3285 C. ~~In new or extensively remodeled retail food establishments, each walk in refrigerator used for~~  
3286 ~~iced products, hanging meats or which requires flushing shall either be equipped with a floor~~  
3287 ~~drain installed only with indirect waste and discharged through an air gap into an approved~~  
3288 ~~receptor or constructed so all parts of the floor of such walk in refrigerator shall be graded to~~  
3289 ~~drain to the outside of the refrigerator through a waste pipe, doorway or other opening.~~

3290

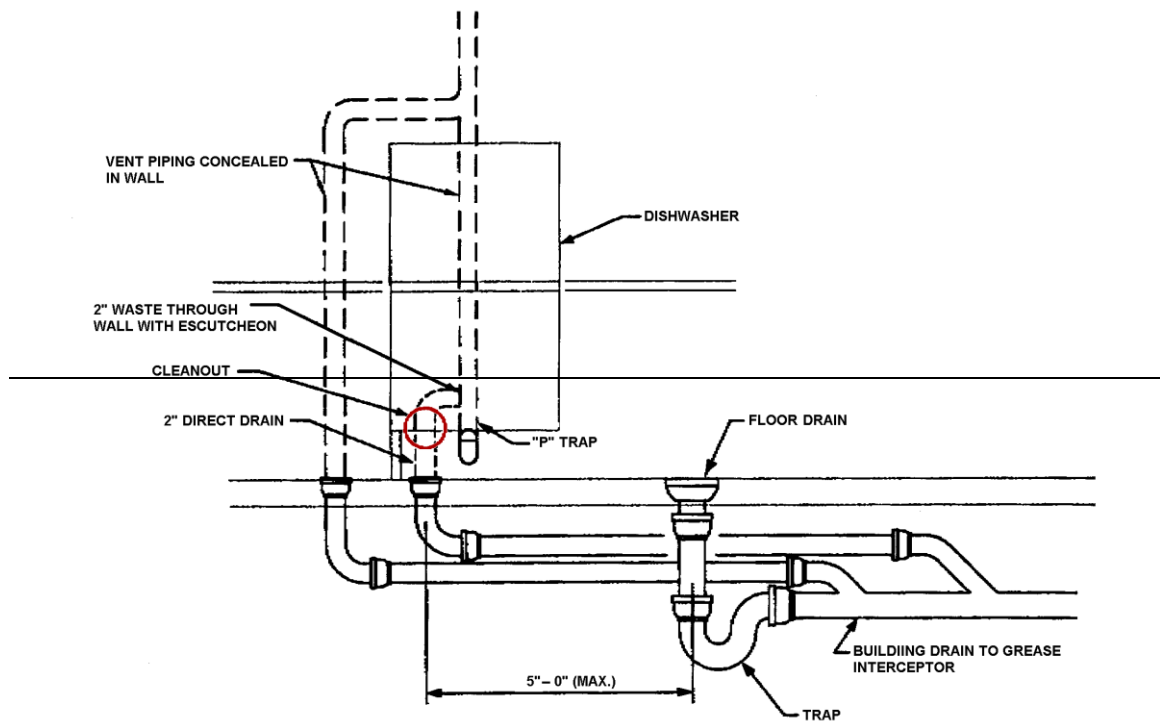


FIGURE 4

3291  
32923293 **5-207 — Drainage System Installation**

3294 Drain lines from equipment shall not discharge liquid waste in a manner that permits the flooding of  
 3295 floors, or the flowing of water across working or walking areas, or into difficult to clean areas that  
 3296 create a nuisance.

3297 **5-208 — Handwashing Lavatory, Water Temperature, and Flow**

3298 \*A. — The number of fixtures shall comply with the requirements of the plumbing code adopted by  
 3299 the respective local jurisdiction, or in the absence of such local requirements with the  
 3300 minimum plumbing fixtures listed in the 2009 International Plumbing Code.

3301 \*B. — Handsinks shall be conveniently located to employees involved in food preparation, food  
 3302 dispensing, warewashing and utensil handling. Handsinks shall be unobstructed and  
 3303 accessible to employees at all times and used only for handwashing. Sinks used for food  
 3304 preparation or for washing equipment shall not be used for handwashing. Handsinks used  
 3305 for toilet rooms shall be located in the toilet rooms.

3306 \*C. — Handwashing sink water temperatures. Each handsink shall be provided with water at least  
 3307 100°F (38°C) by means of a mixing valve or combination faucet. Any self-closing, slow-  
 3308 closing, or metering faucet used shall be designed to provide a flow of water for at least 15  
 3309 seconds without the need to reactivate the faucet.

3310 \*D. — A supply of hand-cleansing soap or detergent shall be available at each handsink or group of  
 3311 two (2) adjacent handwashing sinks. A continuous cloth towel system that supplies the user  
 3312 with a clean towel, individual disposable towels, or a hand-drying device providing heated or



- 3313 high velocity pressurized air shall be conveniently located near each handsink or group of  
3314 adjacent handwashing sinks.
- 3315 \*E. — Common towels are prohibited for the drying of hands.
- 3316 F. — Hand towels shall be stored to protect unused towels from becoming contaminated.
- 3317 G. — If disposable towels are used, an easily cleanable waste receptacle shall be conveniently  
3318 located near the handsink.
- 3319 H. — Handsinks, soap dispensers, hand drying devices and all related fixtures shall be kept clean  
3320 and in good repair.
- 3321 I. — Automatic Handwashing Facilities:
- 3322 1. — If the model, installation, location, and conditions of use are approved, and the unit  
3323 is capable of removing the types of soils encountered in the food operations  
3324 involved, automatic handwashing facilities may be substituted for handwashing  
3325 sinks in a food establishment that has at least one additional handwashing sink that  
3326 is easily accessible.
- 3327 2. — An automatic handwashing facility shall be installed and used in accordance with  
3328 manufacturer's instructions.
- 3329 J. — Handwashing Sink Specifications for New or Extensively Remodeled Establishments
- 3330 1. — The height of the sink's flood rim shall be between 30 inches (76cm) and 48 inches  
3331 (122 cm) above the floor.
- 3332 2. — The diameter of the handwashing sink basin shall be a minimum of 10 inches (25  
3333 cm) in any direction.
- 3334 3. — When installed in a counter top, handwashing sink faucets shall be within 24 inches  
3335 (61cm) of the front edge of the counter top.
- 3336 4. — The clearance between the flood rim of handwashing sink and the base or underside  
3337 of any overhead cabinets, shelves, or other equipment shall be a minimum of 24  
3338 inches (61cm).
- 3339 5. — Handwashing sink faucets shall be installed on the side of the sink basin directly  
3340 opposite the user.
- 3341 **5-209 — Toilets and Urinals**
- 3342 \*A. — Toilet facilities shall be installed according to law, shall be the number required by law, shall  
3343 be conveniently located, and shall be accessible to employees and patrons.
- 3344 B. — Separate toilet facilities shall be required for each sex in establishments with seating capacity  
3345 in excess of 20 patrons or more than 20 employees. In all new or extensively remodeled  
3346 retail food establishments, these facilities shall be installed to comply with the requirements  
3347 of the Plumbing Code adopted by the respective local jurisdictions, or in the absence of such  
3348 local requirements, with the minimum numbers of plumbing fixtures listed in the 2009  
3349 International Plumbing Code.
- 3350 C. — Separate toilet facilities are not required for each sex in places of 15 or fewer seating  
3351 capacity for patrons, or 20 or fewer employees where there is no seating capacity, provided  
3352 the toilet is a single occupancy facility and the door can be secured from the inside.

- 3353 ~~D. — Retail food establishments with no space on the premises for consumption of food by patrons~~  
 3354 ~~are required to provide toilet facilities only for employees. Patron facilities shall be available~~  
 3355 ~~where parking is provided primarily for consumption of food on the premise. In all new or~~  
 3356 ~~extensively remodeled retail food establishments where parking is provided primarily for~~  
 3357 ~~consumption of food on the premise, the number of necessary fixtures shall comply with the~~  
 3358 ~~minimum plumbing fixtures required by the Plumbing Code or Building Code adopted by~~  
 3359 ~~the respective local jurisdiction, or in the absence of such local requirements, with the~~  
 3360 ~~numbers listed in 2009 International Plumbing Code, table 403.1.~~
- 3361 ~~E. — Employees and patrons may use the same toilet facility provided that patrons have access to~~  
 3362 ~~them without entering the food preparation, food storage, or warewashing or utensil storage~~  
 3363 ~~areas of the establishment.~~
- 3364 ~~F. — Public toilets in multiple activity areas such as shopping centers, sports centers, etc., may~~  
 3365 ~~suffice for the use of retail food establishment patrons and employees, if fixtures are~~  
 3366 ~~provided in adequate numbers conveniently located to the retail food establishment and~~  
 3367 ~~available at all times the retail food establishment is in operation.~~
- 3368 ~~G. — Except where a toilet room is located outside a food establishment and does not open directly~~  
 3369 ~~into the food establishment such as a toilet room that is provided by the management of a~~  
 3370 ~~shopping mall, a toilet room located on the premises shall be completely enclosed and~~  
 3371 ~~provided with a tight fitting and self-closing door.~~
- 3372 ~~H. — Toilet facilities, including toilet fixtures and any related vestibules, shall be kept clean and in~~  
 3373 ~~good repair. A supply of toilet tissue in a permanently mounted dispenser shall be provided~~  
 3374 ~~at each toilet at all times.~~
- 3375 ~~I. — Easily cleanable trash receptacles shall be provided. A toilet room used by females shall be~~  
 3376 ~~provided with a covered trash receptacle for sanitary products. Trash receptacles shall be~~  
 3377 ~~emptied at least once a day, and more frequently when necessary to prevent excessive~~  
 3378 ~~accumulation of refuse.~~

3379 **5-210 — Utility Facility**

- 3380 ~~A. — In new or extensively remodeled retail food establishments, at least one conveniently located~~  
 3381 ~~utility sink or curbed cleaning facility with a floor drain and hot and cold water shall be~~  
 3382 ~~provided and used for the cleaning of mops or similar wet floor cleaning tools and for the~~  
 3383 ~~disposal of mop water or similar liquid wastes.~~
- 3384 ~~B. — Suitable cleaning equipment and supplies, such as high pressure pumps, hot water, steam,~~  
 3385 ~~and detergent, shall be provided as necessary for effective cleaning of equipment and~~  
 3386 ~~receptacles for refuse, recyclables, and returnables. If approved by the Department, off-~~  
 3387 ~~premise cleaning services may be used.~~
- 3388 ~~\*C. — A utility sink cannot be used for food preparation or warewashing.~~
- 3389 ~~D. — Dump Sinks~~
- 3390 ~~— In new or extensively remodeled establishments, bars, juice bars, coffee bars, drink stations,~~  
 3391 ~~wait stations or other areas where soiled drinking glasses and mugs are emptied and staged~~  
 3392 ~~for warewashing, a dump sink shall be provided and used for the sanitary disposal of liquid~~  
 3393 ~~drink waste, ice and/or collection of debris emptied from glasses and mugs.~~
- 3394 ~~1. — Dump sinks shall be fitted with a removable strainer basket, and shall be plumbed with hot~~  
 3395 ~~and cold running water.~~
- 3396 ~~2. — Blender station sinks and food preparation sinks shall not be utilized as dump sinks.~~

3397 3. ~~Other methods may be used if approved by the Department.~~

3398 ~~\*5-211 Sewage~~

3399 All sewage shall be disposed of by a sewage disposal system constructed, maintained and operated  
3400 according to law.

3401 ~~\*5-212 Water Reservoir of Fogging Devices, Cleaning~~

3402 A. ~~A reservoir used to supply water to a device, such as a produce fogger shall be:~~

3403 1. ~~Installed and maintained in accordance with manufacturer's specifications; and~~

3404 2. ~~Cleaned in accordance with manufacturer's specifications or according to the~~  
3405 ~~procedures specified in paragraph B of this section, whichever is more stringent.~~

3406 B. ~~Cleaning procedures shall include at least the following steps and shall be conducted at least~~  
3407 ~~once a week:~~

3408 1. ~~Draining and complete disassembly of the water and aerosol contact parts;~~

3409 2. ~~Brush cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable~~  
3410 ~~detergent solution;~~

3411 3. ~~Flushing the complete system with water to remove the detergent solution and~~  
3412 ~~particulate accumulation; and~~

3413 4. ~~Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and~~  
3414 ~~discharge nozzles with at least 50 ppm (mg/L) hypochlorite solution.~~

3415 ~~5-3 REFUSE, RECYCLABLES, AND RETURNABLES~~

3416 ~~5-301 Containers~~

3417 A. ~~Garbage, refuse, compost, and recyclables shall be held in durable, easily cleanable~~  
3418 ~~containers that do not leak and do not absorb liquids. Plastic bags and/or wet strength paper~~  
3419 ~~bags shall be used to line these containers. Such bags and durable plastic garbage and refuse~~  
3420 ~~containers shall be used for storage inside the food establishment.~~

3421 B. ~~Containers stored in food preparation and utensil washing areas shall be emptied when full.~~

3422 C. ~~Containers stored outside the food establishment, including dumpsters, compactors, and~~  
3423 ~~compactor systems, shall be easily cleanable, shall be insect and rodent proof, shall be~~  
3424 ~~provided with tight fitting lids, doors, or covers, and shall be kept covered when not in actual~~  
3425 ~~use. Drains in receptacles and waste handling units for refuse, recyclables and returnables~~  
3426 ~~shall have drain plugs in place.~~

3427 D. ~~There shall be a sufficient number of containers to hold all the garbage, refuse, compost and~~  
3428 ~~recyclables that accumulate.~~

3429 E. ~~Soiled containers, including dumpsters, compactors, and compactor systems, shall be cleaned~~  
3430 ~~at a frequency to prevent insect and rodent attraction. Each container shall be thoroughly~~  
3431 ~~cleaned on the inside and outside in a way that does not contaminate food, equipment,~~  
3432 ~~utensils, or food preparation areas. Suitable facilities, detergent, and hot water or steam,~~  
3433 ~~shall be provided and used for cleaning containers. Liquid waste from compacting or~~  
3434 ~~cleaning operations shall be disposed of as sewage.~~

3435 **5-302 — Storage**

3436 A. ~~Garbage, refuse, compost and recyclables, on the premises, shall be stored in a manner to be~~  
3437 ~~inaccessible to insects and rodents. Cardboard or other packaging material not containing~~  
3438 ~~garbage or food wastes need not be stored in covered containers provided such materials do~~  
3439 ~~not create a nuisance.~~

3440 B. ~~Indoor garbage or refuse storage rooms, compost and recycling areas if provided, shall be~~  
3441 ~~constructed of easily cleanable, nonabsorbent, washable materials, shall be kept clean, and~~  
3442 ~~shall be insect and rodent resistant. These areas shall be large enough to store all garbage~~  
3443 ~~and refuse containers.~~

3444 C. ~~Outside storage areas or enclosures, if provided, shall be kept clean and shall be large enough~~  
3445 ~~to store all the garbage and refuse containers. Garbage, refuse, compost, recycling~~  
3446 ~~containers, dumpsters, and compactor systems located outside, shall be stored on a smooth~~  
3447 ~~surface of nonabsorbent material, such as concrete or machine laid asphalt, that is kept clean~~  
3448 ~~and maintained in good repair.~~

3449 **5-303 — Disposal**

3450 A. ~~Garbage, refuse, compost and recyclable materials shall be removed often enough to prevent~~  
3451 ~~the development of objectionable odors and the attraction of insects and rodents.~~

3452 B. ~~Where garbage or refuse is burned on the premises, it shall be done by controlled~~  
3453 ~~incineration in accordance with the law. Areas around incineration units shall be kept clean~~  
3454 ~~and orderly.~~

3455 **5-304 — Storage Areas, Redeeming Machines, Equipment, and Receptacles, Location**

3456 A. ~~An area designated for refuse, recyclables, compost, returnables and, a redeeming machine~~  
3457 ~~for recyclables or returnables, except as specified in paragraph B of this section, shall be~~  
3458 ~~located separate from food, equipment, utensils, linens, and single service and single use~~  
3459 ~~articles, and a public health nuisance is not created.~~

3460 B. ~~A redeeming machine may be located in the packaged food storage area or consumer area of~~  
3461 ~~a retail food establishment if food, equipment, utensils, linens, and single service and single-~~  
3462 ~~use articles are not subject to contamination from the machines and a public health nuisance~~  
3463 ~~is not created.~~

3464 C. ~~The location of equipment and receptacles for refuse, recyclables, compost and returnables~~  
3465 ~~may not create a public health nuisance or interfere with the cleaning of adjacent space.~~

3466

3467

**CHAPTER 6**

3468

**PHYSICAL FACILITIES**3469 **6-1 — FLOORS**3470 **6-101 — Floor Construction**

3471 A. — Floors and floor coverings in all food preparation, food storage, warewashing areas, walk-in  
3472 refrigeration units, dressing rooms, locker rooms, utility sink areas, toilet rooms, garbage  
3473 rooms, and around permanently installed buffets, salad bars and soft drink dispensers shall  
3474 be constructed of smooth, durable, nonabsorbent and easily cleanable material and shall be  
3475 maintained in good repair. Areas subject to spilling or dripping of grease or fatty substances  
3476 shall be of grease resistant material. Nothing in this section shall prohibit the use of anti-slip  
3477 floor coverings in areas where necessary for safety reasons.

3478 B. — Floors which are water flushed or which receive discharges of water or other fluid wastes or  
3479 are in areas where pressure spray methods for cleaning are used, shall be provided with  
3480 properly installed trapped drains and graded to drain. In all new establishments, floor drains  
3481 and floor sinks shall be installed to be accessible for cleaning.

3482 **6-102 — Floor Carpeting**

3483 Carpeting, if used as a floor covering, shall be of closely woven construction, properly installed,  
3484 easily cleanable, and maintained in good repair. Carpeting shall not be used in food preparation,  
3485 warewashing, food storage, utility sink areas, or in toilet room areas where urinals or fixtures are  
3486 located. Carpeting is permitted in the retail sales area provided it is maintained in good repair and  
3487 kept clean.

3488 **6-103 — Utility Line Installation**

3489 Exposed utility service lines and pipes shall be installed in a way that does not obstruct or prevent  
3490 cleaning of the floor. In all new or extensively remodeled food establishments, installation of  
3491 exposed horizontal utility service lines and pipes on the floor is prohibited.

3492 **6-104 — Floor Junctures**

3493 All floors installed in food preparation, food storage and warewashing areas, and in walk-in  
3494 refrigerators, dressing or locker rooms, utility sink areas, and toilet rooms, shall provide a coved  
3495 juncture between the floor and wall. In all cases, the juncture between the floor and wall shall be  
3496 closed and sealed.

3497 **6-105 — Prohibited Floor Covering**

3498 Cardboard, newspapers, sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or  
3499 similar materials shall not be used as floor coverings; however, these materials may be used in  
3500 amounts necessary for immediate spot clean-up of spills or drippage on floors.

3501 ~~6-106 — Mats and Duckboards~~

3502 Mats and duckboards shall be designed to be removable, easily cleanable, and be maintained clean  
3503 and in good repair.

3504 ~~6-2 — WALLS AND CEILINGS~~3505 ~~6-201 — Construction~~

3506 A. ~~Walls, wall coverings, and ceilings shall be designed, constructed and installed to be smooth,~~  
3507  ~~durable and easily cleanable.~~

3508 B. ~~Except for in dry storage units, walls, including non-supporting partitions, wall coverings~~  
3509 ~~and ceilings of walk-in refrigerating units, food preparation areas, food storage areas,~~  
3510 ~~equipment washing and warewashing areas shall be smooth, nonabsorbent, easily cleanable,~~  
3511 ~~and maintained in good repair. Concrete or pumice blocks used for interior wall construction~~  
3512 ~~in these locations shall be finished and sealed to provide an easily cleanable surface.~~  
3513 ~~Acoustical material, free of porous perforations, smooth and durable enough to be washed~~  
3514 ~~with a cloth or sponge, may be used. Walls, including non-supporting partitions and wall~~  
3515 ~~coverings in toilet rooms shall be smooth, nonabsorbent, and easily cleanable. Porous~~  
3516 ~~acoustical ceilings are permitted in toilet rooms and their vestibules.~~

3517 ~~6-202 — Attachments, Exposed Construction~~

3518 A. ~~Except as specified in paragraph C of this section, attachments to walls and ceilings such as~~  
3519 ~~light fixtures, mechanical room ventilation system components, vent covers, wall-mounted~~  
3520 ~~fans, decorative items, and other attachments shall be easily cleanable.~~

3521 B. ~~Studs, joists, and rafters shall not be exposed in those areas listed in section 6-201(B) of~~  
3522 ~~these rules and regulations. If exposed in other rooms or areas, they shall be kept clean.~~

3523 C. ~~In consumer and backbar areas limited to beverage service and the heating of pre-prepared~~  
3524 ~~foods for immediate service, wall and ceiling surfaces and decorative items and attachments~~  
3525 ~~that are provided for ambiance need not meet this requirement if they are kept clean.~~

3526 D. ~~Exposed utility service lines and pipes shall not obstruct or prevent cleaning of walls and~~  
3527 ~~ceilings. Utility service lines or pipes shall not be unnecessarily exposed on walls or ceilings~~  
3528 ~~in those areas listed in section 6-201(B) of these rules and regulations.~~

3529 ~~6-3 — LIGHTING~~3530 ~~6-301 — Light Intensity~~

3531 A. ~~Permanently fixed artificial light sources shall be installed to provide at least 50 foot candles~~  
3532 ~~(540 lux) of light on all food preparation surfaces and at warewashing work levels.~~

3533 B. ~~Permanently fixed artificial light sources shall be installed to provide, at a distance of 30~~  
3534 ~~inches (76 cm) from the floor:~~

3535 1. ~~At least 20 foot candles (215 lux) of light in sales areas, at consumer service areas~~  
3536 ~~such as buffets and salad bars, utensil and equipment storage areas, and in lavatory~~  
3537 ~~and toilet areas; and~~

3538 2. ~~At least 10 foot candles (108 lux) of light throughout walk-in refrigeration and~~  
3539 ~~freezer units, dry food storage areas, and in all other areas.~~

3540 **6-302 — Light Bulbs, Protective Shielding**

3541 A. ~~Except as specified in paragraph B of this section, light bulbs shall be shielded, coated, or~~  
3542 ~~otherwise shatter resistant in areas where there is exposed food, clean equipment, utensils,~~  
3543 ~~linens, or unwrapped single-service and single-use articles.~~

3544 B. ~~Shielded, coated or otherwise shatter-resistant bulbs are not required in areas used only for~~  
3545 ~~storing food in unopened packages if:~~

3546 1. ~~The integrity of the packages cannot be affected by broken glass falling onto them;~~  
3547 ~~and~~

3548 2. ~~The packages are capable of being cleaned of debris from broken bulbs before the~~  
3549 ~~packages are opened.~~

3550 C. ~~An infrared or other heat lamp shall be protected against breakage by a shield surrounding~~  
3551 ~~and extending beyond the bulb so that only the face of the bulb is exposed.~~

3552 **6-4 — OPERATION AND MAINTENANCE**

3553 **6-401 — Cleaning Physical Facilities**

3554 A. ~~Cleaning of floors, walls, and ceilings shall be done as needed, preferably during periods~~  
3555 ~~when the least amount of food is exposed, such as after closing.~~

3556 B. ~~Only dustless methods for cleaning floors, walls, and ceilings shall be used, such as vacuum~~  
3557 ~~cleaning, wet cleaning, treated dust mops, or the use of dust-arresting sweeping compounds~~  
3558 ~~with brooms.~~

3559 C. ~~Floors, mats, duckboards, walls, ceilings, and attachments (e.g., light fixtures, vent covers,~~  
3560 ~~wall and ceiling-mounted fans, and similar equipment), and decorative materials (e.g., signs~~  
3561 ~~and advertising materials), shall be kept clean.~~

3562 D. ~~Mop water shall be changed as needed to prevent the recontamination of cleaned surfaces.~~

3563 **6-402 — Cleaning Equipment Storage**

3564 ~~Maintenance and cleaning tools, such as brooms, mops, vacuum cleaners, and similar equipment,~~  
3565 ~~shall be maintained in good repair and stored in a way that does not contaminate food, utensils,~~  
3566 ~~equipment, or linens. Maintenance and cleaning tools shall be stored in an orderly manner to~~  
3567 ~~facilitate the cleaning of the storage area. After use, mops shall be placed in a position that allows~~  
3568 ~~them to air-dry without soiling walls, equipment, or supplies.~~

3569 **6-5 — PREMISES**

3570 **6-501 — General**

3571 A. ~~Retail food establishments and all parts of the property used in connection with operations of~~  
3572 ~~the retail food establishment shall be kept free of litter, maintained clean and in good repair,~~  
3573 ~~and shall comply with local ordinances.~~

3574 B. ~~The outdoor walking and driving areas shall be surfaced with concrete, asphalt, gravel or~~  
3575 ~~other materials that have been effectively treated to minimize dust, facilitate maintenance,~~  
3576 ~~and minimize muddy conditions. These surfaces shall be graded to drain and kept free of~~  
3577 ~~litter. Exterior surfaces of buildings shall be of weather-resistant materials and shall comply~~  
3578 ~~with law.~~

3579 C. ~~Only articles necessary to the operation and maintenance of the retail food establishment~~  
3580 ~~shall be stored on the premises.~~

3581 **~~6-502 Living Areas~~**

3582 ~~No retail food establishment operation shall be conducted in any area used as living or sleeping~~  
3583 ~~quarters. A retail food establishment operation shall be separated from any living or sleeping~~  
3584 ~~quarters by complete partitioning and solid, self-closing doors, and shall comply with local~~  
3585 ~~requirements.~~

3586 **~~6-503 Dressing Rooms and Locker Areas~~**

3587 A. ~~Dressing rooms or dressing areas shall be designated if employees routinely change their~~  
3588 ~~clothes in the establishment.~~

3589 B. ~~Designated areas or other suitable facilities shall be provided for the orderly storage of~~  
3590 ~~employees' clothing and other possessions.~~

3591 C. ~~If the retail food establishment provides a storage area for any food belonging to employees~~  
3592 ~~it shall be inside a covered, leakproof container designated for the storage of employee food~~  
3593 ~~and maintained by the facility.~~

3594



3595

**CHAPTER 7**

3596

**~~POISONOUS OR TOXIC MATERIALS~~**3597 **~~7-1 LABELING AND IDENTIFICATION~~**3598 **~~\*7-101 Identifying Information, Prominence~~**

3599 Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's  
3600 label.

3601 **~~\*7-102 Working Containers~~**

3602 Working containers used for storing poisonous or toxic material, such as cleaners and sanitizers taken  
3603 from bulk supplies, shall be clearly and individually identified with at least the name of the material.

3604 **~~\*7-103 Separation~~**

3605 Poisonous or toxic materials shall be stored so they do not contaminate food, equipment, utensils,  
3606 linens, or single service and single use articles by:

3607 A. ~~Separating the poisonous or toxic materials by spacing or partitioning; and~~

3608 B. ~~Locating the poisonous or toxic materials in an area that is not above food, equipment,~~  
3609 ~~utensils, linens, and single service or single use articles. Except that equipment and utensil~~  
3610 ~~cleaners and sanitizers may be stored in warewashing areas for availability and convenience~~  
3611 ~~if such materials are stored to prevent contamination of food, equipment, utensils, linens, or~~  
3612 ~~single service and single use articles.~~

3613 C. ~~Poisonous or toxic materials stored or displayed for retail sale shall be separated from food~~  
3614 ~~and single service articles by spacing, partitioning, or dividers. These materials shall not be~~  
3615 ~~stored or displayed above food or single service articles.~~

3616 **~~\*7-104 Restriction~~**

3617 A. ~~Only those poisonous or toxic materials required for the operation and maintenance of a~~  
3618 ~~retail food establishment, such as for the cleaning and sanitizing of equipment and utensils~~  
3619 ~~and the control of insects and rodents, shall be allowed in a retail food establishment.~~

3620 B. ~~Paragraph A of this section does not apply to packaged poisonous or toxic materials that are~~  
3621 ~~for retail sale.~~

3622 **~~\*7-105 Use of Materials~~**

3623 A. ~~Sanitizers, disinfectants, cleaning compounds, or other compounds intended for use on food-~~  
3624 ~~contact surfaces shall not be used in a way that leaves a toxic residue on such surfaces in~~  
3625 ~~accordance with 40 CFR 180.940 (2005).~~

3626 B. ~~Poisonous or toxic materials shall not be used in a way that contaminates food, food contact~~  
3627 ~~surfaces, equipment, utensils, or single service articles, nor in a way other than in full~~  
3628 ~~compliance with the manufacturer's labeling.~~

3629 ~~\*7-106—Food Containers~~

3630 ~~A container previously used to store poisonous or toxic materials shall not be used as a food contact~~  
3631 ~~surface. A container previously used to store food shall not be used as a container to store toxic~~  
3632 ~~materials.~~

3633 ~~\*7-107—Chemicals for Washing Fruits and Vegetables, Criteria~~

3634 ~~Chemicals used to wash whole fruits and vegetables shall meet the requirements of Chemicals Used~~  
3635 ~~In Washing Or To Assist In The Lye Peeling Of Fruits And Vegetables, 21 CFR section 173.315,~~  
3636 ~~(2003).~~

3637 ~~\*7-108—Boiler Water Additives, Criteria~~

3638 ~~Chemicals used as boiler water additives shall meet the requirements specified in Boiler Water~~  
3639 ~~Additives, 21 CFR section 173.310, (2003) (see Appendix D).~~

3640 ~~\*7-109—Drying Agents, Criteria~~

3641 ~~Drying agents used in conjunction with sanitization shall be approved by the Department.~~

3642 ~~\*7-110—Personal Medications~~

3643 ~~Only those medications necessary for the health of employees shall be present in the retail food~~  
3644 ~~establishment. Medications and cosmetics shall be stored in properly labeled containers and located~~  
3645 ~~so that food and food contact surfaces of equipment, utensils, linens, single service and single use~~  
3646 ~~articles cannot be contaminated. Medications requiring refrigeration and stored in a food refrigerator~~  
3647 ~~shall be properly identified, double packaged and located on the lowest shelf. This paragraph does~~  
3648 ~~not apply to medications that are stored or displayed for retail sale.~~

3649 ~~\*7-111—First Aid Supplies~~

3650 ~~First aid supplies shall be properly labeled and stored in a way that prevents them from contaminating~~  
3651 ~~food and food contact surfaces, equipment, utensils, linens, single service and single use articles.~~

3652

3653

**CHAPTER 8**

3654

**INSECT, RODENT AND ANIMAL CONTROL****8-1 — PREVENTION****8-101 — Outer Openings, Protected**

3657 A. — ~~Openings to the outdoors shall be protected against the entry of insects and rodents by:~~

3658 1. — ~~Closed, tight fitting windows; and~~

3659 2. — ~~Solid self closing, tight fitting doors; or~~

3660 B. — ~~If windows or doors are kept open, the openings shall be protected against the entry of~~  
3661 ~~insects and rodents by:~~

3662 1. — ~~16 mesh to 1 inch (16 mesh to 25.4 mm) screens,~~

3663 2. — ~~Properly designed and installed air curtains to control flying insects, or~~

3664 3. — ~~Other effective means.~~

3665 C. — ~~Paragraph B of this section does not apply in customer areas if flying insects and other pests~~  
3666 ~~are absent due to the location of the retail food establishment, the weather, or other limiting~~  
3667 ~~conditions.~~

3668 D. — ~~Doors used only for delivery or emergency exit are not required to be equipped with self-~~  
3669 ~~closing devices, but shall remain closed at all other times.~~

3670 E. — ~~All foundations shall be rodent proof. Openings between the floor and bottom of outer doors,~~  
3671 ~~when closed, shall be no greater than one fourth inch (1/4") (0.635 cm).~~

**8-102 — Controlling Pests**

3673 ~~The presence of insects, rodents, and other pests shall be controlled to minimize their presence on~~  
3674 ~~the premises by:~~

3675 A. — ~~Routinely inspecting incoming shipments of food and supplies;~~

3676 B. — ~~Routinely inspecting the premises for evidence of pests;~~

3677 \*C. — ~~Using methods, if pests are found, such as trapping devices or other means of pest control as~~  
3678 ~~specified in sections 8-103 and 8-104;~~

3679 D. — ~~Eliminating harborage conditions; and~~

3680 E. — ~~Eliminating infestations.~~

**8-103 — Insect Control Devices, Design and Installation**

3682 A. — ~~Devices used to electrocute flying insects and that may impel insects or insect fragments~~  
3683 ~~shall be:~~

3684 1. — ~~Designed to have escape resistant trays; and~~

3685 \*2. — ~~Installed so that:~~

- 3686 a. ~~— The devices are not located over a food preparation area; and~~
- 3687 b. ~~— Dead insects and insect fragments are prevented from falling on or being~~
- 3688 ~~impelled onto exposed food, clean equipment, utensils, linens, and~~
- 3689 ~~unwrapped single service and single use articles.~~
- 3690 \*B. ~~— Devices used to trap insects by adherence may not be installed above exposed food, clean~~
- 3691 ~~equipment, utensils, linens, or unwrapped single service and single use articles unless the~~
- 3692 ~~device is designed to completely contain the trapped insects.~~

3693 **\*8-104 Pesticide Application**

- 3694 A. ~~— Only pesticides registered for application in a food establishment are permitted and shall be~~
- 3695 ~~applied according to label directions.~~
- 3696 B. ~~— A pesticide shall be applied so that direct or indirect contact with food, equipment, utensils,~~
- 3697 ~~linens, and single service and single use articles is prevented by protecting those items as~~
- 3698 ~~follows:~~
- 3699 1. ~~— Removing the items;~~
- 3700 2. ~~— Covering the items with impermeable covers; or~~
- 3701 3. ~~— Taking other appropriate preventive actions; and~~
- 3702 4. ~~— Cleaning and sanitizing equipment and utensils after the application of a pesticide.~~
- 3703 C. ~~— Bait shall be contained in a covered tamper proof bait station.~~
- 3704 D. ~~— Only nontoxic tracking powder such as talcum or flour may be used provided it does not~~
- 3705 ~~contaminate food, equipment, utensils, linens, single service or single use articles.~~

3706 **\*8-105 Removing Birds, Insects, Rodents, and Other Pests**

- 3707 Birds, insects, rodents, and other pests shall be removed from control devices and the premises at a
- 3708 frequency that prevents their accumulation, decomposition, or the attraction of pests.

3709 **\*8-106 Prohibiting of Animals**

- 3710 \*A. ~~— Except as specified in (B) and (C) of this section, live animals may not be allowed on the~~
- 3711 ~~premises of a food establishment.~~
- 3712 B. ~~— Provided that the contamination of food; clean equipment, utensils, and linens; and~~
- 3713 ~~unwrapped single service and single use articles is controlled, live animals are allowed in the~~
- 3714 ~~following situations:~~
- 3715 1. ~~— Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under~~
- 3716 ~~refrigeration, and shellfish and crustacea in display tank systems;~~
- 3717 2. ~~— Patrol dogs accompanying police or security officers in offices and dining, sales, and~~
- 3718 ~~storage areas, and sentry dogs running loose in outside fenced areas;~~
- 3719 3. ~~— In areas that are not used for food preparation and that are usually open for~~
- 3720 ~~customers, such as dining and sales areas, service animals that are controlled by the~~
- 3721 ~~disabled employee or person. This does not apply to incidental food contact~~
- 3722 ~~surfaces including dining tables, grocery carts and baskets;~~

- 3723 ~~4. Pets in the common dining areas of institutional care facilities such as nursing~~  
3724 ~~homes, assisted living facilities, group homes, or residential care facilities at times~~  
3725 ~~other than during meals if:~~
- 3726 ~~a. Effective partitioning and self-closing doors separate the common dining~~  
3727 ~~areas from food storage or food preparation areas;~~
- 3728 ~~b. Condiments, equipment, and utensils are stored in enclosed cabinets or~~  
3729 ~~removed from the common dining areas when pets are present; and~~
- 3730 ~~c. Dining areas including tables, countertops, and similar surfaces are~~  
3731 ~~effectively cleaned before the next meal service; and~~
- 3732 ~~5. In areas that are not used for food preparation, storage, sales, display, or dining, in~~  
3733 ~~which there are caged animals or animals that are similarly confined, such as in a~~  
3734 ~~variety store that sells pets or a tourist park that displays animals.~~
- 3735 ~~C. Live fish bait shall be stored to prevent contamination of food; clean equipment, utensils, and~~  
3736 ~~linens; and unwrapped single-service and single-use articles.~~
- 3737  
3738  
3739  
3740

3741

**CHAPTER 9**

3742

**MOBILE RETAIL FOOD ESTABLISHMENTS OR PUSHCARTS**

3743

**9-1 — MOBILE RETAIL FOOD ESTABLISHMENT**

3744

**9-101 — General**

3745 A. — Mobile retail food establishments and pushcarts shall comply with the requirements of these  
 3746 rules and regulations except as otherwise provided in this chapter. The Department may  
 3747 impose additional requirements to protect against health hazards related to the conduct of the  
 3748 mobile retail food establishment or pushcart and may prohibit the sale of any potentially  
 3749 hazardous foods (time/temperature control for safety foods). This may include maintaining  
 3750 receipts, logs, or any other records. If restrictions are imposed by the Department, they shall  
 3751 be in writing with a copy provided on the mobile unit at all times. A list of menu items  
 3752 prepared and/or served by the operator shall be submitted to the Department and available at  
 3753 all times. The original retail food establishment license shall be posted on the unit at all  
 3754 times as per Section 11-101.

3755 — When no apparent health hazard will result, the Department may waive or modify  
 3756 requirements of these rules and regulations relating to physical facilities, except those  
 3757 requirements of sections 9-104 and 9-105.

3758 B. — Mobile retail food establishments shall have equipment installed and/or mounted, according  
 3759 to Section 4-302, within the mobile retail food establishment with the exception of a grill  
 3760 and/or a smoker, approved by the Department, which shall be allowed outside of the mobile  
 3761 retail food establishment for cooking of food only. \*All foods shall be prepared, assembled  
 3762 and served from within the mobile retail food establishment and not from the external piece  
 3763 of cooking equipment.

3764 C. — Pushcarts shall be limited to cooking approved menu items and serving commercially  
 3765 prepared or commissary prepared food that will result in simple assembly. All items related  
 3766 to the operation of the pushcart shall be kept on the unit, except for those items specified in  
 3767 Section 9-108(A).

3768

**9-102 — Exemptions**

3769 Mobile retail food establishments and pushcarts are exempt from requirements for self-contained  
 3770 water or sewage systems, and cleaning and sanitization of equipment under the following conditions:

3771 A. — The menu is limited to commercially packaged potentially hazardous foods  
 3772 (time/temperature control for safety foods) or food that is prepared, then packaged in  
 3773 individual servings, transported and stored and served without further handling under  
 3774 conditions meeting the requirements of these rules and regulations; and

3775 B. — Beverages served are dispensed from covered urns or other protected equipment; and

3776 C. — The required equipment for cleaning and sanitization exists at the commissary.

3777 **9-103 — Single-service Articles**

3778 Mobile retail food establishments and pushcarts shall provide only single-service articles for use by  
3779 the consumer.

3780 **9-104 — Water System**

3781 \*A. — A mobile retail food establishment or a pushcart that does not meet the exemptions of section  
3782 9-102 of these rules and regulations shall provide hot and cold drinking water under pressure  
3783 with sufficient capacity for food preparation, utensil cleaning and sanitizing, in accordance  
3784 with the requirements of these rules and regulations.

3785 B. — The water supply tank shall be designed so that it can be flushed and with a drain that  
3786 permits complete drainage of the tank. The drinking water tank shall have no common  
3787 interior partition with the tank holding non-potable water or other liquids. The water tank  
3788 overflow or vent shall terminate in a downward direction and shall be located and  
3789 constructed so as to prevent the entrance of contaminants.

3790 \*C. — When a mobile retail food establishment or pushcart is equipped with a three-compartment  
3791 warewashing sink, the water supply shall be sized to adequately fill warewashing sinks at  
3792 least once every four (4) hours of operation. In addition, the mobile retail food establishment  
3793 or pushcart must supply three (3) gallons of water to each hand-washing sink for each hour  
3794 of operation. Where other water-using fixtures such as toilets, utility sinks, food preparation  
3795 sinks, coffee, espresso and soft drink machines are provided, the water supply shall be sized  
3796 in accordance with the manufacturer's specification for each fixture.

3797 \*D. — The water supply tank for push-carts shall have a minimum capacity of at least five (5)  
3798 gallons.

3799 \*E. — Adequate water pressure must be provided at all fixtures at all times. A minimum flow rate  
3800 of one (1) gallon per minute or thirty-two (32) ounces per fifteen (15) seconds shall be  
3801 provided.

3802 \*F. — Water heating systems shall be adequate to fill the warewashing sink with 110°F water  
3803 without interruptions and to supply hand-sinks with three (3) gallons per hour of 100°F water  
3804 at all times and other hot water-using fixtures and equipment with a continuous supply of hot  
3805 water. Standard tank-type heating systems shall be sized in accordance with Section 5-108.

3806 G. — The water inlet shall be located so that it will not be contaminated by waste discharge, road  
3807 dust, oil, or grease, and it shall be kept capped unless being filled. The water inlet shall be  
3808 provided with a connection of a size or type that will prevent its use for any other service.  
3809 All water distribution pipes or tubing shall be constructed and installed in accordance with  
3810 the requirements of these rules and regulations.

3811 \*H. — When a mobile retail food establishment is connected to a pressurized water supply, it shall  
3812 be provided with approved backflow prevention devices. This shall include the protection of  
3813 the water source as well as protection of each individual water service connection.

3814 \*I. — The water supply hose and couplings shall be of a size and type compatible with the water  
3815 supply tank inlet fixture and shall be free of cracks and checks. Hose couplings shall be  
3816 constructed to permit a tight connection between the mobile retail food establishment  
3817 coupling and the water supply hose bib. Hose ends must be capped, connected or otherwise  
3818 fully protected when not in use. Only food-grade hoses shall be used to fill or transfer  
3819 drinking water to or within a mobile retail food establishment or a pushcart.

3820 ~~\*J. Water systems and components shall be disinfected and flushed in accordance with 25-1.5-2,~~  
 3821 ~~C.R.S., Colorado Primary Drinking Water Regulations, prior to use, if the mobile retail food~~  
 3822 ~~establishment or pusheart is not in daily use.~~

### 3823 ~~9-105 Wastewater Retention~~

3824 ~~\*A. A mobile retail food establishment or pusheart that does not meet all the restrictions of~~  
 3825 ~~section 9-102 of these rules and regulations must provide a waste water retention tank. All~~  
 3826 ~~liquid waste, except drainage from clean ice made with drinking water, generated by a~~  
 3827 ~~mobile retail food establishment or pusheart shall be stored in a retention tank that is at least~~  
 3828 ~~15 percent larger than the water supply tank. Liquid waste shall be discharged from the~~  
 3829 ~~retention tank to an approved sewage disposal system and flushed as often as necessary to~~  
 3830 ~~maintain sanitary conditions. Discharge onto the surface of the ground shall be strictly~~  
 3831 ~~prohibited. Drainage from uncontaminated ice made with drinking water can be discharged~~  
 3832 ~~onto the surface of the ground provided it does not create a nuisance.~~

3833 ~~B. All connections on the vehicle for servicing mobile food unit waste disposal facilities shall~~  
 3834 ~~be of a different size or type than those used for supplying potable drinking water to the~~  
 3835 ~~mobile food establishment. The waste water outlet connection shall be located lower than~~  
 3836 ~~the drinking water inlet connection to prevent contamination of the drinking water system.~~

3837 ~~C. Liquid waste discharge piping and the drinking water hose shall not be stored in a manner~~  
 3838 ~~that may result in contamination.~~

### 3839 ~~\*9-106 Handwashing Facilities~~

3840 ~~A mobile retail food establishment or pusheart that does not meet all the exemptions of section 9-102~~  
 3841 ~~of these rules and regulations must be equipped with a convenient, accessible handsink installed as~~  
 3842 ~~specified in Section 5-208(J) for employee handwashing. The handsink must be capable of providing~~  
 3843 ~~a hands free, continuous flow of 100°F water as specified in Section 9-104(F). Soap and individually~~  
 3844 ~~dispensed paper towels must also be provided at the handsink.~~

### 3845 ~~9-107 Commissary~~

3846 ~~A. The commissary is considered to be an essential part of the mobile food retail food~~  
 3847 ~~establishment and push cart operation. The commissary shall be constructed and operated in~~  
 3848 ~~compliance with the requirements of these rules and regulations. Mobile retail food~~  
 3849 ~~establishments and pushearts shall operate from a commissary or other fixed retail food~~  
 3850 ~~establishment and shall report every 24 hours (on operational days) to that location for~~  
 3851 ~~supplies, cleaning and servicing operations.~~

3852 ~~— The use of the proposed commissary for each mobile retail food establishments or pushearts~~  
 3853 ~~shall be submitted and approved by the department. The mobile retail food establishment or~~  
 3854 ~~pusheart shall provide an agreement from the commissary operator to the department each~~  
 3855 ~~calendar year and upon change of a commissary location.~~

3856 ~~— The agreement shall specify the mobile retail food establishment or push cart is allowed to~~  
 3857 ~~report to the commissary daily, and is allowed to use the facility's warewashing equipment,~~  
 3858 ~~refrigeration, food preparation equipment and storage areas as a base for operation. The~~  
 3859 ~~agreement shall also specify how and where the commissary use log will be maintained.~~  
 3860 ~~These commissary records shall be made available to the Department when requested.~~

3861 ~~B. Accommodations for a servicing area shall be available with a drinking water supply for the~~  
 3862 ~~mobile retail food establishment or push cart. Servicing may include vehicle and equipment~~



- 3863 cleaning, discharging liquid or solid wastes, refilling water tanks, and restocking of ice bins,  
3864 and food.
- 3865 1. ~~Drinking water servicing equipment shall be installed according to the law and shall be~~  
3866 ~~stored and handled to protect the water and equipment from contamination~~  
3867 ~~according to section 5-101 and 5-102.~~
- 3868 2. ~~The mobile retail food establishment and push cart liquid waste retention tank shall be~~  
3869 ~~thoroughly drained and flushed during servicing. All liquid waste shall be~~  
3870 ~~discharged to a sanitary sewage system in accordance with section 5-211 of these~~  
3871 ~~rules and regulations.~~
- 3872 3. ~~There shall be a location provided for the flushing and drainage of liquid wastes that is~~  
3873 ~~separate from the location provided for obtaining drinking water and for the loading~~  
3874 ~~and unloading of food and related supplies.~~
- 3875 ~~C. When servicing areas are provided as part of the commissary, the floor surfaces of the~~  
3876 ~~servicing area shall be constructed of a smooth, nonabsorbent material such as concrete or~~  
3877 ~~machine laid asphalt and shall be maintained in good repair, kept clean, and be graded to~~  
3878 ~~drain.~~
- 3879 ~~The construction of the walls and ceilings of the servicing area is exempt from the provisions~~  
3880 ~~of sections 6-201 and 6-202 of these rules and regulations.~~
- 3881 ~~D. A self-contained mobile retail food establishment is not required to report to a commissary~~  
3882 ~~if:~~
- 3883 1. ~~Adequate storage areas are provided within the mobile retail food establishment for~~  
3884 ~~food, dry goods, single service articles and cleaning supplies; and~~
- 3885 2. ~~Adequate facilities including a hand sink, food preparation sink, warewashing~~  
3886 ~~facilities, mop sink, mechanical refrigeration, and any additional equipment are~~  
3887 ~~provided as required by the menu.~~
- 3888 3. ~~Adequate accommodations for food preparation, storage of food, equipment, utensils~~  
3889 ~~and other supplies; and~~
- 3890 4. ~~Approved arrangements and facilities are provided and used to supply drinking~~  
3891 ~~water to the mobile unit and for the disposal of wastewater generated by the~~  
3892 ~~establishment; and~~
- 3893 5. ~~A written operational plan is submitted by the mobile retail food establishment,~~  
3894 ~~which demonstrates that this process can be accomplished in compliance with these~~  
3895 ~~rules and regulations. Review and approval of this plan must include the menu and~~  
3896 ~~standard operating procedures for the mobile unit. Once an operational plan is~~  
3897 ~~approved, any additions or changes to the approved plan must be approved by the~~  
3898 ~~Department prior to implementation. The approved operational plan must be~~  
3899 ~~available on the mobile retail food establishment at all times.~~
- 3900 ~~E. A mobile retail food establishment is prohibited from acting as a commissary for another~~  
3901 ~~retail food establishment.~~

### 3902 ~~9-108~~ **Additional Requirements**

- 3903 A. ~~Spare tires, tools, and other equipment relating to the mechanical operation of the vehicle~~  
3904 ~~shall be stored in a way that does not contaminate food, food equipment, or utensils.~~

- 3905 ~~B. Except for service windows, any openable windows and doors must be screened. Service~~  
3906 ~~windows must be self-closing.~~
- 3907 ~~C. Restroom facilities shall be available to employees at all times that the mobile retail food~~  
3908 ~~establishment or pushcart is in operation.~~
- 3909 ~~\*D. Equipment shall be adequate to maintain potentially hazardous foods (time/temperature~~  
3910 ~~control for safety foods) at required temperatures in accordance with Parts 3-5 and 3-6. In~~  
3911 ~~addition:~~
- 3912 ~~1. Mobile retail food establishments shall utilize mechanical refrigeration to hold and~~  
3913 ~~serve potentially hazardous foods (time/temperature control for safety foods).~~
- 3914 ~~2. Pushcarts may use no more than two (2) hard-sided coolers to maintain food at~~  
3915 ~~required temperatures. One cooler shall be used for all raw animal foods and the~~  
3916 ~~other cooler for all other potentially hazardous foods (time/temperature control for~~  
3917 ~~safety foods). If the facility needs additional refrigeration space, the pushcart shall~~  
3918 ~~provide commercial mechanical refrigeration.~~
- 3919 ~~\*E. Mobile retail food establishments and pushcarts shall provide enough clean utensils to satisfy~~  
3920 ~~the requirements of section 4-407(C).~~
- 3921 ~~F. Items for customer self-service shall be adequately protected from contamination.~~
- 3922

3923 **CHAPTER 10**

3924 **TEMPORARY RETAIL FOOD ESTABLISHMENTS**

3925 **10-1 TEMPORARY RETAIL FOOD ESTABLISHMENTS**

3926 **10-101 General**

3927 A temporary retail food establishment shall comply with all requirements of these rules and  
3928 regulations, except as otherwise provided in this chapter.

3929 A temporary event vendor application, which shall include a list of food items to be sold, shall be  
3930 submitted to the Department for each event. The vendor application shall be submitted at least ten  
3931 (10) working days prior to the event. Approval will be based upon menu, equipment, setup and the  
3932 ability to protect against public health hazards.

3933 Mobile retail food establishments and pushcarts operating at temporary events shall operate  
3934 according to chapter 9 of these rules and regulations.

3935 **10-102 Operations**

3936 \*A. Food preparation at the event shall be limited to seasoning, cooking, assembly of pre-  
3937 prepared foods and service of packaged foods stored at required temperatures.

3938 \*B. All slicing, chopping, peeling, dicing, shredding and washing of produce shall be done at an  
3939 approved commissary.

3940 C. Food and food contact surfaces of equipment shall be protected from contamination by  
3941 consumers or other sources. Appropriate coverings, packaging, shields, barriers, or other  
3942 means shall be provided as necessary to prevent contamination.

3943 \*D. Equipment shall be maintained and operated per its intended use and design.

3944 E. Equipment shall be located and installed to facilitate cleaning. No grease from grease  
3945 producing equipment shall discharge onto the ground or into any storm drainage system.

3946 **10-103 Commissary**

3947 A. Temporary Retail Food Establishment vendors shall operate from a commissary approved by  
3948 the Department and shall provide a commissary agreement to the Department for each event.  
3949 Vendors with limited menus operating from licensed self-contained mobile units in  
3950 accordance with section 9-107(D) may be allowed to operate without a commissary.

3951 B. The commissary for vendors operating at an event of more than one (1) day in duration shall  
3952 be within 30 minutes or 30 miles of the event.

3953 C. All foods, utensils, and single use articles shall be transported from the commissary to the  
3954 event site in a manner that protects them from contamination. Food product temperature  
3955 shall be maintained as required in section 3-501.

3957  
 3958 ~~D. — The commissary shall be constructed and operated in compliance with the requirements of~~  
 3959 ~~these rules and regulations. Temporary retail food establishments shall operate from a~~  
 3960 ~~commissary or other fixed retail food establishment and shall report at a minimum of every~~  
 3961 ~~24 hours (on operational days) to that location for all supplies, all cleaning, advanced food~~  
 3962 ~~preparation, and servicing operations. The commissary operator, as requested by the~~  
 3963 ~~Department, shall verify to the Department when the temporary retail food establishment~~  
 3964 ~~reports to the commissary.~~

3965 1. ~~— The agreement shall specify the temporary retail food establishment is allowed to~~  
 3966 ~~report to the commissary daily, is allowed to use the facility's warewashing~~  
 3967 ~~equipment, refrigeration, food preparation equipment and storage areas as a base for~~  
 3968 ~~operation. The commissary operator shall maintain written documentation or a log~~  
 3969 ~~as to when the temporary retail food establishment utilizes the commissary. These~~  
 3970 ~~records shall be made available to the Department when requested.~~

3971 2. ~~— Temporary retail food establishment operators shall maintain written records of~~  
 3972 ~~purchases detailing the source of all foods being held, stored, offered for sale, sold~~  
 3973 ~~and distributed and expenses including receipts for expenditures such as servicing~~  
 3974 ~~operations. These records shall be made available to the Department when~~  
 3975 ~~requested.~~

#### 3976 ~~10-104 Minimum Event Site Equipment Requirements~~

3977 \*A. ~~— Equipment for heating and holding food cold and hot, shall be sufficient in number and~~  
 3978 ~~capacity to maintain foods at required temperatures. Equipment utilizing fuel gel canister is~~  
 3979 ~~prohibited at outdoor venues unless approved by the Department.~~

3980 \*B. ~~— A conveniently located hand washing station shall be provided within the Temporary Retail~~  
 3981 ~~Food Establishment.~~

3982 \*C. ~~— Extra utensils and in use food contact surfaces (cutting boards, tongs, knives, etc.) shall be~~  
 3983 ~~provided to allow soiled items to be replaced at a minimum of every four (4) hours.~~  
 3984 ~~Warewashing of equipment and utensils shall be conducted at an approved facility. Onsite~~  
 3985 ~~warewashing is prohibited unless otherwise approved by the Department.~~

3986 D. ~~— A sufficient number of smooth, non absorbent, and easily cleanable work surfaces shall be~~  
 3987 ~~provided where food is being handled.~~

3988 E. ~~— Coolers and containers used to store food shall be durable, smooth, non absorbent and easily~~  
 3989 ~~cleanable. Styrofoam and soft sided coolers are prohibited.~~

3990 F. ~~— A clean trash receptacle shall be provided.~~

#### 3991 ~~\*10-105 Ice~~

3992 ~~Only ice which has been manufactured from drinking water and handled in a sanitary manner shall be~~  
 3993 ~~used or offered for sale. Ice used as a cooling medium for food storage, beverage containers, food~~  
 3994 ~~containers or food utensils shall not be used or sold for human consumption.~~

#### 3995 ~~10-106 Single Service Articles~~

3996 ~~All temporary retail food establishments shall provide only single service articles for use by the~~  
 3997 ~~consumer.~~

3998 ~~\*10-107 Water~~

3999 A sufficient quantity of drinking water shall be available for food preparation, wiping cloth solutions,  
4000 and sanitization of food contact surfaces. The water supply system hoses, piping, and fixtures shall be  
4001 fabricated of approved food contact materials. The water supply system must be installed to preclude  
4002 the backflow of contaminants into the drinking water supply.

4003 ~~10-108 Wet Storage~~

4004 Packaged food may be stored in direct contact with drinking ice or drinking water if the packaging,  
4005 wrapping, or container is not subject to entry of water. The storage of food and/or beverage, in  
4006 undrained ice is prohibited.

4007 ~~\*10-109 Waste~~

4008 All sewage, including liquid waste, shall be disposed of according to law. Waste water shall not be  
4009 discharged onto ground or into storm drainage system. Drainage from clean drinking ice may be  
4010 discharged onto the surface of the ground provided it does not create a nuisance.

4011 ~~\*10-110 Handwashing~~

4012 A. ~~— A minimum of five (5) gallons of drinking water shall be provided for hand washing. The~~  
4013 ~~required volume of water will be based upon menu, equipment, and hours of operation. Push~~  
4014 ~~button spigots on the water supply containers are not permitted.~~

4015 B. ~~— Soap and dispensed paper towels shall be provided at each hand washing station.~~

4016 C. ~~— A hand washing station that is capable of providing hands free continuous flowing warm~~  
4017 ~~water of adequate pressure shall be provided.~~

4018 D. ~~— A basin that is capable of capturing hand washing waste water and conveying it into a closed~~  
4019 ~~waste water container shall be provided.~~

4020 ~~\*10-111 Screening and Enclosures~~

4021 Screening or other provisions may be required to prevent the entrance of pests and debris.

4022 ~~\*10-112 Grounds~~

4023 Areas within the Temporary Retail Food Establishment shall be free from standing water, mud, dust  
4024 and fecal material. Additional ground covering material may be required such as removable  
4025 platforms, duckboards, wood chips or other suitable material.

4026 ~~\*10-113 Overhead Protection~~

4027 Overhead protection shall be provided and be made of wood, canvas, or other materials that protect  
4028 the interior of the establishment from weather, or other contamination. Any grease producing  
4029 equipment or equipment with open flames shall not be located under overhead protection.

4030

## CHAPTER 11

### COMPLIANCE PROCEDURES

#### 11-1 — COMPLIANCE

##### 11-101 — General

A person shall have a valid retail food establishment license, certificate of license, as defined in section 25-4-1602, C.R.S. and administration and inspection fees pursuant to sections 25-4-1607, C.R.S., to operate a retail food establishment. A person operating a retail food establishment without a valid license, certificate of license or appropriate administration and inspection fees may be prosecuted under sections 16-13-305, 25-4-1609, and 25-14-1610 C.R.S. Only a person who complies with the requirements of these rules and regulations shall be entitled to receive or retain such a license or certificate. Licenses, certificates, or administration and inspection fees are not transferable. When issued, a valid license or certificate shall be posted in every retail food establishment.

##### 11-102 — Issuance of License or Certificate of License

A. — Any person desiring to operate a retail food establishment shall make written application for a license or certificate of license or pay administration and inspections fees using forms provided by the Department. Each application form shall include the name and address of each applicant, the location and type of the proposed retail food establishment, and the signature of each applicant.

B. — Prior to approval of an application for a license or certificate of license, the Department may inspect the proposed retail food establishment to determine compliance with the rules and regulations.

C. — The Department shall approve a license or certificate of license for the applicant if its inspection reveals that the proposed retail food establishment complies with the requirements of these rules and regulations.

D. — An existing Retail Food Establishment shall be required to obtain a new Retail Food Establishment license when there is a change of ownership that requires a new Colorado Department of Revenue Sales Tax Account Number, or if the physical location of the establishment changes.

##### 11-103 — License Renewal

The Department may refuse to renew a retail food establishment license or certificate of license for any violation of sections 25-4-1601 et seq., C.R.S., of these rules and regulations, or as otherwise provided by law. This notification shall be presented to license or certificate holders during the last quarter of each calendar year. Denial of a license renewal shall be treated in all respects as a revocation and, hence, procedures for revocation shall be followed. In a case in which the license or certificate holder has made timely and sufficient application for renewal of license, the existing license shall not expire until such application has been finally acted upon by the Department.

4068 **11-104—Judicial Review**

4069 A license or certificate holder adversely affected or aggrieved by a Departmental action may appeal  
4070 the final action of the Department as provided in section 24-4-106, C.R.S. Suspension or revocation  
4071 of a license may be reviewed, upon application for an order in the nature of mandamus or otherwise,  
4072 by any court of general jurisdiction as provided in section 25-4-1609, C.R.S.

4073 **11-105—Closure Without Suspension**

4074 Acting under sections 25-1.5-101(1)(a) and 25-1.5-102(1)(a) & (d), C.R.S., the Department, or its  
4075 authorized representative, shall have the power and duty to close retail food establishments and forbid  
4076 the gathering of people therein to protect the public health from the cause of epidemic and  
4077 communicable diseases. Immediate closure shall be used only when the situation imperatively  
4078 requires emergency action or the operator has been guilty of deliberate and willful violation that is  
4079 injurious or creates an imminent public health hazard as defined in Section 1-201(A)(57).

4080 **11-106—Injunctive Relief**

4081 When serious or repeated violations of these rules and regulations have been found, the Department  
4082 or its authorized agents may abate the nuisance by seeking injunctive relief through judicial means, as  
4083 provided under section 16-13-308 and 309, C.R.S.

4084 **11-2—INSPECTIONS**

4085 **11-201—Inspection Frequency**

4086 A. An inspection of a retail food establishment shall be performed at least twice every calendar or  
4087 fiscal year; or

4088 B. The *Colorado Retail Food Establishment Risk Based Inspectional Frequency Methodology*  
4089 *Guidance Document* may be used as a model for an alternative method for determining  
4090 inspectional frequency. If this model is modified by an agency, the agency must be able to  
4091 defend the modifications utilizing the public health risk factors contained in the model. The  
4092 public health risk factors include: 1) food served, 2) operations, 3) weekly meal volume, and  
4093 4) inspectional history including critical and non-critical violations. The minimum inspection  
4094 frequency for an establishment falling in the low risk category is once every two years.

4095 C. Additional inspections may be performed based upon additional assessments of potential risks of  
4096 foodborne illness including a history of non-compliance with these rules and regulations; the  
4097 hazards associated with the particular foods being prepared, stored or served; the method and  
4098 extent of food storage, preparation and service; and the number and demographic  
4099 characteristics of the consumers.

4100 **11-202—Access**

4101 Agents of the Department, after proper identification, shall be permitted to enter any retail food  
4102 establishment during business hours and at other times during which activity is evident in accordance  
4103 with 25-4-1604(1)(e) to determine compliance with these rules and regulations. The agents shall be  
4104 permitted to examine documents or true copies of documents, excluding prices, that pertain directly  
4105 to food and supplies purchased, received or used, information pertinent to their HACCP plan, or to  
4106 persons employed in food and beverage operations when such examination is expected to produce

4107 information necessary to protect the public health, enforce these rules and regulations or investigate  
4108 suspected incidents of foodborne illnesses.

4109 **11-203—Report of Inspections**

4110 Whenever an inspection of a retail food establishment or commissary is made, the findings shall be  
4111 recorded on an inspection report form. The inspection report form shall summarize the requirements  
4112 of these rules and regulations. The Department shall document, on the inspection report form,  
4113 specific factual observations of violative conditions or other deviations from these rules and  
4114 regulations. Once the inspection has been completed and the inspection report form is finalized, a  
4115 copy of the completed inspection report form shall be furnished to the person in charge of the  
4116 establishment. The completed inspection report form is a public document that shall be made  
4117 available for public disclosure to any person who requests it according to law.

4118 **11-204—Correction of Violations**

4119 A. The inspection report form shall specify a reasonable period of time for the correction of the  
4120 violations found and correction of the violations shall be accomplished within the period  
4121 specified, in accordance with the following provisions:

4122 1. If an imminent health hazard exists, such as, but not limited to, absence of adequate  
4123 of refrigeration, no water supply, non functional water heating system, severe and  
4124 active pest infestation, or sewage backup into the establishment, the establishment  
4125 shall immediately cease food operations. Operations shall not be resumed until  
4126 authorized by the Department.

4127 2. All critical violations are to be corrected as soon as possible, but in any event, by the  
4128 date and time specified by the Department, but in no case to exceed ten (10) days.

4129 3. All non critical violations shall be corrected by the date and time agreed to or  
4130 specified by the Department based upon the severity of potential health hazards,  
4131 which could result from the non critical violation. The Department is not required  
4132 to conduct follow up activities on non critical violations.

4133 B. The inspection report shall state that failure to comply with any time limits may result in the  
4134 initiation of administrative or legal regulatory action. An opportunity for appeal of the  
4135 inspection findings and time limitation will be provided if a written request for an  
4136 administrative hearing is filed with the Department within thirty (30) days following the date  
4137 of receipt of inspection. If the request for a hearing is received, a hearing shall be held no  
4138 sooner than twenty (20) days after the operator is notified of the hearing.

4139 C. Whenever a retail food establishment is required under the provisions of these rules and  
4140 regulations to cease operations, it shall not resume operations until a re-inspection  
4141 determines that conditions responsible for the requirement to cease operations no longer  
4142 exists. Opportunity for re-inspection shall be offered within a reasonable time.

4143



4144 **11-205 Inspection Report**

4145 The format of an inspection form shall be based upon critical and non-critical categories. The  
 4146 following items must be included:

| <b>Item</b>  | <b>Category</b>     |
|--|---------------------|
| <del>FOOD SOURCE DATE MARKING AND CONSUMER ADVISORY</del><br><del>— a. Approved source</del><br><del>— b. Wholesome, free of spoilage</del><br><del>— c. Cross Contamination</del><br><del>— d. Specialized Processes/HACCP plan</del><br><del>— e. Date marking</del><br><del>— f. Consumer Advisory</del>  | <del>CRITICAL</del> |
| <del>PERSONNEL</del><br><del>Employee Health</del><br><del>— a. Personnel with infections restricted</del><br><del>— b. Wounds properly covered</del><br><del>Hygienic Practices</del><br><del>— c. Hands washed as needed</del><br><del>— d. Hygienic practices</del><br><del>— e. Smoking, eating, drinking</del><br><del>Demonstration of knowledge</del><br><del>— f. Training needed</del><br><del>— g. Preventing food contamination from bare hands</del>   | <del>CRITICAL</del> |
| <del>FOOD TEMPERATURE CONTROL</del><br><del>Temperature Control Procedures</del><br><del>— a. Rapidly cool foods to 41° F or less</del><br><del>— b. Rapidly reheat to 165° F or greater</del><br><del>— c. Hot hold at 135° F or greater</del><br><del>— d. Required cook temperature</del><br><del>— e. Cold hold at 41° F or less</del><br><del>Temperature Control Equipment</del><br><del>— f. Use of Food thermometer (probe type)</del><br><del>— g. Adequate equipment to maintain food temperatures</del> | <del>CRITICAL</del> |
| <del>SANITIZATION RINSE</del><br><del>— a. Clean</del><br><del>— b. Temperature</del><br><del>— c. Concentration</del><br><del>— d. Exposure</del>   | <del>CRITICAL</del> |

| <b>Item</b>   | <b>Category</b>         |
|---|-------------------------|
| <del>WATER, SEWAGE, PLUMBING SYSTEMS</del>  | <del>CRITICAL</del>     |
| <ul style="list-style-type: none"> <li><del>— a. Safe water source</del></li> <li><del>— b. Hot and cold water under pressure</del></li> <li><del>— c. Backflow, backsiphonage</del></li> <li><del>— d. Sewage disposal</del></li> </ul>  |                         |
| <del>HANDWASHING FACILITIES</del>   | <del>CRITICAL</del>     |
| <ul style="list-style-type: none"> <li><del>— a. Adequate number, location</del></li> <li><del>— b. Accessible</del></li> <li><del>— c. Soap and drying devices available</del></li> </ul>  |                         |
| <del>PEST CONTROL</del>   | <del>CRITICAL</del>     |
| <ul style="list-style-type: none"> <li><del>— a. Evidence of insects or rodents</del></li> <li><del>— b. Pesticide application</del></li> <li><del>— c. Animals prohibited</del></li> </ul>   |                         |
| <del>POISONOUS OR TOXIC ITEMS</del>   | <del>CRITICAL</del>     |
| <ul style="list-style-type: none"> <li><del>— a. Properly stored</del></li> <li><del>— b. Properly labeled</del></li> <li><del>— c. Properly used</del></li> </ul>  |                         |
| <del>FOOD LABELING , FOOD PROTECTION</del>  | <del>NON CRITICAL</del> |
| <ul style="list-style-type: none"> <li><del>— a. Original container, properly labeled</del></li> <li><del>— b. Food protected from contamination</del></li> </ul>   |                         |
| <del>EQUIPMENT DESIGN CONSTRUCTION</del>  | <del>NON CRITICAL</del> |
| <ul style="list-style-type: none"> <li><del>— a. Food contact surfaces</del></li> <li><del>— b. Nonfood contact surfaces</del></li> <li><del>— c. Dishwashing facilities</del></li> </ul>   |                         |
| <del>TESTING DEVICES</del>  | <del>NON CRITICAL</del> |
| <ul style="list-style-type: none"> <li><del>— a. Refrigeration units provided with accurate, conspicuous thermometers</del></li> <li><del>— b. Dishmachines provided with accurate thermometer and gauge cock</del></li> <li><del>— c. Chemical test kits provided, accessible</del></li> </ul> |                         |
| <del>CLEANING OF EQUIPMENT AND UTENSILS</del>   | <del>NON CRITICAL</del> |
| <ul style="list-style-type: none"> <li><del>— a. Food contact surfaces</del></li> <li><del>— b. Nonfood contact surfaces</del></li> <li><del>— c. Dishwashing operations</del></li> <li><del>— d. Wiping cloths</del></li> </ul>  |                         |

| <b>Item</b>   | <b>Category</b>         |
|---|-------------------------|
| <del>UTENSILS, SINGLE SERVICE ARTICLES</del>                          | <del>NON CRITICAL</del> |
| <del>— a. Utensils provided, used, stored</del>                       |                         |
| <del>— b. Single service articles stored, dispensed, used</del>       |                         |
| <del>— c. No reuse of single service articles</del>                   |                         |
| <del>PHYSICAL FACILITIES</del>  | <del>NON CRITICAL</del> |
| <del>— a. Plumbing: installed, maintained</del>                       |                         |
| <del>— b. Garbage and refuse</del>                                    |                         |
| <del>— c. Floors, walls, ceiling</del>                                |                         |
| <del>— d. Lighting</del>  |                         |
| <del>— e. Ventilation</del>   |                         |
| <del>— f. Locker rooms</del>  |                         |
| <del>— g. Premises maintained</del>                                   |                         |
| <del>— h. Separation of living, laundry</del>                         |                         |
| <del>— i. Restroom facilities</del>                                   |                         |
| <del>OTHER OPERATIONS</del>   | <del>NON CRITICAL</del> |
| <del>— a. Personnel: clean clothes, hair restraints, authorized</del> |                         |
| <del>— b. Linen properly stored</del>                                 |                         |

4147 ~~11-3 CONDEMNATION AND EMBARGO OF FOOD~~

4148 ~~11-301 General~~

4149 ~~The power and duty to condemn and embargo food that the Department finds probable cause to~~  
 4150 ~~believe is in violation of section 3-101 of these rules and regulations has been given to the~~  
 4151 ~~Department under the statutory authority of sections 25-1.5-104(a) and 25-5-406 et. seq., C.R.S.~~

4152 ~~11-302 Voluntary Condemnation~~

4153 ~~When the Department finds food that it has probable cause to believe is in violation of section 3-101~~  
 4154 ~~of these rules and regulations, the Department shall bring the fact to the attention of the person in~~  
 4155 ~~charge and request that the food be voluntarily destroyed. If the person in charge agrees to destroy~~  
 4156 ~~the suspect food, a voluntary condemnation agreement shall be completed and signed. The person in~~  
 4157 ~~charge shall denature the food under the supervision of the Department. A copy of the voluntary~~  
 4158 ~~condemnation agreement shall be left with the person in charge.~~

4159 ~~11-303 Embargo Placement~~

4160 ~~When the Department finds food that it has probable cause to believe is in violation of section 3-101~~  
 4161 ~~of these rules and regulations, the Department shall bring the fact to the attention of the person in~~  
 4162 ~~charge and request that the food be voluntarily destroyed. Should the person in charge refuse to~~  
 4163 ~~voluntarily destroy the food, the Department shall embargo the remainder of the food. An embargo~~  
 4164 ~~notice shall be completed and signed. A copy of the embargo notice shall be left with the person in~~  
 4165 ~~charge. The remainder of the food product shall be set aside for storage in a container sealed with~~

4166 ~~sampling tape to prevent usage. No person shall remove or dispose of such embargoed article by sale~~  
 4167 ~~or otherwise.~~

4168 ~~**11-304—Embargo Release**~~

4169 ~~A. The Department shall complete and sign an embargo release which dictates the subsequent~~  
 4170 ~~disposition of the product by:~~

4171 ~~1. Use of the product in the establishment where it was found if demonstrated to be in~~  
 4172 ~~compliance with section 3-101 of these rules and regulations; or~~

4173 ~~2. Use of the product by other approved means; or~~

4174 ~~3. Destruction of the product.~~

4175 ~~B. A copy of this release shall be given to the person in charge.~~

4176 ~~C. Neither the Department nor the State shall be held liable for damages because of such~~  
 4177 ~~embargo.~~

4178 ~~**11-305—Condemnation of Product**~~

4179 ~~Should the food be found to be not sound or contaminated with filth and a voluntary destruction~~  
 4180 ~~cannot be obtained, the Department shall petition the court of jurisdiction for seizure and disposition~~  
 4181 ~~of the food.~~

4182 ~~**11-4—REVIEW OF PLANS**~~

4183 ~~**11-401—Submission of Plans**~~

4184 ~~It shall be necessary to submit to the Department detailed plans and specifications of a proposed~~  
 4185 ~~newly constructed retail food establishment and or the affected areas of any proposed extensively~~  
 4186 ~~remodeled retail food establishment. Each retail food operator, or person intending to become a retail~~  
 4187 ~~food operator, shall be responsible for submitting all plans and specifications. Those assisting an~~  
 4188 ~~operator may submit plans and specifications on the operator's authority. The Department shall be~~  
 4189 ~~consulted before preparation of plans and specifications. Approval of both plans and specifications is~~  
 4190 ~~necessary before construction begins. A minimum of two (2) weeks shall be necessary for the~~  
 4191 ~~Department to review the plans. Any revision of plans shall be submitted to the Department for~~  
 4192 ~~review and modification or approval.~~

4193 ~~**11-402—Contents of Plans and Specifications**~~

4194 ~~Contents of the plans and specifications shall show evidence that the facility complies with applicable~~  
 4195 ~~portions of these rules and regulations. A plan view scale drawing of the establishment shall be~~  
 4196 ~~provided. The plans shall include the location of all retail food equipment, plumbing fixtures and~~  
 4197 ~~connections, ventilation systems, menu and other pertinent information. A dimensional sketch of the~~  
 4198 ~~entrance, exits, streets, roadways and alleys shall also be included. Specifications shall be provided~~  
 4199 ~~on a form supplied by the Department.~~

4200 ~~**11-403—Contents of a HACCP Plan**~~

4201 ~~A. For a food establishment that is required in section 3-506 to have a HACCP plan, the plan~~  
 4202 ~~and specifications shall indicate:~~

- 4203 1. ~~A categorization of the types of potentially hazardous foods (time/temperature~~  
 4204 ~~control for safety foods) that are specified in the menu such as soups and sauces,~~  
 4205 ~~salads, and bulk, solid food such as meat roasts, or of other foods that are specified~~  
 4206 ~~by the Department;~~
- 4207 2. ~~A flow diagram by specific food or category type identifying critical control points~~  
 4208 ~~and providing information on the following:~~
- 4209 a. ~~Ingredients, materials, and equipment used in the preparation of that food;~~  
 4210 ~~and~~
- 4211 b. ~~Formulations or recipes that delineate methods and procedural control~~  
 4212 ~~measures that address the food safety concerns involved;~~
- 4213 3. ~~Food employee and supervisory training plan that addresses the food safety issues of~~  
 4214 ~~concern.~~
- 4215 4. ~~A statement of standard operating procedures for the plan under consideration~~  
 4216 ~~including clearly identifying:~~
- 4217 a. ~~Each critical control point;~~
- 4218 b. ~~The critical limits for each critical control point;~~
- 4219 c. ~~The method and frequency for monitoring and controlling each critical~~  
 4220 ~~control point by the food employee designated by the person in charge;~~
- 4221 d. ~~The method and frequency for the person in charge to routinely verify that~~  
 4222 ~~the food employee is following standard operating procedures and~~  
 4223 ~~monitoring critical control point;~~
- 4224 e. ~~Action to be taken by the person in charge if the critical limits for each~~  
 4225 ~~critical control point are not met; and~~
- 4226 f. ~~Records to be maintained by the person in charge to demonstrate that the~~  
 4227 ~~HACCP plan is properly operated and managed; and~~
- 4228 5. ~~Additional scientific data or other information, as required by the Department,~~  
 4229 ~~supporting the determination that food safety is not compromised by the proposal.~~

#### 4230 ~~11-404—Pre-Operational Inspection~~

4231 ~~Whenever plans and specifications are required by section 11-401 of these rules and regulations to be~~  
 4232 ~~submitted to the Department, the Department shall inspect the retail food establishment prior to its~~  
 4233 ~~beginning operation to determine compliance with the approved plans and specifications and with the~~  
 4234 ~~requirements of these rules and regulations. It shall be necessary to arrange for a pre-opening~~  
 4235 ~~inspection fourteen (14) days in advance of the date of the intended inspection. For areas of the state~~  
 4236 ~~without a Local Health Department, it shall be necessary to arrange for a pre-opening inspection~~  
 4237 ~~twenty-one (21) days in advance of the date of the intended inspection.~~

#### 4238 ~~11-5—PROCEDURE WHEN INFECTION IS SUSPECTED~~

##### 4239 ~~11-501—General~~

4240 ~~When the Department has reasonable cause to suspect the possibility of disease transmission from~~  
 4241 ~~any retail food establishment employee, it may secure a morbidity history of the suspected employee~~

- 4242 ~~or make any other investigation as necessary and shall take appropriate action. The Department may~~  
 4243 ~~require any or all of the following measures:~~
- 4244 A. ~~The immediate exclusion of the employee from all retail food establishments in accordance~~  
 4245 ~~with 2-202;~~
- 4246 B. ~~The immediate closing of the retail food establishment concerned until, in the opinion of the~~  
 4247 ~~Department, no further danger of disease outbreak exists;~~
- 4248 C. ~~Restriction of the employee's services to some area of the establishment where there would~~  
 4249 ~~be no danger of disease transmission in accordance with 2-203;~~
- 4250 D. ~~Adequate medical and laboratory examination of the employee and other employees in~~  
 4251 ~~accordance with 2-203.~~

## 4252 ~~11-6~~ **VARIANCE PROCEDURE**

### 4253 ~~11-601~~ **Variance Procedure**

- 4254 A. ~~Any retail food establishment may request a variance from any requirement of these rules~~  
 4255 ~~and regulations when such an establishment believes that the requirement results in an undue~~  
 4256 ~~economic hardship or when it is believed a standard may not apply to the specific situation.~~
- 4257 B. ~~Requests shall be submitted in writing to the Colorado Department of Public Health and~~  
 4258 ~~Environment and shall include the name and location of the business, the name of the~~  
 4259 ~~licensee or prospective licensee when applicable, and the section for which a variance is~~  
 4260 ~~being requested. This request must be accompanied with a recommendation for approval or~~  
 4261 ~~denial from the health agency of jurisdiction. Evidence of undue economic hardship should~~  
 4262 ~~include estimates and costs for compliance. If it is believed that a standard may not apply to~~  
 4263 ~~the specific situation, an explanation shall be included.~~
- 4264 C. ~~Any person who requests a variance for the provisions of these regulations shall have the~~  
 4265 ~~burden of supplying the Department with information that demonstrates the conditions exist~~  
 4266 ~~which warrant the granting of a variance. All doubts shall be resolved in favor of denial.~~
- 4267 D. ~~The Colorado Department of Public Health and Environment may grant a variance if:~~
- 4268 1. ~~Such variance is consistent with the purpose and intent of the act and these~~  
 4269 ~~regulations; and~~
- 4270 2. ~~It is consistent with the protection of the public health; and~~
- 4271 3. ~~The circumstances of the retail food establishment are unique; and~~
- 4272 4. ~~The cost of compliance is so great that it would threaten economic viability of the~~  
 4273 ~~retail food establishment or the retail food establishment would be in grave jeopardy~~  
 4274 ~~if compliance were enforced; and~~
- 4275 5. ~~The damage to the retail food establishment's economic viability is in fact caused by~~  
 4276 ~~compliance.~~
- 4277 E. ~~A variance shall expire upon a change of circumstances from those supporting the variance~~  
 4278 ~~or upon a change of ownership of the retail food establishment. The approved variance and~~  
 4279 ~~all associated documentation shall be located at the establishment and made available to the~~  
 4280 ~~Department when requested.~~

4281 F. ~~After review and in circumstances where the Department intends to deny a variance, the~~  
 4282 ~~Department shall refer the request to an advisory panel of three persons, two persons who~~  
 4283 ~~represent the retail food industry and a representative from a local health department, to~~  
 4284 ~~make recommendations to the Department.~~

4285 G. ~~Any retail food establishment for which a variance has been denied may appeal such denial~~  
 4286 ~~by requesting a hearing which will be held in accordance with section 24-4-105 (15), C.R.S.~~

## 4287 ~~11-7—REFERENCE CITATIONS~~

### 4288 ~~11-701—General~~

4289 ~~These regulations incorporated by reference (as indicated within) materials originally published~~  
 4290 ~~elsewhere. Such incorporation does not include later amendments to or editions of the referenced~~  
 4291 ~~material. The Department maintains certified copies of the complete text of any material incorporated~~  
 4292 ~~by reference for public inspection during regular business hours and shall provide certified copies of~~  
 4293 ~~the incorporated material at cost upon request. Information regarding how to obtain or examine the~~  
 4294 ~~incorporated material is available from the Division Director, Division of Environmental Health and~~  
 4295 ~~Sustainability, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive~~  
 4296 ~~South, Denver, CO 80246-1530.~~

4297 ~~Copies of the incorporated materials have been provided to the State Publications Depository and~~  
 4298 ~~Distribution Center, and are available for interlibrary loan. Any incorporated material may be~~  
 4299 ~~examined at any State Publications Depository Library.~~

### 4300 ~~11-702—Safe Materials~~

4301 ~~The Colorado Pure Food and Drug Law, the Federal Food, Drug and Cosmetic Act and applicable~~  
 4302 ~~regulations of the U.S. Food and Drug Administration used for the determination of material safety in~~  
 4303 ~~section 1-202(56) of these rules and regulations may be obtained from the Division Director, Division~~  
 4304 ~~of Environmental Health and Sustainability, Colorado Department of Public Health and Environment,~~  
 4305 ~~4300 Cherry Creek Drive South, Denver, CO 80246-1530 and/or the U.S. Federal Food and Drug~~  
 4306 ~~Administration.~~

### 4307 ~~11-703—Food Protection Act~~

4308 ~~Copies of section 25-4-1601 et seq., C.R.S. may be obtained from the Director of the Division of~~  
 4309 ~~Environmental Health and Sustainability of the Colorado Department of Public Health and~~  
 4310 ~~Environment.~~

### 4311 ~~11-704—Milk Standards~~

4312 ~~Copies of the Grade A Standards referenced in section 3-305 of these regulations may be obtained~~  
 4313 ~~from the Director of the Division of Environmental Health and Sustainability of the Colorado~~  
 4314 ~~Department of Public Health and Environment.~~

### 4315 ~~11-705—Ventilation Requirements~~

4316 ~~Copies of the 2006 International Mechanical Code or Local Ventilation Codes referenced in section~~  
 4317 ~~4-212 of these rules and regulations may be obtained from the International Conference of Building~~

4318 ~~Officials, 503 Alhambra Avenue, Los Angeles, California 90032-3490 or the Local Building~~  
4319 ~~Department of jurisdiction, respectively.~~  
4320



- 4321
- 4322 **11-706—Code of Federal Regulations**
- 4323 Copies of the ~~(2005) Code of Federal Regulations~~ referenced in sections 3-101, 3-312, 3-408, 3-607,  
4324 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  
4325 Director, Office of the Federal Register, National Archives and Records Administration, Washington  
4326 DC 20408.
- 4327 **11-707—Plumbing Requirements**
- 4328 Copies of the 2009 International Plumbing Code or Local Plumbing Codes referenced in sections 5-  
4329 201, 5-208, and 5-209 may be obtained from the International Association of Plumbing and  
4330 Mechanical Officials, 20001 Walnut Drive South, Walnut, California, 91789-2825 and/or the Local  
4331 Building Department of jurisdiction, respectively.
- 4332 **11-708—Administrative Statutes**
- 4333 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.;  
4334 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.;  
4335 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,  
4336 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,  
4337 and 11-601 of these rules and regulations may be obtained from the Director of the Division of  
4338 Environmental Health and Sustainability of the Colorado Department of Public Health and  
4339 Environment.
- 4340 **11-709—American National Standards Institute (ANSI)**
- 4341 Copies of the National Sanitation Foundation Standards for food equipment that are classified for  
4342 sanitation by an American National Standards Institute (ANSI) accredited certification program  
4343 referenced in section 4-101 of these rules and regulations may be obtained from the Director of  
4344 the Division of Environmental Health and Sustainability of the Colorado Department of Public  
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## APPENDIX A—Potentially Hazardous Foods

4719 Potentially hazardous food (PHF/TCS food) is defined in terms of whether or not it requires time/temperature  
4720 control for safety to limit pathogen growth or toxin formation. The term does not include foods that do not  
4721 support growth but may contain a pathogenic microorganism or chemical or physical food safety hazard at a  
4722 level sufficient to cause foodborne illness or injury. The progressive growth of all foodborne pathogens is  
4723 considered whether slow or rapid.

4724 The definition of PHF/TCS food takes into consideration pH,  $a_w$ , pH and  $a_w$  interaction, heat treatment, and  
4725 packaging for a relatively simple determination of whether the food requires time/temperature control for  
4726 safety. If the food is heat treated to eliminate vegetative cells, it needs to be addressed differently than a raw  
4727 product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat treatment to  
4728 destroy vegetative cells and subsequently packaged to prevent re-contamination, higher ranges of pH and/or  
4729  $a_w$  can be tolerated because remaining spore forming bacteria are the only microbial hazards of concern.  
4730 While foods will need to be cooled slightly to prevent condensation inside the package, they must be  
4731 protected from contamination in an area with limited access and packaged before temperatures drop below  
4732 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  
4733 to control or eliminate pathogen growth; however, the interaction of pH and  $a_w$  may be able to accomplish it.  
4734 This is an example of a hurdle technology. Hurdle technology involves several inhibitory factors being used  
4735 together to control or eliminate pathogen growth, when they would otherwise be ineffective if used alone.  
4736 When no other inhibitory factors are present and the pH and/or  $a_w$  values are unable to control or eliminate  
4737 bacterial pathogens which may be present, growth may occur and foodborne outbreaks result. Cut melons, cut  
4738 tomatoes, and cut leafy greens are examples where intrinsic factors are unable to control bacterial growth  
4739 once pathogens are exposed to the cellular fluids and nutrients after cutting.

4740 In determining if time/temperature control is required, combination products present their own challenge. A  
4741 combination product is one in which there are two or more distinct food components and an interface between  
4742 the two components may have a different property than either of the individual components. A determination  
4743 must be made about whether the food has distinct components such as pie with meringue topping, focaccia  
4744 bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform consistency such as gravies,  
4745 puddings, or sauces. In these products, the pH at the interface is important in determining if the item is a  
4746 PHF/TCS food.

4747 A well designed inoculation study or other published scientific research should be used to determine whether  
4748 a food can be held without time/temperature control when:

- 4749 ● process technologies other than heat are applied to destroy foodborne pathogens (e.g.,  
4750 irradiation, high pressure processing, pulsed light, ozonation);
- 4751 ● combination products are prepared; or
- 4752 ● other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential,  
4753 salt content, and antimicrobials) are used to control or eliminate pathogen growth.

4754 Before using Tables A and B listed in the definition section under item 79 for "potentially hazardous food  
4755 (time/temperature control for safety food)" in determining whether a food requires time/temperature control  
4756 for safety (TCS), answers to the following questions should be considered:

- 4757 ● Is the intent to hold the food without using time or temperature control?
  - 4758 ○ If the answer is No, no further action is required. The decision tree later in this  
4759 Appendix is not needed to determine if the item is a PHF/TCS food.
- 4760 ● Is the food raw, or is the food heat treated?
- 4761 ● Does the food already require time/temperature control for safety utilizing the definition of  
4762 "potentially hazardous food (time/temperature control for safety food)"?

- 4763 ● ~~Does a product history with sound scientific rationale exist indicating a safe history of use?~~
- 4764 ● ~~Is the food processed and packaged so that it no longer requires TCS such as ultra-high temperature~~
- 4765 ~~(UHT) creamers or shelf-stable canned goods?~~
- 4766 ● ~~What is the pH and  $a_w$  of the food in question using an independent laboratory and Association of~~
- 4767 ~~Official Analytical Chemists (AOAC) methods of analysis?~~

4768 A food designated as product assessment required (PA), in either table should be considered PHF/TCS Food  
 4769 until further study proves otherwise. The PA means that based on the food's pH and  $a_w$  and whether it was raw  
 4770 or heat-treated or packaged, it has to be considered PHF until inoculation studies or some other acceptable  
 4771 evidence shows that the food is a PHF/TCS food or not. The Rules and Regulations require a variance request  
 4772 to the regulatory authority with the evidence that the food does not require time/temperature control for  
 4773 safety.

4774 The Rules and Regulations definition designates certain raw plant foods as PHF/TCS food because they have  
 4775 been shown to support the growth of foodborne pathogens in the absence of temperature control and to lack  
 4776 intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these  
 4777 designations are supported by Tables A and B. For example:

4778 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-  
 4779 treated), and cut tomatoes (pH 4.23-5.04,  $a_w > 0.99$ , not heat treated), Table B indicates that they are  
 4780 considered PHF/TCS Foods unless a product assessment shows otherwise. Maintaining these products under  
 4781 the temperature control requirements prescribed in this code for PHF/TCS food will limit the growth of  
 4782 pathogens that may be present in or on the food and may help prevent foodborne illness.

4783 If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than flavor  
 4784 enhancement, a HACCP plan and approval from the department is required under 3-606. A HACCP plan is  
 4785 required whether the food is a PHF/TCS food as in Section 3-606(A)(3)(a) of these rules and regulations or  
 4786 not a PHF/TCS food, as in Section 3-606(A)(3)(a) of these rules and regulations. A standardized recipe  
 4787 validated by lab testing for pH and  $a_w$  would be an appropriate part of the approval process with annual (or  
 4788 other frequency as specified by the regulatory authority) samples tested to verify compliance with the  
 4789 conditions of the variance.

#### 4790 **Instructions for using the following Decision Tree and Table A and Table B:**

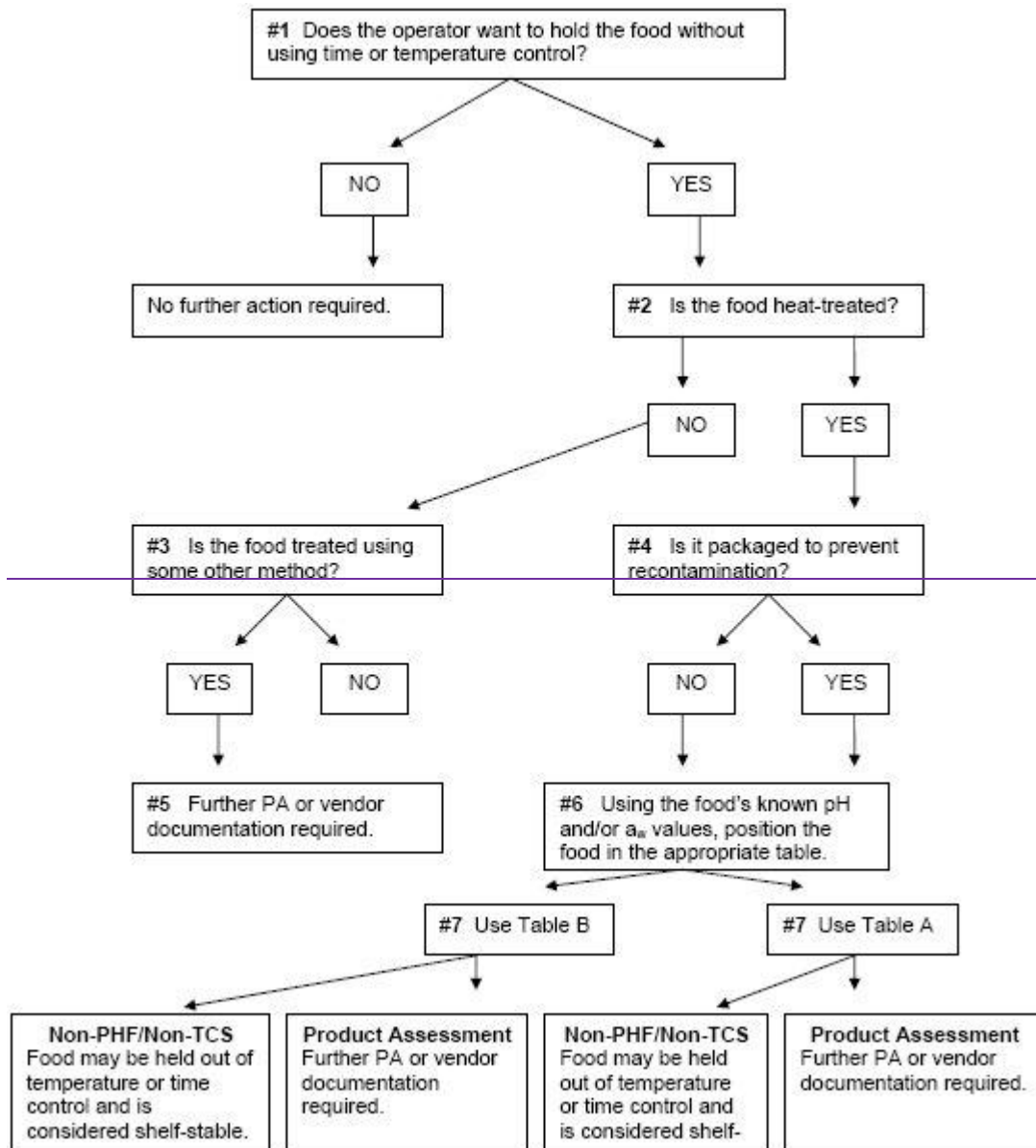
- 4791 1. ~~Does the operator want to hold the food without using time or temperature control?~~
  - 4792 a. ~~No—Continue holding the food at  $\leq 41^\circ\text{F}$  ( $5^\circ\text{C}$ ) or  $\geq 135^\circ\text{F}$  ( $57^\circ\text{C}$ ) for safety and/or quality.~~
  - 4793 b. ~~Yes—Continue using the decision tree to identify which table to use to determine whether~~
  - 4794 ~~time/temperature control for safety (TCS) is required.~~
- 4795 2. ~~Is the food heat treated?~~
  - 4796 a. ~~No—The food is either raw, partially cooked (not cooked to the temperature specified in~~
  - 4797 ~~section 3-502 of the Rules and Regulations) or treated with some other method other than~~
  - 4798 ~~heat. Proceed to step #3.~~
  - 4799 b. ~~Yes—If the food is heat treated to the required temperature for that food as specified under~~
  - 4800 ~~section 3-502 of the Rules and Regulations, vegetative cells will be destroyed although~~
  - 4801 ~~spores will survive. Proceed to step #4.~~
- 4802 3. ~~Is the food treated using some other method?~~
  - 4803 a. ~~No—The food is raw or has only received a partial cook allowing vegetative cells and spores~~
  - 4804 ~~to survive. Proceed to step #6.~~
  - 4805 b. ~~Yes—If a method other than heat is used to destroy pathogens such as irradiation, high~~
  - 4806 ~~pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the~~

- 4807 effectiveness of the process needs to be validated by inoculation studies or other means.  
4808 Proceed to step #5.
- 4809 4. ~~Is it packaged to prevent re-contamination?~~
- 4810 a. ~~No. Re-contamination of the product can occur after heat treatment because it is not  
4811 packaged. Proceed to step #6.~~
- 4812 b. ~~Yes. If the food is packaged immediately after heat treatment to prevent re-contamination,  
4813 higher ranges of pH and/or  $a_w$  can be tolerated because spore-forming bacteria are the only  
4814 microbial hazard. Proceed to step #7.~~
- 4815 5. ~~Further product assessment or vendor documentation required.~~
- 4816 a. ~~The vendor of this product may be able to supply documentation that inoculation studies  
4817 indicate the food can be safely held without time/temperature control for safety.~~
- 4818 b. ~~Food prepared or processed using new technologies may be held without time/temperature  
4819 control provided the effectiveness of the use of such technologies is based on a validated  
4820 inoculation study.~~
- 4821 6. ~~Using the food's known pH and/or  $a_w$  values, position the food in the appropriate table.~~
- 4822 a. ~~Choose the column under "pH values" that contains the pH value of the food in question.~~
- 4823 b. ~~Choose the row under " $a_w$  values" that contains the  $a_w$  value of the food in question.~~
- 4824 c. ~~Note where the row and column intersect to identify whether the food is "non-PHF/non-TCS  
4825 food" and therefore does not require time/temperature control, or whether further product  
4826 assessment (PA) is required. Other factors such as redox potential, competitive  
4827 microorganisms, salt content, or processing methods may allow the product to be held  
4828 without time/temperature control but an inoculation study is required.~~
- 4829 7. ~~Use Table A for foods that are heat treated and packaged OR use Table B for foods that are not heat  
4830 treated or heat treated but not packaged.~~
- 4831 8. ~~Determine if the item is non-PHF/non-TCS or needs further product assessment (PA).~~
- 4832



4833  
4834  
4835  
4836

**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**



4837

4838

**TABLE A AND TABLE B**

| <b>TABLE A. INTERACTION OF PH AND <math>A_w</math> FOR CONTROL OF SPORES IN FOOD<br/>HEAT-TREATED TO DESTROY VEGETATIVE CELLS AND SUBSEQUENTLY PACKAGED</b> |                         |                       |                      |
|---|-------------------------|-----------------------|----------------------|
| <b><math>A_w</math><br/>VALUES</b>  | <b><u>PH VALUES</u></b> |                       |                      |
|   | <b>4.6 OR LESS</b>      | <b>&gt; 4.6 - 5.6</b> | <b>&gt; 5.6</b>      |
| <b><math>\leq 0.92</math></b>   | NON-PHF*/NON-TCS FOOD** | NON-PHF/NON-TCS FOOD  | NON-PHF/NON-TCS FOOD |
| <b><math>&gt; 0.92 - .95</math></b>   | NON-PHF/NON-TCS FOOD    | NON-PHF/NON-TCS FOOD  | PA***                |
| <b><math>\geq 0.95</math></b>   | NON-PHF/NON-TCS FOOD    | PA                    | PA                   |

4839

\* PHF MEANS POTENTIALLY HAZARDOUS FOOD

4840

\*\* TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY

4841

FOOD

4842

\*\*\* PA MEANS PRODUCT ASSESSMENT REQUIRED

4843

~~**TABLE B. INTERACTION OF PH AND A<sub>w</sub> FOR CONTROL OF VEGETATIVE CELLS AND SPORES IN FOOD NOT HEAT-TREATED OR HEAT-TREATED BUT NOT PACKAGED**~~

| <b>A<sub>w</sub><br/>VALUES</b> | <b><u>PH VALUES</u></b>        |                             |                             |                             |
|---------------------------------|--------------------------------|-----------------------------|-----------------------------|-----------------------------|
|                                 | <b>&lt;4.2</b>                 | <b>4.2-4.6</b>              | <b>&gt;4.6-<br/>5.0</b>     | <b>≥5.0</b>                 |
| <b>&lt;0.88</b>                 | NON-PHF*/<br>NON-TCS<br>FOOD** | NON-PHF/<br>NON-TCS<br>FOOD | NON-PHF/<br>NON-TCS<br>FOOD | NON-PHF/<br>NON-TCS<br>FOOD |
| <b>0.88-<br/>0.90</b>           | NON-PHF/<br>NON-TCS<br>FOOD    | NON-PHF/<br>NON-TCS<br>FOOD | NON-PHF/<br>NON-TCS<br>FOOD | PA***                       |
| <b>≥0.90-<br/>0.92</b>          | NON-PHF/<br>NON-TCS<br>FOOD    | NON-PHF/<br>NON-TCS<br>FOOD | PA                          | PA                          |
| <b>&gt;0.92</b>                 | NON-PHF/<br>NON-TCS<br>FOOD    | PA                          | PA                          | PA                          |

4844

4845 \* PHF MEANS POTENTIALLY HAZARDOUS FOOD

4846 \*\* TCS FOOD MEANS TIME/TEMPERATURE CONTROL FOR SAFETY FOOD

4847 \*\*\* PA MEANS PRODUCT ASSESSMENT REQUIRED

4848

4849 The following is a limited list of specific food products that have been classified to be potentially  
4850 hazardous:

- 4851 1. ~~Bacon~~ If it has not been fully cooked.
- 4852 2. ~~Balutes~~ Fertile eggs, generally chicken or duck eggs, which are incubated for a period of  
4853 time shorter than is necessary for hatching. The developing embryo is incubated generally  
4854 14 to 18 days and is considered a delicacy by various ethnic populations when eaten raw or  
4855 cooked.
- 4856 3. ~~Beans~~ All types of cooked beans.
- 4857 4. ~~Whipped Butter~~ Hazardous because of the apparent reduced microbiological safety factor  
4858 created by whipping.
- 4859 5. ~~Cheese~~ Soft unripened cheese. Ripened, low moisture hard cheese such as wheels, flats,  
4860 blocks or longhorns of cheddar cheese produced from pasteurized milk, when waxed or

4861 packaged in "shrink" wrapping with the wax or packaging intact, can be safely shipped or  
 4862 stored for a short period of time without refrigeration but it is not recommended. If wheels,  
 4863 flats, blocks, longhorns, or any other forms of cheese have been damaged, cut and  
 4864 repackaged for display and/or sale, thereby exposing interior surfaces to possible  
 4865 contamination, the cut portions as well as the remaining cheese shall be held under  
 4866 refrigeration.

4867 6. ~~Coffee Creaming Agents~~ All non dairy coffee creaming agents in liquid form, except  
 4868 aseptically processed ultra high temperature (UHT) liquid coffee creaming agents.

4869 7. ~~Cut Leafy Greens~~ Following 24 multi-state outbreaks between 1998 and 2008, cut leafy  
 4870 greens was added to the definition of potentially hazardous food requiring time-temperature  
 4871 control for safety (TCS). The term used in the definition includes a variety of cut lettuces and  
 4872 leafy greens. Raw agricultural commodities (RACs) that are not processed or cut on-site are  
 4873 excluded from the definition of cut leafy greens. Herbs such as cilantro or parsley are also  
 4874 not considered cut leafy greens. The pH, water activity, available moisture and nutrients of  
 4875 cut leafy greens supports the growth of foodborne pathogens and refrigeration at 41°F (5°C)  
 4876 or less inhibits growth and promotes general die-off in some pathogens such as *E. coli*  
 4877 O157:H7, *Salmonella*, *E. coli* O157:H7 and *Listeria monocytogenes*, once attached to the  
 4878 surface or internalized into cut surfaces of leafy greens, are only marginally affected by  
 4879 chemical sanitizers.

4880 8. ~~Cut Tomatoes~~ Historically, uncooked fruits and vegetables, such as cut tomatoes, have been  
 4881 considered non-PHF unless they were epidemiologically implicated in foodborne illness  
 4882 outbreaks and are capable of supporting the growth of pathogenic bacteria in the absence of  
 4883 temperature control. The US Food and Drug Administration (FDA) has reported that since  
 4884 1990, at least 12 multi-state foodborne illness outbreaks have been associated with different  
 4885 varieties of tomatoes and additionally, from 1998-2006, outbreaks associated with tomatoes  
 4886 made up 17% of the produce related outbreaks reported to FDA nationwide. *Salmonella* has  
 4887 been the pathogen of concern most often associated with tomato outbreaks.

4888 9. ~~Eggs~~ Cooked, cracked, fresh with outer shell removed, peeled hard-boiled eggs, and hard-  
 4889 boiled eggs with intact shells which have been hard-boiled and then cooled in liquid.  
 4890 Refrigeration of raw whole eggs in the shell is required.

4891 10. ~~Garlic~~ Garlic in oil products.

4892 11. ~~Mayonnaise or Other Acidified Salad Dressings~~ If the pH is above 4.6 and/or combined  
 4893 with other food products.

4894 12. ~~Onions~~ Cooked and dehydrated that have been reconstituted.

4895 13. ~~Pasta~~ All types that have been cooked.

4896 14. ~~Pastries~~ Meat, cheese and cream filled.

4897 15. ~~Pies~~ Meat, fish, poultry, natural cream, synthetic cream, custard, pumpkin and pies that are  
 4898 covered with toppings which will support microbial growth.

4899 16. ~~Potatoes~~ Baked, boiled or fried.

4900 17. ~~Rice~~ Boiled, steamed, fried, Spanish and cooked rice used in sushi.

4901 18. ~~Sour Cream~~ If the pH is above 4.6 and/or combined with other food products.

4902 19. ~~Soy Protein~~ Tofu and other moist soy protein products.

4903 20. ~~Seed Sprouts~~ All types.

4904 ~~FOODS WHICH ARE NOT POTENTIALLY HAZARDOUS ARE:~~

- 4905 1. ~~Hard Boiled eggs with shells intact which have been air dried; and~~
- 4906 2. ~~Foods which have been adequately commercially processed and remain in their unopened~~
- 4907 ~~hermetically sealed container.~~

4908 ***APPENDIX B – Safe Materials Colorado Pure Food and Drug Law***

4909

4910 **Sections ~~25-5-402 (3) and (12)~~, C.R.S.**

4911

4912 (3) a. "Color additive" means a material which:

4913 (I.) — Is a dye, pigment, or other substance made by a process of synthesis or similar  
4914 artifice or extracted, isolated, or otherwise derived, with or without intermediate or final  
4915 change of identity, from a vegetable, animal, mineral, or other source; and

4916 (II.) — When added or applied to a food, drug, or cosmetic or to the human body or any part  
4917 thereof; is capable (alone or through reaction with other substance) of imparting color  
4918 thereto; except that such term does not include any material which is exempted under the  
4919 federal act.

4920 b. — Nothing in this subsection (3) shall be construed to apply to any pesticide chemical, soil or  
4921 plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or  
4922 otherwise affecting, directly or indirectly, the growth or other natural physiological process or  
4923 produce of the soil and thereby affecting its color, whether before or after harvest.

4924 (12) — "Food additive" means any substance, the intended use of which results or may be reasonably  
4925 expected to result, directly or indirectly, in its becoming a component or otherwise affecting the  
4926 characteristics of any food (including any substance intended for use in producing, manufacturing,  
4927 packing, processing, preparing, treating, packaging, transporting, or holding such substance is not  
4928 generally recognized among experts qualified by scientific training and experience to evaluate its  
4929 safety as having been adequately shown through scientific procedures or, in the case of a substance  
4930 used in a food prior to January 1, 1958, through either scientific procedures or experience based on  
4931 common use in food) to be safe under the conditions of its intended use. The term does not include:

4932 a. — A pesticide chemical in or on a raw agricultural commodity;

4933 b. — A pesticide chemical to the extent that it is intended for use or is used in the production,  
4934 storage, or transportation of any raw agricultural commodity;

4935 e. — A color additive; or

4936 d. — Any substance used in accordance with a sanction or approval granted prior to the enactment  
4937 of the amendment to the federal act known as the "Food Additives Amendment of 1958," the  
4938 Poultry Products Inspectional Act" (21 U.S.C. 451-470), or the "Meat Inspection Act of March  
4939 4, 1907," as amended and extended (21 U.S.C. 71-91)

4940 ***APPENDIX C - Worksheets for Calculating Minimum Hot Water***  
 4941 ***Requirements***

4942

4943 The following worksheet is provided to assist operators in calculating hot water usage and sizing of the  
 4944 water heater system required for the operation.

4945

4946 What is the distance between the water heating system(s) and the fixture that is farthest from the heating  
 4947 system?

4948

4949 Fixture: \_\_\_\_\_ Feet from water heating system: \_\_\_\_\_

4950

4951 Standard Tank Type Systems:

4952

4953 I. \_\_\_\_\_ Calculate Total Water Required By All Fixtures:

4954 A. \_\_\_\_\_ Three compartment sink calculation of water usage:

4955 1. \_\_\_\_\_ Measure dimensions, in inches, of each compartment, if compartments are not  
 4956 the same dimensions see note below.

4957

4958 Length = \_\_\_\_\_ Width = \_\_\_\_\_ Depth = \_\_\_\_\_

4959

4960 2. \_\_\_\_\_ Insert measurements into equation:

4961

4962  $(\frac{\text{_____}}{\text{length}} \times \frac{\text{_____}}{\text{width}} \times \frac{\text{_____}}{\text{depth}} \times 3 \times 0.375) \div 2.31 = \text{_____} \text{ GPH}$

4963 \_\_\_\_\_ water usage

4964

4965 Note: If all the compartment sizes of the sink are not the same, then 3 is taken out of the equation,  
 4966 and the above calculation is done for each compartment. The volumes are added to obtain the  
 4967 total gallons per hour of hot water used in the sink.

4968

4969 Enter number into the attached "Table to Calculate Total Water Required By All Fixtures," found  
 4970 on page C-4.

4971

4972 B. \_\_\_\_\_ Utensil soak sink

4973 1. \_\_\_\_\_ Measure dimensions, in inches, of the sink

4974

4975 Length = \_\_\_\_\_ Width = \_\_\_\_\_ Depth = \_\_\_\_\_ GPH

4976

4977  
 4978 2. ~~Insert measurements into equation:~~

4979  
 4980 
$$\left( \frac{\text{length}}{\text{length}} \times \frac{\text{width}}{\text{width}} \times \frac{\text{depth}}{\text{depth}} \times .375 \right) \div 2.31 = \frac{\text{water usage}}{\text{water usage}}$$

4981  
 4982 Enter number into the attached “Table to Calculate Total Water Required By All Fixtures,” found  
 4983 on page C-4.

4984  
 4985 C. ~~Dishmachine and conveyor pre-rinse water usage:~~

4986 1. ~~Use manufacturer’s rating in gallons per hour. Enter number into attached~~  
 4987 ~~“Table to Calculate Total Water Required By All Fixtures,” found on page C-4.~~

4988  
 4989 2. ~~Clothes washer water usage:~~

- 4990 • ~~Use manufacturer’s rating: \_\_\_\_\_, or~~  
 4991 • ~~32 GPH for 9-12 pound washer, or~~  
 4992 • ~~42 GPH for 16 pound washer.~~

4993  
 4994 Enter number into the attached “Table to Calculate Total Water Required By All Fixtures,” found  
 4995 on page C-4.

4996  
 4997 D. ~~“Calculate Total Water Required By All Fixtures” and the number of fixtures in the~~  
 4998 ~~operation to determine maximum hourly usage for each type of fixture in the operation.~~

4999  
 5000 Total water (GPH) required by all fixtures: \_\_\_\_\_ GPH.

5001  
 5002 H. ~~Calculate Maximum Hourly Hot Water Usage~~

5003 ~~If gas water heater is used go to Step A; if electric, Step B.~~

5004 A. ~~Gas Water Heater: If a gas water heater is to be used, calculate the maximum~~  
 5005 ~~hourly hot water usage for the facility by adjusting the total water required by all fixtures~~  
 5006 ~~for altitude. The altitude adjustment is 4% per 1000 feet of elevation, or 20% at 5000~~  
 5007 ~~feet.~~

5008  
 5009 Use the following equations to determine the maximum hourly hot water usage when a gas  
 5010 powered water heater is to be used:

5011  
 5012 
$$\left( 0.04 \times \frac{\text{elevation of facility}}{\text{elevation of facility}} \div 1000 \right) + 1 = \frac{\text{adjustment factor}}{\text{adjustment factor}}$$

5014



5015 
$$\frac{\text{_____}}{\text{_____}} \times \frac{\text{_____}}{\text{_____}} = \text{_____ GPH}$$

5016 ~~adjustment factor~~ ~~total water required~~ ~~maximum hourly~~

5017 ~~by all fixtures~~ ~~hot water usage~~

5018

5019 Example, if the total gallon per hour usage for an establishment at an elevation of 5000 feet is 100

5020 GPH, the adjustment factor is 1.2. Therefore, a water heater with 120 GPH recovery rate would

5021 be required.

5022

5023 Use this value in the equation to calculate the minimum BTU rating of the water heater.

5024

5025 B. ~~Electric Water Heater: If an electric water heater is to be used, the maximum~~

5026 ~~hourly usage for the operation is the same as the total water required by all fixtures. Use~~

5027 ~~this value in the equation to calculate the minimum Kilowatt (KW) rating of the water~~

5028 ~~heater.~~

5029

5030 C. ~~the value determined in Step A or B the minimum recovery rate of the water~~

5031 ~~heater which should be provided for the facility.~~

5032

5033 III. ~~Calculate the minimum BTU or Kilowatt rating of water heater:~~

5034 A. ~~For gas water heater, calculate the minimum BTU rating:~~

5035

5036 ~~$$\frac{(\text{max hourly usage as calculated above}) \times (100^{\circ}\text{F}^*) \times (8.33)}{\text{_____}} = \text{minimum BTU rating}$$~~

5037 ~~.80 or use manufacturer's thermal efficiency~~

5038

5039 B. ~~For electric water heater, calculate the minimum Kilowatt rating:~~

5040

5041 ~~$$\frac{(\text{max hourly usage as calculated above}) \times (100^{\circ}\text{F}^*) \times (8.33)}{\text{_____}} = \text{minimum KW rating}$$~~

5042 ~~3412~~

5043 ~~\*If there is no high temperature dishwashing machine or other fixtures requiring input water~~

5044 ~~temperature of 140°F (100°F rise) or more, then 80°F rise can be used.~~

5045

5046 C. ~~Select water heater based upon BTU or Kilowatt rating.~~

5047

5048 Make: \_\_\_\_\_ ; Model #: \_\_\_\_\_

5049

5050 BTU or Kilowatt Rating: \_\_\_\_\_

5051

5052 Recovery rate: \_\_\_\_\_ gallons per hour at 100°F rise at sea level.

5053

5054 D. ~~Heat reclaim systems:~~

5055

5056

Make: \_\_\_\_\_; Model #: \_\_\_\_\_

5057

5058

BTU Rating: \_\_\_\_\_

5059

5060

Recovery rate: \_\_\_\_\_ gallons per hour at 100°F rise at sea level.

5061

5062

5063

Table to Calculate Total Water Required For All Fixtures.

| Plumbing Fixture                             | Water Usage<br>(gallons per hour) | Number of<br>Fixtures | Maximum Hourly<br>Water Usage Per<br>Type of Fixture<br>(gallon per hour) |
|--|-----------------------------------|-----------------------|---|
| <i>example: dishwashing<br/>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<br>conveyor pre-rinse    |                                   |                       |   |
| Clothes washer                               |                                   |                       |   |
| Hand-operated pre-rinse<br>sprayer*          | 32                                |                       |   |
| Hand-washing sinks<br>(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:  |                                   |                       |   |

5064

5065

5066

\*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.

5067  
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5113

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 \_\_\_\_\_ ) : \_\_\_\_\_ = \_\_\_\_\_~~

|                                |                                     |                              |   |
|--------------------------------|-------------------------------------|------------------------------|---|
| <del>_____</del>               | <del>_____</del>                    | <del>_____</del>             | <del>_____</del>                        |
| <del>manufacturer’s flow</del> | <del>water use value from</del>     | <del>GPM standard flow</del> | <del>new water</del>                    |
| <del>use value rate</del>      | <del>Table to Calculate Total</del> | <del>rate</del>              | <del>to be entered into Table</del>     |
| <del>_____</del>               | <del>Water Required for All</del>   | <del>_____</del>             | <del>to Calculate Total Water</del>     |
| <del>_____</del>               | <del>Fixtures on page C-4</del>     | <del>_____</del>             | <del>Required for All Fixtures on</del> |
| <del>_____</del>               | <del>_____</del>                    | <del>_____</del>             | <del>page C-4)</del>                    |

~~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 \_\_\_\_\_~~

|                                |                                     |                              |   |
|--------------------------------|-------------------------------------|------------------------------|---|
| <del>_____</del>               | <del>_____</del>                    | <del>_____</del>             | <del>_____</del>                        |
| <del>manufacturer’s flow</del> | <del>water use value from</del>     | <del>GPM standard flow</del> | <del>new water</del>                    |
| <del>use value rate</del>      | <del>table to Calculate Total</del> | <del>rate</del>              | <del>to be entered into table</del>     |
| <del>_____</del>               | <del>Water Required for All</del>   | <del>_____</del>             | <del>to Calculate Total Water</del>     |
| <del>_____</del>               | <del>Fixtures on page C-4</del>     | <del>_____</del>             | <del>Required for All Fixtures on</del> |
| <del>_____</del>               | <del>_____</del>                    | <del>_____</del>             | <del>page C-4)</del>                    |

~~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.~~

5114

5115 Requirements for Dishwashing Machine Booster Heaters:5116 I. Dishwashing Machine

5117

5118 Manufacturer: \_\_\_\_\_

5119

5120 Model Number: \_\_\_\_\_

5121

5122 Final Sanitizing Rinse Cycle Gallons Per Hour Water Consumption: \_\_\_\_\_ GPH

5123

5124 H. Calculate the minimum BTU or Kilowatt rating of the booster heater:

5125

5126 A. For gas booster heater, calculate the minimum BTU rating:

5127

5128 
$$\frac{(\text{Gallons Per Hour Water Consumption}) \times (40^{\circ}\text{F}) \times (8.33)}{\text{efficiency}} = \text{minimum BTU rating}$$

5129

.80 or use manufacturer's thermal efficiency

5130

5131 B. For electric water heater, calculate the minimum Kilowatt rating:

5132

5133 
$$\frac{(\text{Gallons Per Hour Water Consumption}) \times (40^{\circ}\text{F}) \times (8.33)}{3412} = \text{minimum KW rating}$$

5134

3412

5135 C. Select booster heater based upon BTU or Kilowatt rating. The booster heater must have recovery  
5136 rate greater than the dishwashing machine's final rinse water consumption.

5137

5138 Make: \_\_\_\_\_ ; Model #: \_\_\_\_\_

5139

5140 BTU or Kilowatt Rating: \_\_\_\_\_

5141

5142 Recovery rate: \_\_\_\_\_ gallons per hour at 40°F rise at sea level.

5143 Tankless or Instantaneous Systems5144 I. Heater Specifications:

5145

5146 Manufacturer\*: \_\_\_\_\_

5147

5148 Model Number: \_\_\_\_\_

5149

5150 Flow Rate in Gallons Per Minute (GPM) at 100°F rise\*\*\*: \_\_\_\_\_ GPM

5151

5152 BTU Rating: \_\_\_\_\_ BTU\*\*\*

5153

\*—Units must be designed for commercial use.

5154 ~~\*\* If there are no high temperature dishwashing machine or other fixtures requiring input water~~  
 5155 ~~temperature of 140°F (100°F rise) or more, then 80°F rise can be used.~~

5156 ~~\*\*\* Electric units will only be approved as a dedicated hot water supply to hand washing sinks.~~

5157 III. Calculate the total hot water demand flow rate in Gallons Per Minute (GPM) using this table.

| PLUMBING FIXTURE   | WATER USAGE<br>(GALLONS PER MINUTE) | NUMBER OF<br>FIXTURES | WATER DEMAND<br>FLOW RATE IN<br>GALLONS PER<br>MINUTE |
|--|-------------------------------------|-----------------------|---|
| <del>EXAMPLE: DISHWASHING<br/>MACHINE † HOBART AM-14</del> | <del>8.0</del>                      | <del>1</del>          | <del>(8.0 × 1) = 8.0</del>                            |
| <del>EXAMPLE: HANDSINK(S)</del>                            | <del>0.5</del>                      | <del>4</del>          | <del>(0.5 × 4) = 2.0</del>                            |
|  |                                     |                       |   |
| 3-COMPARTMENT SINK*  | 2.0 FOR EACH FAUCET                 |                       |   |
| 3-COMPARTMENT SINK<br>(BAR)*                               | 2.0 FOR EACH FAUCET                 |                       |   |
| UTENSIL SOAK SINK  | 1.0                                 |                       |   |
| DISHWASHING MACHINE †                                      |                                     |                       |   |
| DISHWASHING MACHINE<br>CONVEYOR PRE-RINSE †                |                                     |                       |   |
| CLOTHES WASHER   | 2.0                                 |                       |   |
| HAND OPERATED PRE-RINSE<br>SPRAYER †                       | 2.0                                 |                       |   |
| FOOD PREPARATION SINK(S)                                   | 1.0                                 |                       |   |
| HAND-WASHING SINKS<br>(INCLUDING RESTROOMS)*               | 0.5                                 |                       |   |
| MOP/UTILITY SINKS  | 2.0                                 |                       |   |
| GARBAGE CAN WASHER   | 1.0                                 |                       |   |
| SHOWERS †  | 1.0                                 |                       |   |
| HOSE BIB USED FOR<br>CLEANING                              | 5.0                                 |                       |   |
| TOTAL WATER DEMAND (GPM) REQUIRED:                         |                                     |                       |   |

5158

5159 ~~\*A flow rate reduction can be used for low flow water faucets installed on 3-compartment sinks, hand-operated pre-~~  
 5160 ~~rinse sprayers, food preparation sinks, hand washing sinks and showers by entering the manufacturer's flow rate listed~~  
 5161 ~~for the faucet or faucet's aerator.~~

5162 ~~†Use manufacturer's flow rate in GPM for specific make and model of dishwashing machine or shower head.~~

5163 ~~IV. Calculate the maximum flow rate for the establishment. The thermal efficiency of the water~~  
 5164 ~~heating units must be adjusted for altitude. The altitude adjustment is 4% per 1000 feet of~~  
 5165 ~~elevation, or 20% at 5000 feet.~~

5166  
 5167 Use the following equations to determine the establishment's maximum flow rate in GPM:

5168  
 5169  $(0.04 \times \frac{\text{elevation of facility}}{1000} + 1) = \text{adjustment factor}$

5170  
 5171  
 5172  $\frac{\text{adjustment factor} \times \text{total water demand for all fixtures calculated in III}}{\text{maximum GPM hot water usage}} = \text{maximum GPM}$

5173 Use calculated maximum GPM hot water usage value in this equation to determine the minimum  
 5174 number of heating units that will be required in IV below.

5175  
 5176  
 5177 ~~V. Determine the number of heating units that will be needed to meet the required flow rate.~~

5178  
 5179  
 5180  
 5181  
 5182  $\frac{\text{maximum demand (GPM) calculated in PART III}}{\text{manufacturer's flow rate in GPM @ 100°F}} = \text{number of heating units required*}$

5183  
 5184  
 5185 ~~\*Multiple units must be installed and plumbed to operate in a parallel configuration.~~

5186  
 5187 VI. Storage Tank Sizing:

5188 If a dishwashing machine(s) is to be installed the instantaneous water heating system must  
 5189 include a storage tank. The storage tank must be at least 25 gallons or at least 25% of the gallons  
 5190 per hour (GPH) demand of the dishwashing machine(s). The larger value of the two is the  
 5191 required storage tank size.

5192  
 5193 Dishwashing Machine\*  
 5194 Manufacturer: \_\_\_\_\_

5195  
 5196 Model Number: \_\_\_\_\_

5197  
 5198 Gallons Per Hour Water Consumption: \_\_\_\_\_ x 0.25 = \_\_\_\_\_  
 5199 \_\_\_\_\_ storage tank capacity  
 5200 \_\_\_\_\_ in gallons

5201 Calculated Storage Tank Capacity: \_\_\_\_\_ vs. 25 Gallons Storage Tank

5202

5203 Enter the larger of the two: \_\_\_\_\_ Required Storage Tank Capacity\*\*

5204

5205 \*High temperature, heat sanitizing dishwashing machines must be provided with a separate  
5206 booster heater. Use of an instantaneous unit is not allowed for use as a booster heater.

5207 \*\*The storage tank must be installed in the hot water supply line located between the heater  
5208 unit(s) and the hot water distribution line. A recirculation line, equipped with a recirculation  
5209 pump and aquastat, (water thermostat) must be installed at the storage tank to assure the water in  
5210 the tank remains at the appropriate temperature (120-140°F). The recirculation line must be  
5211 connected between the storage tank and the cold water supply line at the heater unit(s).



5212

***APPENDIX D—Specific Usage Additives***

5213 ~~173.310—Boiler water additives.~~

5214

5215 ~~———— Boiler water additives may be safely used in the preparation of steam that will contact food, under~~  
 5216 ~~the following conditions:~~

5217 ~~A. — The amount of additive is not in excess of that required for its functional purpose, and the~~  
 5218 ~~amount of steam in contact with food does not exceed that required to produce the~~  
 5219 ~~intended effect in or on the food.~~

5220 ~~B. — The compounds are prepared from substances identified in paragraphs (C) and (D) of this~~  
 5221 ~~section, and are subject to the limitations, if any, prescribed:~~

5222 ~~C. — List of substances:~~

| Substances  | Limitations   |
|---|---|
| <p><del>Acrylamide-sodium acrylate resin.....</del></p> <p><del>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.</del></p> <p><del>Ammonium alginate.</del></p> <p><del>Cobalt sulfate (as catalyst).</del></p> <p><del>1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4) and its sodium and potassium salts.</del></p> <p><del>Lignosulfonic acid.</del></p> | <p><del>Contains not more than 0.05 percent by weight of acrylamide monomer.</del></p> <p><del>Total not to exceed 20 parts per million (active) in boiler feedwater.</del></p>   |
| <p><del>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.</del></p> <p><del>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.</del></p> <p><del>Polyethylene glycol.....</del></p>   | <p><del>Minimum mol. Wt. 1,500.</del></p> <p><del>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).</del></p> <p><del>As defined in 172.820 of this chapter.</del></p> |

| Substances   | Limitations   |
|--|---|
| <p><del>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].</del></p> <p><del>Polyoxypropylene glycol .....</del></p> <p><del>Potassium carbonate.</del></p> <p><del>Potassium tripolyphosphate.</del></p> <p><del>Sodium acetate.</del></p> <p><del>Sodium alginate.</del></p> <p><del>Sodium aluminate.</del></p> <p><del>Sodium carbonate.</del></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><del>Sodium carboxy-methylcellulose .....</del></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><del>Sodium glucoheptonate .....</del></p> <p><del>Sodium hexametaphosphate.</del></p> <p><del>Sodium humate.</del></p> <p><del>Sodium hydroxide.</del></p> <p><del>Sodium lignosulfonate.</del></p> <p><del>Sodium metabisulfite.</del></p> <p><del>Sodium metasilicate.</del></p> <p><del>Sodium nitrate.</del></p> <p><del>Sodium phosphate (mono-, di-, tri-).</del></p> <p><del>Sodium polyacrylate.</del></p> <p><del>Sodium polymethacrylate.</del></p> <p><del>Sodium silicate.</del></p> <p><del>Sodium sulfate.</del></p> <p><del>Sodium sulfite (neutral or alkaline).</del></p> <p><del>Sodium tripolyphosphate.</del></p> <p><del>Tannin (including quebracho extract).</del></p> <p><del>Tetrasodium EDTA.</del></p> <p><del>Tetrasodium pyrophosphate.</del></p> | <p>Less than 1 part per million cyanide in the sodium glucoheptonate.</p>   |

5224 ~~D. Substances used alone or in combination with substances in paragraph (C) of this~~  
 5225 ~~section:~~

| <b>Substances</b>                            | <b>Limitations</b>   |
|--|--|
| <del>Cyclohexylamine .....</del>             | <del>Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.</del>              |
| <del>Diethylaminoethanol .....</del>         | <del>Not to exceed 15 parts per million in steam, and excluding use of such steam in contact with milk and milk products.</del>              |
| <del>Hydrazine .....</del>                   | <del>Zero in steam.</del>  |
| <del>Morpholine .....</del>                  | <del>Not to exceed 10 parts per million in steam, and excluding use of such steam in contact with milk and milk products.</del>              |
| <del>Octadecylamine .....</del>              | <del>Not to exceed 3 parts per million in steam, and excluding use of such steam in contact with milk and milk products</del>                |
| <del>Trisodium nitrilotriacetate .....</del> | <del>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.</del> |

5226

5227 ~~E. To assure safe use of the additive, in addition to the other information required by the~~  
 5228 ~~Act, the label or labeling shall bear:~~

5229 ~~1. The common or chemical name or names of the additive or additives.~~

5230 ~~2. Adequate directions for use to assure compliance with all the provisions of this~~  
 5231 ~~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.             |
| <del>BHA.</del>  |  |
| <del>BHT.</del>  |  |
| <del>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.</del>   | <del>Addition to food not to exceed 10 parts per million.</del>  |
| <del>α-Butyl-omega-hydroxypoly(oxypropylene); minimum molecular weight 1,500; Chemical Abstracts Service Registry No. 9003-13-8.</del>   | <del>Do.</del>   |
| <del>Castor oil .....</del>  | <del>Do.</del>   |
| <del>Castor oil, dehydrated .....</del>  | <del>Do.</del>   |
| <del>Castor oil, partially dehydrated .....</del>  | <del>Do.</del>   |
| <del>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 (C<sub>14</sub>-C<sub>18</sub>) and where the aluminum silicate is derived from bentonite.</del> | <del>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.</del> |
| <del>Dimethylpolysiloxane (viscosity greater than 300 centistokes).</del>  | <del>Addition to food not to exceed 1 part per million.</del>  |

| 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 sequestrant 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><math>\alpha</math>-Hydro-<math>\omega</math>-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-<math>\alpha</math>- and/or phenyl-<math>\beta</math>-naphthylamine .....</p> <p>Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C<sub>11-14</sub>-alkylamines.</p> <p>Phosphoric acid, mono- and diisooctyl esters, reacted with tertalkyl and (C<sub>12</sub>-C<sub>14</sub>) 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 (C<sub>16</sub>- and C<sub>18</sub>-) 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.~~

~~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.~~

5254

***APPENDIX F - SANITIZERS***

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5256

***Refer to 40 CFR § 180.940, (2010) — Sanitizing solutions***



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## ***APPENDIX G – HACCP Guidelines***

### **1. Introduction to HACCP**

#### **A. What is HACCP and how can it be used by operators and regulators of retail food and food service establishments?**

Hazard Analysis and Critical control point (HACCP) is a systematic approach to identifying, evaluating, and controlling food safety hazards. Food safety hazards are biological, chemical, or physical agents that are reasonably likely to cause illness or injury in the absence of their control. Because a HACCP program is designed to ensure that hazards are prevented, eliminated, or reduced to an acceptable level before a food reaches the consumer, it embodies the preventive nature of "active managerial control."

Active managerial control through the use of HACCP principles is achieved by identifying the food safety hazards attributed to products, determining the necessary steps that will control the identified hazards, and implementing on-going practices or procedures that will ensure safe food.

Like many other quality assurance programs, HACCP provides a common-sense approach to identifying and controlling problems that are likely to exist in an operation. Consequently, many food safety management systems at the retail level already incorporate some, if not all, of the principles of HACCP. Combined with good basic sanitation, a solid employee training program, and other prerequisite programs, a food safety management system based on HACCP principles will prevent, eliminate, or reduce the occurrence of foodborne illness risk factors that lead to out-of-control hazards.

HACCP represents an important tool in food protection that small independent businesses as well as national companies can use to achieve active managerial control of risk factors. The Food Code requires a comprehensive HACCP plan when conducting certain specialized processes at retail such as when a variance is granted or when a reduced oxygen packaging method is used. However, in general, the implementation of HACCP at the retail level is voluntary. FDA endorses the voluntary implementation of food safety management systems based on HACCP principles as an effective means for controlling the occurrence of foodborne illness risk factors that result in out-of-control hazards.

While the operator is responsible for developing and implementing a system of controls to prevent foodborne illness risk factors, the role of the regulator is to assess whether the system the operator has in place is achieving control of foodborne illness risk factors. Using HACCP principles during inspections will enhance the effectiveness of routine inspections by incorporating a risk-based approach. This helps inspectors focus their inspection on evaluating the effectiveness of food safety management systems implemented by industry to control foodborne illness risk factors.

For regulatory program managers, the use of risk-based inspection methodology based on HACCP principles is a viable and practical option for evaluating the degree of active managerial control operators have over the foodborne illness risk factors.

5297 **B. ~~What are the Seven HACCP Principles?~~**

5298 In November 1992, the National Advisory Committee on Microbiological Criteria for  
 5299 Foods (NACMCF) defined seven widely accepted HACCP principles that explained the  
 5300 HACCP process in great detail. In 1997, NACMCF reconvened to review the 1992  
 5301 document and compare it to current HACCP guidance prepared by the CODEX  
 5302 Committee on Food Hygiene. Based on this review, NACMCF again endorsed HACCP  
 5303 and defined HACCP as a systematic approach to the identification, evaluation, and  
 5304 control of food safety. Based on a solid foundation of prerequisite programs to control  
 5305 basic operational and sanitation conditions, the following seven basic principles are used  
 5306 to accomplish this objective:

- 5307 1. ~~Principle 1: Conduct a hazard analysis~~
- 5308 2. ~~Principle 2: Determine the critical control points (CCPs)~~
- 5309 3. ~~Principle 3: Establish critical limits~~
- 5310 4. ~~Principle 4: Establish monitoring procedures~~
- 5311 5. ~~Principle 5: Establish corrective actions~~
- 5312 6. ~~Principle 6: Establish verification procedures~~
- 5313 7. ~~Principle 7: Establish record keeping and documentation procedures.~~

5314 This appendix will provide a brief overview of each of the seven principles of HACCP. A  
 5315 more comprehensive discussion of these principles is available from FDA by accessing  
 5316 the NACMCF guidance document<sup>4</sup>. Following the overview, a practical scheme for  
 5317 applying and implementing the HACCP principles in retail and food service  
 5318 establishments is presented.

5319 **C. ~~What are Prerequisite Programs?~~**

5320 In order for a HACCP system to be effective, a strong foundation of procedures that  
 5321 address the basic operational and sanitation conditions within an operation must first be  
 5322 developed and implemented. These procedures are collectively termed "prerequisite  
 5323 programs." When prerequisite programs are in place, more attention can be given to  
 5324 controlling hazards associated with the food and its preparation. Prerequisite programs  
 5325 may include such things as:

- 5326 ○ ~~Vendor certification programs~~
- 5327 ○ ~~Training programs~~
- 5328 ○ ~~Allergen management~~
- 5329 ○ ~~Buyer specifications~~
- 5330 ○ ~~Recipe/process instructions~~
- 5331 ○ ~~First In First Out (FIFO) procedures~~
- 5332 ○ ~~Other Standard Operating Procedures (SOPs).~~

5333 Basic prerequisite programs should be in place to:

5334 ○ Protect products from contamination by biological, chemical, and physical food  
5335 safety hazards

5336 ○ Control bacterial growth that can result from temperature abuse

5337 ○ Maintain equipment.

5338 Additional information about prerequisite programs and the types of activities usually  
5339 included in them can be found in the FDA's Retail HACCP manuals discussed later in  
5340 this Appendix or by accessing the NACMCF guidance document on the FDA Web Page.

## 5341 **2. The HACCP Principles**

### 5342 **A. Principle #1: Conduct a Hazard Analysis**

#### 5343 **1. What is a food safety hazard?**

5344 A hazard is a biological, chemical, or physical property that may cause a food to  
5345 be unsafe for human consumption.

#### 5346 **2. What are biological hazards?**

5347 Biological hazards include bacterial, viral, and parasitic microorganisms. See  
5348 Table 1 in this Appendix for a listing of selected biological hazards. Bacterial  
5349 pathogens comprise the majority of confirmed foodborne disease outbreaks and  
5350 cases. Although cooking destroys the vegetative cells of foodborne bacteria to  
5351 acceptable levels, spores of spore-forming bacteria such as *Bacillus cereus*,  
5352 *Clostridium botulinum*, and *Clostridium perfringens* survive cooking and may  
5353 germinate and grow if food is not properly cooled or held after cooking. The  
5354 toxins produced by the vegetative cells of *Bacillus cereus*, *Clostridium*  
5355 *botulinum*, and *Staphylococcus aureus* may not be destroyed to safe levels by  
5356 reheating. Post-cook recontamination with vegetative cells of bacteria such as  
5357 *Salmonellae* and *Campylobacter jejuni* is also a major concern for operators of  
5358 retail and food-service establishments.

5359 Viruses such as norovirus, hepatitis A, and rotavirus are directly related to  
5360 contamination from human feces. Recent outbreaks have also shown that these  
5361 viruses may be transmitted via droplets in the air. In limited cases, foodborne  
5362 viruses may occur in raw commodities contaminated by human feces (e.g.,  
5363 shellfish harvested from unapproved, polluted waters). In most cases, however,  
5364 contamination of food by viruses is the result of cross-contamination by ill food  
5365 employees or unclean equipment and utensils. Unlike bacteria, a virus cannot  
5366 multiply outside of a living cell. Cooking as a control for viruses may be  
5367 ineffective because many foodborne viruses seem to exhibit heat resistance  
5368 exceeding cooking temperature requirements, under laboratory conditions.  
5369 Obtaining food from approved sources, practicing no bare hand contact with  
5370 ready-to-eat food as well as proper handwashing, and implementing an employee  
5371 health policy to restrict or exclude ill employees are important control measures  
5372 for viruses.

5373 Parasites are most often animal host specific, but can include humans in their life  
 5374 cycles. Parasitic infections are commonly associated with undercooking meat  
 5375 products or cross contamination of ready to eat food with raw animal foods,  
 5376 untreated water, or contaminated equipment or utensils. Like viruses, parasites do  
 5377 not grow in food, so control is focused on destroying the parasites and/or  
 5378 preventing their introduction. Adequate cooking destroys parasites. In addition,  
 5379 parasites in fish to be consumed raw or undercooked can also be destroyed by  
 5380 effective freezing techniques. Parasitic contamination by ill employees can be  
 5381 prevented by proper handwashing, no bare hand contact with ready to eat food,  
 5382 and implementation of an employee health policy to restrict or exclude ill  
 5383 employees.

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**Appendix G, Table 1. Selected Biological Hazards Found at Retail, Associated Foods, and Control Measures**

| <b>Hazard</b>   |   | <b>Associated Foods</b>   | <b>Control Measures</b>  |
|-----------------|---|---|--|
| <b>Bacteria</b> | <i>Bacillus cereus</i> (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  |
|                 | <i>Campylobacter jejuni</i>   | Poultry, raw milk   | Cooking, handwashing, prevention of cross contamination  |
|                 | <i>Clostridium botulinum</i>  | 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.   |
|                 | <i>Clostridium perfringens</i>  | Cooked meat and poultry, Cooked meat and poultry products including casseroles, gravies   | Cooling, cold holding, reheating, hot holding  |
|                 | <i>E. coli</i> O157:H7 (other shiga toxin producing <i>E. coli</i> )  | 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  |
| <b>Parasites</b> | <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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|                |  |  |   |
|----------------|--|--|---|
| <b>Viruses</b> | 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 Regulations<sup>5</sup>, 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 Cosmetics<sup>6</sup>. 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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5420 ~~response is commonly characterized by hives or other itchy rashes, nausea,~~  
 5421 ~~abdominal pain, vomiting and/or diarrhea, wheezing, shortness of breath, and~~  
 5422 ~~swelling of various parts of the body. In severe cases, anaphylactic shock and~~  
 5423 ~~death may result.~~

5424 ~~Many foods, with or without identifiable allergens, have been reported to cause~~  
 5425 ~~food allergies. However, FDA believes there is scientific consensus that the~~  
 5426 ~~following foods can cause a serious allergic reaction in sensitive individuals;~~  
 5427 ~~these foods account for 90% or more of all food allergies:~~

5428 ~~▪—Milk~~

5429 ~~▪—Egg~~

5430 ~~▪—Fish (such as bass, flounder, or cod)~~

5431 ~~▪—Crustacean shellfish (such as crab, lobster, or shrimp)~~

5432 ~~▪—Tree nuts (such as almonds, pecans, or walnuts)~~

5433 ~~▪—Wheat~~

5434 ~~▪—Peanuts~~

5435 ~~▪—Soybeans.~~

5436 ~~Consumers with food allergies rely heavily on information contained on food~~  
 5437 ~~labels to avoid food allergens. Each year, FDA receives reports from consumers~~  
 5438 ~~who have experienced an adverse reaction following exposure to a food allergen.~~  
 5439 ~~Frequently, these reactions occur either because product labeling does not inform~~  
 5440 ~~the consumer of the presence of the allergenic ingredient in the food or because~~  
 5441 ~~of the cross-contact of a food with an allergenic substance not intended as an~~  
 5442 ~~ingredient of the food during processing and preparation.~~

5443 ~~In August 2004, the Food Allergen Labeling and Consumer Protection Act~~  
 5444 ~~(Public Law 108-282, Title II) was enacted, which defines the term "major food~~  
 5445 ~~allergen." The definition of "major food allergen" adopted for use in the Food~~  
 5446 ~~Code (see paragraph 1-201.10(B)) is consistent with the definition in the new~~  
 5447 ~~law. The following requirements are included in the new law:~~

5448 ~~▪—For foods labeled on or after January 1, 2006, food manufacturers must~~  
 5449 ~~identify in plain language on the label of the food any major food allergen~~  
 5450 ~~used as an ingredient in the food, including a coloring, flavoring, or~~  
 5451 ~~incidental additive.~~

5452 ~~▪—FDA is to conduct inspections to ensure that food facilities comply with~~  
 5453 ~~practices to reduce or eliminate cross-contact of a food with any major food~~  
 5454 ~~allergens that are not intentional ingredients of the food.~~

5455 ~~▪—Within 18 months of the date of enactment of the new law (i.e., by February~~  
 5456 ~~2, 2006), FDA must submit a report to Congress that analyzes the results of~~  
 5457 ~~its food inspection findings and addresses a number of specific issues related~~  
 5458 ~~to the production, labeling, and recall of foods that contain an undeclared~~  
 5459 ~~major food allergen.~~





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|-------------------------|---|--|--|
|                         | (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.  |
|                         | Phtyohaemmagglutinin  | 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. |
| <b>Added Chemicals:</b> | 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  |

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|---|--|---|
| 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.<br>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:<br><br>Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)<br><br>Nitrites/nitrates<br><br>Niacin | Fresh fruits and Vegetables<br>Shrimp<br>Lobster<br>Wine<br><br>Cured meats, fish, any food exposed to accidental contamination, spinach<br><br>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.<br><br>Do not use on raw produce in food establishments.<br><br>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<br>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"> <li>▪ Milk</li> <li>▪ Egg</li> <li>▪ Fish</li> <li>▪ Crustacean shellfish</li> <li>▪ Tree nuts</li> </ul>                           | Use a rigorous sanitation regime to prevent cross contact between allergenic and non-allergenic ingredients.  |

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|  |  | <ul style="list-style-type: none"> <li>▪—Wheat</li> <li>▪—Peanuts</li> <li>▪—Soybeans</li> </ul> |  |
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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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| <b>Appendix G, Table 3. Main Materials of Concern as Physical Hazards and Common Sources<sup>a, b</sup></b> |   |   |
|---|---|---|
| <b>Material</b>   | <b>Injury Potential</b>   | <b>Sources</b>  |
| 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<br>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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<sup>a</sup> Adapted from Corlett (1991).

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<sup>b</sup> 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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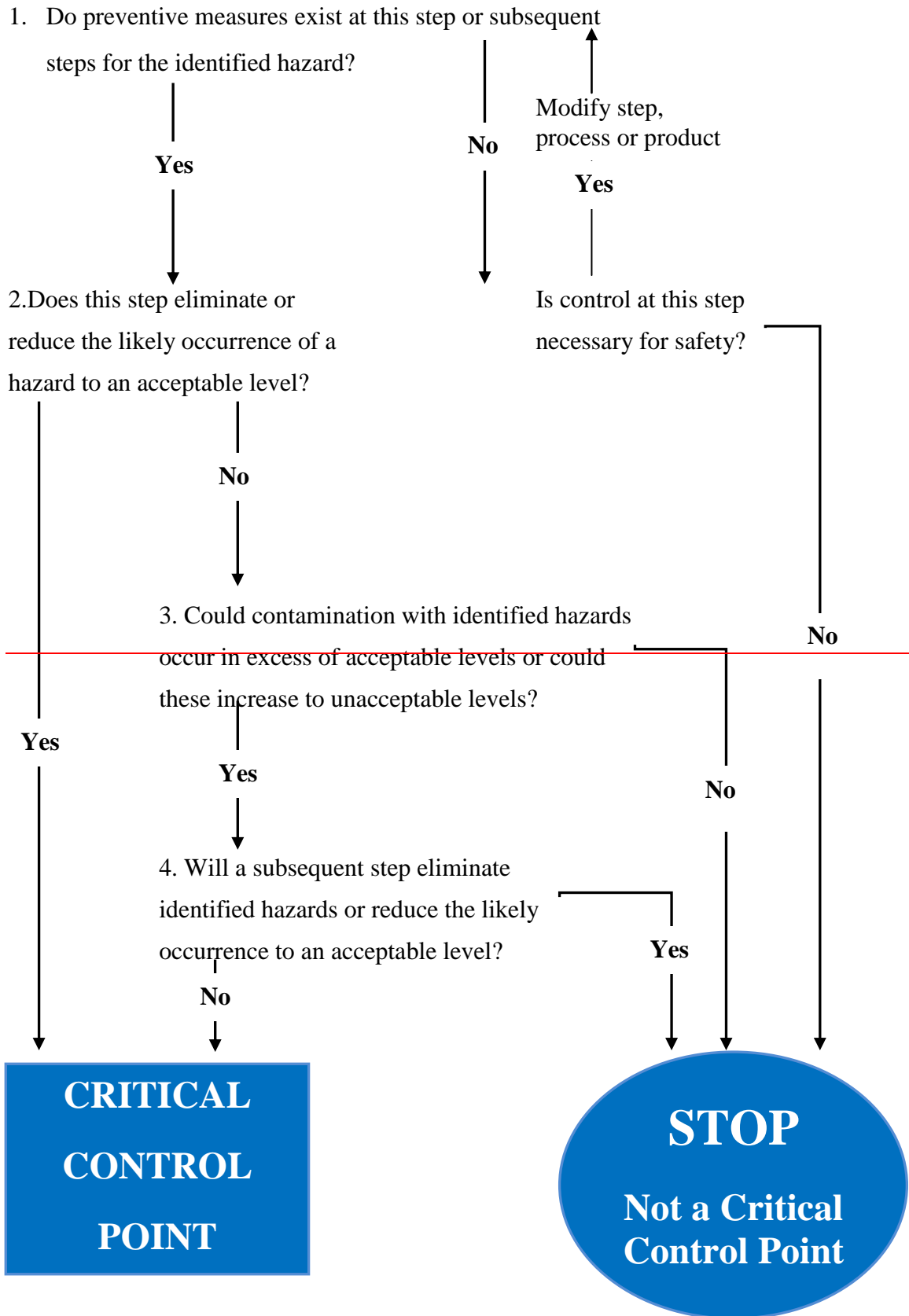
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5560 **C. ~~Principle #3: Establish Critical Limits~~**

5561 **1. ~~What is a critical limit and what is its purpose?~~**

5562 A critical limit is a prescribed parameter (e.g., minimum and/or maximum value)  
 5563 that must be met to ensure that food safety hazards are controlled at each CCP. A  
 5564 critical limit is used to distinguish between safe and unsafe operating conditions  
 5565 at a CCP. Each control measure at a CCP has one or more associated critical  
 5566 limits. Critical limits may be based upon factors like temperature, time, moisture  
 5567 level, water activity ( $a_w$ ), or pH. They must be scientifically based and  
 5568 measurable.

5569 **2. ~~What are examples of critical limits?~~**

5570 Examples of critical limits are the time/temperature parameters for cooking  
 5571 chicken (165°F for 15 seconds). In this case, the critical limit designates the  
 5572 minimum criteria required to eliminate food safety hazards or reduce them to an  
 5573 acceptable level. The critical limit for the acidification of sushi rice, a pH of  $\leq 4.6$ ,  
 5574 sets the maximum limit for pH necessary to control the growth of spore and  
 5575 toxin forming bacteria. Critical limits may be derived from regulatory standards  
 5576 such as the rules and regulations, other applicable guidelines, performance  
 5577 standards, or experimental results.

5578 **D. ~~Principle #4: Establish Monitoring Procedures~~**

5579 **1. ~~What is the purpose of monitoring?~~**

5580 Monitoring is the act of observing and making measurements to help determine if  
 5581 critical limits are being met and maintained. It is used to determine whether the  
 5582 critical limits that have been established for each CCP are being met.

5583 **2. ~~What are examples of monitoring activities?~~**

5584 Examples of monitoring activities include visual observations and measurements  
 5585 of time, temperature, pH, and water activity. If cooking chicken is determined to  
 5586 be a CCP in an operation, then monitoring the internal temperature of a select  
 5587 number of chicken pieces immediately following the cook step would be an  
 5588 example of a monitoring activity. Alternatively, the temperature of an oven or  
 5589 fryer and the time required to reach an internal temperature of 165°F could also  
 5590 be monitored.

5591 **3. ~~How is monitoring conducted?~~**

5592 Typically, monitoring activities fall under two broad categories:

5593 \* ~~measurements~~

5594 \* ~~observations~~

5595 Measurements usually involve time and temperature but also include other  
 5596 parameters such as pH. If an operation identifies the acidification of sushi rice as



5597 a CCP and the critical limit as the final pH of the product being  $\leq 4.6$ , then the  
5598 pH of the product would be measured to ensure that the critical limit is met.

5599 Observations involve visual inspections to monitor the presence or absence of a  
5600 food safety activity. If date marking is identified as a CCP in a deli operation for  
5601 controlling *Listeria monocytogenes* in ready-to-eat deli meats, then the  
5602 monitoring activity could involve making visual inspections of the date marking  
5603 system to monitor the sell, consume, or discard dates.

#### 5604 **4. How often is monitoring conducted?**

5605 Monitoring can be performed on a continuous or intermittent basis. Continuous  
5606 monitoring is always preferred when feasible as it provides the most complete  
5607 information regarding the history of a product at a CCP. For example, the  
5608 temperature and time for an institutional cook-chill operation can be recorded  
5609 continuously on temperature recording charts.

5610 If intermittent monitoring is used, the frequency of monitoring should be  
5611 conducted often enough to make sure that the critical limits are being met.

#### 5612 **5. Who conducts monitoring?**

5613 Individuals directly associated with the operation (e.g., the person in charge of  
5614 the establishment, chefs, and departmental supervisors) are often selected to  
5615 monitor CCPs. They are usually in the best position to detect deviations and take  
5616 corrective actions when necessary. These employees should be properly trained  
5617 in the specific monitoring techniques and procedures used.

### 5618 **E. Principle #5: Establish Corrective Actions**

#### 5619 **1. What are corrective actions?**

5620 Corrective actions are activities that are taken by a person whenever a critical  
5621 limit is not met. Discarding food that may pose an unacceptable food safety risk  
5622 to consumers is a corrective action. However, other corrective actions such as  
5623 further cooking or reheating a product can be used provided food safety is not  
5624 compromised. For example, a restaurant may be able to continue cooking  
5625 hamburgers that have not reached an internal temperature of 155°F for 15  
5626 seconds until the proper temperature is met. Clear instructions should be  
5627 developed detailing who is responsible for performing the corrective actions, the  
5628 procedures to be followed, and when.

### 5629 **F. Principle #6: Establish Verification Procedures**

#### 5630 **1. What is verification?**

5631 Verification includes those activities, other than monitoring, that determine the  
5632 validity of the HACCP plan and show that the system is operating according to  
5633 the plan. Validation is a component of verification which focuses on collecting  
5634 and evaluating scientific and technical information to determine if the HACCP  
5635 system, when properly implemented, will effectively control the hazards. Clear  
5636 instructions should be developed detailing who is responsible for conducting  
5637 verification, the frequency of verification, and the procedures used.

5638 **2. — ~~What is the frequency of verification activities? What are some~~**  
5639 **~~examples of verification activities?~~**

5640 Verification activities are conducted frequently, such as daily, weekly, monthly,  
5641 and include the following:

- 5642 ~~▪—observing the person doing the monitoring and determining whether~~  
5643 ~~monitoring is being done as planned~~
- 5644 ~~▪—reviewing the monitoring records to determine if they are completed~~  
5645 ~~accurately and consistently~~
- 5646 ~~▪—determining whether the records show that the frequency of monitoring~~  
5647 ~~stated in the plan is being followed~~
- 5648 ~~▪—ensuring that corrective action was taken when the person monitoring found~~  
5649 ~~and recorded that the critical limit was not met~~
- 5650 ~~▪—validating that the critical limits are achieving the desired results of~~  
5651 ~~controlling the identified hazard~~
- 5652 ~~▪—confirming that all equipment, including equipment used for monitoring, is~~  
5653 ~~operated, maintained, and calibrated properly.~~

5654 **G. — ~~Principle #7: Establish Record Keeping Procedures~~**

5655 **1. — ~~Why are records important?~~**

5656 Maintaining documentation of the activities in a food safety management system  
5657 can be vital to its success. Records provide documentation that appropriate  
5658 corrective actions were taken when critical limits were not met. In the event that  
5659 an establishment is implicated in a foodborne illness, documentation of activities  
5660 related to monitoring and corrective actions can provide proof that reasonable  
5661 care was exercised in the operation of the establishment. Documenting activities  
5662 provides a mechanism for verifying that the activities in the HACCP plan were  
5663 properly completed. In many cases, records can serve a dual purpose of ensuring  
5664 quality and food safety.

5665 **2. — ~~What types of records are maintained as part of a food safety~~**  
5666 **~~management system?~~**

5667 There are at least 5 types of records that could be maintained to support a food  
5668 safety management system:

- 5669 ~~▪—records documenting the activities related to the prerequisite programs~~
  - 5670 ~~▪—monitoring records~~
  - 5671 ~~▪—corrective action records~~
  - 5672 ~~▪—verification and validation records~~
  - 5673 ~~▪—calibration records.~~
- 5674

5675  
5676 **3. The Process Approach – A Practical Application of HACCP at Retail to Achieve**  
5677 **Active Managerial Control**

5678 **A. Why Focus on HACCP Principles at Retail and Food Service?**

5679 FDA recognizes that there are important differences between using HACCP principles in  
5680 a food safety management system developed for food manufacturing plants and applying  
5681 these same principles in food safety management system developed for use in retail and  
5682 food service establishments.

5683 Since the 1980's, operators and regulators have been exploring the use of the HACCP  
5684 principles in restaurants, grocery stores, institutional care facilities, and other retail food  
5685 establishments. During this time, much has been learned about how these principles can  
5686 be used in these varied operations, collectively referred to as retail food establishments.  
5687 Most of this exploration has centered around the focal question of how to stay true to the  
5688 NACMCF definitions of HACCP and still make the principles useful to an industry that  
5689 encompasses the broadest range of conditions.

5690 Unlike industries such as canning, other food processing, and dairy plants, the retail  
5691 industry is not easily defined by specific commodities or conditions. Consider the  
5692 following characteristics that retail food establishments share that set them apart from  
5693 most food processors:

- 5694 1. Employee and management turnover is exceptionally high in food  
5695 establishments, especially for entry level positions. This means the many  
5696 employees or managers have little experience and food safety training must be  
5697 continuously provided.
- 5698 2. Many establishments are start-up businesses operating without benefit of a large  
5699 corporate support structure and having a relatively low profit margin and perhaps  
5700 less capital to work with than other segments of the food industry.
- 5701 3. There is an almost endless number of production techniques, products, menu  
5702 items, and ingredients used which are not easily adapted to a simple, standardized  
5703 approach. Changes occur frequently and little preparation time is available.

5704 FDA fully recognizes the diversity of retail and food service establishments and their  
5705 varying in-house resources to implement HACCP. That recognition is combined with an  
5706 understanding that the success of such implementation is dependent upon establishing  
5707 realistic and useful food safety strategies that are customized to the operation.

5708 **B. What is the Process Approach?**

5709 When conducting the hazard analysis, food manufacturers usually use food commodities  
5710 as an organizational tool and follow the flow of each product. This is a very useful  
5711 approach for producers or processors since they are usually handling one product at a  
5712 time. By contrast, in retail and food service operations, foods of all types are worked  
5713 together to produce the final product. This makes a different approach to the hazard  
5714 analysis necessary. Conducting the hazard analysis by using the food preparation  
5715 processes common to a specific operation is often more efficient and useful for retail and  
5716 food service operators. This is called the "process approach" to HACCP.

5717 The process approach can best be described as dividing the many food flows in an  
 5718 establishment into broad categories based on activities or stages in the preparation of the  
 5719 food, then analyzing the hazards, and placing managerial controls on each grouping.

5720 **~~C. What are the three food preparation processes most often used in retail and~~**  
 5721 **~~food service establishments and how are they determined?~~**

5722 The flow of food in a retail or food service establishment is the path that food follows  
 5723 from receiving through service or sale to the consumer. Several activities or stages make  
 5724 up the flow of food and are called operational steps. Examples of operational steps  
 5725 include receiving, storing, preparing, cooking, cooling, reheating, holding, assembling,  
 5726 packaging, serving, and selling. The terminology used for operational steps may differ  
 5727 between food service and retail food store operations.

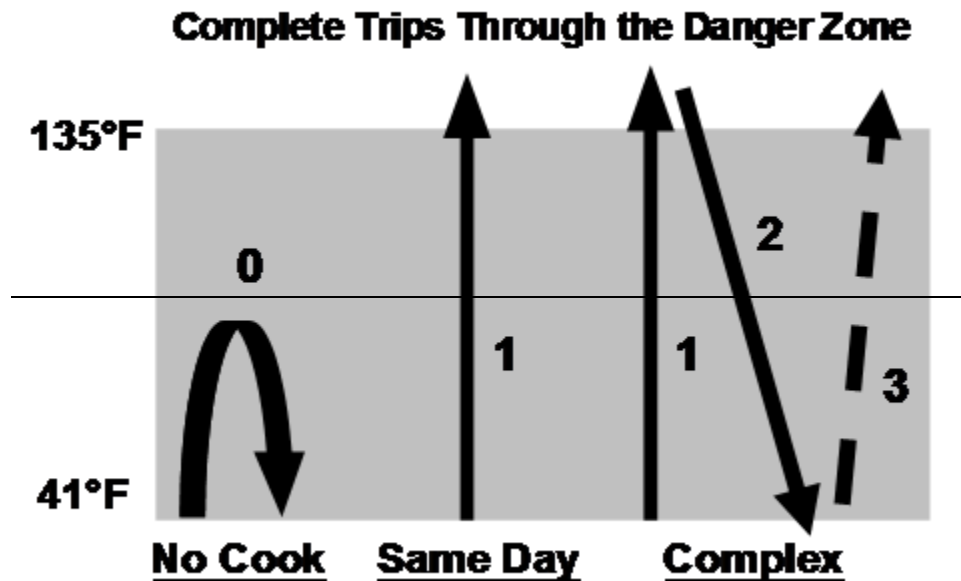
5728 Most food items produced in a retail or food service establishment can be categorized  
 5729 into one of three preparation processes based on the number of times the food passes  
 5730 through the temperature danger zone between 41°F and 135°F:

5731 ~~○ **Process 1: Food Preparation with No Cook Step**~~  
 5732 ~~**Example flow: Receive – Store – Prepare – Hold – Serve**~~  
 5733 ~~(other food flows are included in this process, but there is no cook step to destroy~~  
 5734 ~~pathogens)~~

5735 ~~○ **Process 2: Preparation for Same Day Service**~~  
 5736 ~~**Example flow: Receive – Store – Prepare – Cook – Hold – Serve**~~  
 5737 ~~(other food flows are included in this process, but there is only one trip through the~~  
 5738 ~~temperature danger zone)~~

5739 ~~○ **Process 3: Complex Food Preparation**~~  
 5740 ~~**Example flow: Receive – Store – Prepare – Cook – Cool – Reheat – Hot Hold – Serve**~~  
 5741 ~~(other food flows are included in this process, but there are always two or more complete~~  
 5742 ~~trips through the temperature danger zone)~~

5743 A summary of the three food preparation processes in terms of number of times through  
 5744 the temperature danger zone can be depicted in a Danger Zone diagram. Although foods  
 5745 produced using process 1 may enter the danger zone, they do not pass all the way through  
 5746 it. Foods that go through the danger zone only once are classified as Same Day Service,  
 5747 while foods that go through more than once are classified as Complex food preparation.



5748

5749 The three food preparation processes conducted in retail and food service establishments  
 5750 are not intended to be all-inclusive. For instance, quick service facilities may have "cook  
 5751 and serve" processes specific to their operation. These processes are likely to be different  
 5752 from the "Same Day Service" preparation processes in full service restaurants since many  
 5753 of their foods are generally cooked and hot held before service. In addition, in retail food  
 5754 stores, operational steps such as packaging and assembly may be included in all of the  
 5755 food preparation processes before the product is sold to the consumer. It is also very  
 5756 common for a retail or food service operator to use multiple food preparation processes to  
 5757 create a single menu item.

5758 **D. How is a hazard analysis conducted in process HACCP?**

5759 In the process approach to HACCP, conducting a hazard analysis on individual food  
 5760 items is time and labor intensive and is generally unnecessary. Identifying and controlling  
 5761 the hazards in each food preparation process achieves the same control of risk factors as  
 5762 preparing a HACCP plan for each individual product.

5763 Example: An establishment has dozens of food items (including baked chicken and baked  
 5764 meatloaf) in the "Preparation for Same Day Service" category. Each of the food items  
 5765 may have unique hazards, but regardless of the individual hazards, control via proper  
 5766 cooking and holding will generally ensure the safety of all of the foods in this category.  
 5767 An illustration of this concept follows:

5768 1. Even though they have unique hazards, baked chicken and meatloaf are items  
 5769 frequently grouped in the "Same Day Service" category (Process 2).

5770 2. Salmonella spp. and Campylobacter, as well as spore formers, such as Bacillus cereus  
 5771 and Clostridium perfringens, are significant biological hazards in chicken.

- 5772 3. ~~Significant biological hazards in meatloaf include Salmonella spp., E. coli~~  
 5773 ~~O157:H7, Bacillus cereus, and Clostridium perfringens.~~
- 5774 4. ~~Despite their different hazards, the control measure used to kill pathogens in both~~  
 5775 ~~these products is cooking to the proper temperature.~~
- 5776 5. ~~Additionally, if the products are held after cooking, then proper hot holding or~~  
 5777 ~~time control is also required to prevent the outgrowth of spore formers that are~~  
 5778 ~~not destroyed by cooking.~~

5779 As with product-specific HACCP, critical limits for cooking remain specific to each food  
 5780 item in the process. In the scenario described above, the cooking step for chicken requires  
 5781 a final internal temperature of 165°F for 15 seconds to control the pathogen load for  
 5782 Salmonella spp. Meatloaf, on the other hand, is a ground beef product and requires a final  
 5783 internal temperature of 155°F for 15 seconds to control the pathogen load for both  
 5784 Salmonella spp. and E. coli O157:H7. Some operational steps such as refrigerated storage  
 5785 or hot holding have critical limits that apply to all foods.

5786 Appendix G, Table 4 further illustrates this concept. Note that the only unique control  
 5787 measure applies to the critical limit of the cooking step for each of the products. Other  
 5788 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**

| <b>Process 2: Preparation for Same Day Service</b> |   |   |
|--|---|---|
| <b>Example Products</b>                            | <b>Baked Meatloaf</b>   | <b>Baked Chicken</b>  |
| <b>Example Biological Hazards</b>                  | 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  |
| <b>Example Control Measures</b>                    | 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) |

5789 \*RTE = ready to eat food

5790 **E. — How is the process approach helpful to industry in determining the measures**  
 5791 **that must be implemented to actively manage the foodborne illness risk**  
 5792 **factors that result in out-of-control hazards?**

5793 ~~Even though variations in foods and in the three food preparation process flows used to~~  
 5794 ~~prepare them are common, the control measures will generally be the same based on the~~  
 5795 ~~number of times the food goes through the temperature danger zone. Several of the most~~  
 5796 ~~common control measures associated with each food preparation process are discussed in~~  
 5797 ~~this Appendix. Retail or food service establishments should use these simple control~~  
 5798 ~~measures as the core of their food safety management systems; however, there may be~~  
 5799 ~~other risk factors unique to an operation or process that are not listed here. Each operation~~  
 5800 ~~should be evaluated independently.~~

5801 ~~In developing a voluntary food safety management system, active managerial control of~~  
 5802 ~~risk factors common to each process can be achieved by implementing control measures~~  
 5803 ~~at certain operational steps designated as critical control points (CCPs) or by~~  
 5804 ~~implementing prerequisite programs. This is explained in more detail in the Operator's~~  
 5805 ~~Manual discussed in Part 5 of this Appendix.~~

5806 **F. — Facility-wide Considerations**

5807 In order to have active managerial control over personal hygiene and cross  
 5808 contamination, certain control measures must be implemented in all phases of the  
 5809 operation. All of the following control measures should be implemented regardless of the  
 5810 food preparation process used:

- 5811 ○ ~~No bare hand contact with ready to eat foods (or use of a pre approved, alternative~~  
 5812 ~~procedure) to help prevent the transfer of viruses, bacteria, or parasites from hands to~~  
 5813 ~~food~~
- 5814 ○ ~~Proper handwashing to help prevent the transfer of viruses, bacteria, or parasites from~~  
 5815 ~~hands to food~~
- 5816 ○ ~~Restriction or exclusion of ill employees to help prevent the transfer of viruses,~~  
 5817 ~~bacteria, or parasites from hands to food~~
- 5818 ○ ~~Prevention of cross contamination of ready to eat food or clean and sanitized food-~~  
 5819 ~~contact surfaces with soiled cutting boards, utensils, aprons, etc., or raw animal foods.~~

5820 **G. — Food Preparation Process 1 — Food Preparation with No Cook Step**

5821 Example Flow: RECEIVE → STORE → PREPARE → HOLD → SERVE

5822 Several food flows are represented by this particular process. Many of these food flows  
 5823 are common to both retail food stores and food service facilities, while others only apply  
 5824 to retail operations. Raw, ready to eat food like sashimi, raw oysters, and salads are  
 5825 grouped in this category. Components of these foods are received raw and will not be  
 5826 cooked before consumption.

5827 Foods cooked at the processing level but that undergo no further cooking at the retail  
 5828 level before being consumed are also represented in this category. Examples of these  
 5829 kinds of foods are deli meats, cheeses, and other pasteurized dairy products (such as  
 5830 yogurt). In addition, foods that are received and sold raw but are to be cooked by the

5831 consumer after purchase, e.g., hamburger meat, chicken, and steaks, are also included in  
5832 this category.

5833 All the foods in this category lack a cook step while at the retail or food service facility;  
5834 thus, there are no complete trips through the danger zone. Purchase specifications can be  
5835 required by the retail or food service establishment to ensure that foods are received as  
5836 safe as possible. Without a kill step to destroy pathogens, preventing further  
5837 contamination by ensuring that employees follow good hygienic practices is an important  
5838 control measure.

5839 Cross-contamination must be prevented by properly storing ready-to-eat food away from  
5840 raw animal foods and soiled equipment and utensils. Foodborne illness may result from  
5841 ready-to-eat food being held at unsafe temperatures for long periods of time due to the  
5842 outgrowth of bacteria.

5843 In addition to the facility-wide considerations, a food safety management system  
5844 involving this food preparation process should focus on ensuring active managerial  
5845 control over the following:

5846 ○ Cold holding or using time alone to control bacterial growth and toxin production

5847 ○ Food source (e.g., shellfish due to concerns with viruses, natural toxins, and *Vibrio*  
5848 and for certain marine finfish intended for raw consumption due to concerns with  
5849 ciguatera toxin)

5850 ○ Receiving temperatures (e.g., certain species of marine finfish due to concerns with  
5851 secombrototoxin)

5852 ○ Date marking of ready-to-eat PHF (TCS food) held for more than 24 hours to control  
5853 the growth of psychrophiles such as *Listeria monocytogenes*

5854 ○ Freezing certain species of fish intended for raw consumption due to parasite  
5855 concerns

5856 ○ Cooling from ambient temperature to prevent the outgrowth of spore-forming or  
5857 toxin-forming bacteria.

## 5858 **H. Food preparation Process 2 – Preparation for Same Day Service**

5859 Example Flow: RECEIVE → STORE → PREPARE → COOK → HOLD → SERVE

5860 In this food preparation process, food passes through the danger zone only once in the  
5861 retail or food service facility before it is served or sold to the consumer. Food is usually  
5862 cooked and held hot until served, e.g., fried chicken, but can also be cooked and served  
5863 immediately. In addition to the facility-wide considerations, a food safety management  
5864 system involving this food preparation process should focus on ensuring active  
5865 managerial control over the following:

5866 ○ **Cooking** to destroy bacteria and parasites

5867 ○ **Hot holding or using time alone** to prevent the outgrowth of spore-forming bacteria.



5868 Approved food source, proper receiving temperatures, and proper cold holding before  
 5869 cooking would also be important if dealing with certain marine finfish due to concerns  
 5870 with ciguatera toxin and scombrototoxin.

#### 5871 ~~I. Food Preparation Process 3 – Complex Food Preparation~~

5872 Example Flow: RECEIVE → STORE → PREPARE → COOK → COOL → REHEAT  
 5873 HOT HOLD → SERVE

5874 Foods prepared in large volumes or in advance for next day service usually follow an  
 5875 extended process flow. These foods pass through the temperature danger zone more than  
 5876 one time; thus, the potential for the growth of spore forming or toxigenic bacteria is  
 5877 greater in this process. Failure to adequately control food product temperatures is one of  
 5878 the most frequently encountered risk factors contributing to foodborne illness. Food  
 5879 handlers should minimize the time foods are at unsafe temperatures.

5880 In addition to the facility wide considerations, a food safety management system  
 5881 involving this food preparation process should focus on ensuring active managerial  
 5882 control over the following:

- 5883 ○ ~~Cooking~~ to destroy bacteria and parasites
- 5884 ○ ~~Cooling~~ to prevent the outgrowth of spore forming or toxin forming bacteria
- 5885 ○ ~~Hot and cold holding or using time alone~~ to control bacterial growth and toxin  
 5886 formation
- 5887 ○ ~~Date marking~~ of ready to eat PHF (TCS food) held for more than 24 hours to control the  
 5888 growth of psychrophiles such as *Listeria monocytogenes*
- 5889 ○ ~~Reheating~~ for hot holding, if applicable.

5890 Approved food source, proper receiving temperatures, and proper cold holding before  
 5891 cooking would also be important if dealing with certain marine finfish due to concerns  
 5892 with ciguatera toxin and scombrototoxin.

#### 5893 ~~4. FDA Retail HACCP Manuals~~

5894 ~~A. What guidance has been developed by FDA to assist operators of retail and food  
 5895 service establishments in achieving active managerial control of foodborne illness  
 5896 risk factors?~~

5897 FDA, in partnership with Federal, State, and local regulators, industry, academia, and  
 5898 consumers, has written a guidance document entitled, "Managing Food Safety: A Manual  
 5899 for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail  
 5900 Establishments".<sup>7</sup> Commonly referred to as the "Operator's Manual," this document is  
 5901 designed to assist operators with developing or enhancing food safety management  
 5902 systems based on the process approach to HACCP. The manual presents a step-by-step  
 5903 procedure for writing and voluntarily implementing a food safety management system  
 5904 based on the principles of HACCP. The desired outcome is an operator who employs a  
 5905 preventive rather than a reactive strategy to food safety.

5906 The Operator's Manual embodies FDA's current thinking on the application of HACCP  
 5907 principles at retail. It advocates the voluntary use of HACCP principles using the process  
 5908 approach as a practical and effective means of reducing the occurrence of foodborne

5909 illness risk factors leading to out-of-control hazards. The Operator's Manual is strictly for  
 5910 the voluntary implementation of HACCP principles at retail and should not be used to  
 5911 develop HACCP plans that are required through Federal, State, or local regulations,  
 5912 ordinances, or laws.

5913 **B. ~~What guidance has been developed by FDA to assist regulators of retail and~~**  
 5914 **~~food service establishments in assessing industry's active managerial control~~**  
 5915 **~~of foodborne illness risk factors?~~**

5916 FDA has written a document for regulators of retail and food service establishments  
 5917 entitled, "Managing Food Safety: A Regulator's Manual for Applying HACCP Principles  
 5918 to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food  
 5919 Safety Management Systems." Commonly referred to as the "Regulator's Manual," this  
 5920 document was written to provide a risk-based inspectional "roadmap" for evaluating the  
 5921 degree of active managerial control an operator has over foodborne illness risk factors.

5922 In addition, the manual advocates the use of voluntary intervention strategies, including  
 5923 the development of food safety management systems or risk control plans to bring about  
 5924 a long-term behavior change that will result in a reduction in the occurrence of risk  
 5925 factors. In cases where an operator may want their inspector to provide them with  
 5926 feedback on their voluntarily implemented food safety management system, the manual  
 5927 provides regulators with information on how to validate and verify an existing system.

5928 Annex 5 of the Food Code outlines the basis for conducting successful risk-based  
 5929 inspections and is provided to assist industry in achieving active managerial control of  
 5930 foodborne illness risk factors as outlined in the draft Recommended National Retail Food  
 5931 Regulatory Program Standards and the Regulator's Manual.

## 5932 **5. ~~Advantages of the HACCP Principles~~**

5933 **A. ~~What advantages does using HACCP principles offer operators of retail and food~~**  
 5934 **~~service establishments?~~**

5935 Rather than relying solely on periodic feedback from inspections by regulatory agencies,  
 5936 an establishment operator who implements a food safety management system based on  
 5937 HACCP principles emphasizes continuous problem-solving and prevention. Additionally,  
 5938 HACCP enhances and encourages communication between industry and regulators.

5939 A food safety management system based on HACCP principles offers many other  
 5940 advantages to industry. One advantage is that such a system may provide a method for  
 5941 achieving active managerial control of multiple risk factors associated with an entire  
 5942 operation. Other advantages include:

- 5943 ○ ~~Reduction in product loss~~
- 5944 ○ ~~Increase in product quality~~
- 5945 ○ ~~Better inventory control~~
- 5946 ○ ~~Consistency in product preparation~~
- 5947 ○ ~~Increase in profit~~
- 5948 ○ ~~Increased employee awareness and participation in food safety.~~

5949 **B. ~~What advantage does using HACCP principles offer regulators of retail and food~~**  
5950 **~~service establishments?~~**

5951 Traditional inspections are relatively resource-intensive, inefficient, and reactive rather  
5952 than preventive in nature. Using traditional inspection techniques allows for a satisfactory  
5953 "snapshot" assessment of the requirements of the code at the time of the inspection.  
5954 Unfortunately, unless an inspector asks questions and inquires about the activities and  
5955 procedures being utilized by the establishment even at times when the inspector is not  
5956 there, there is no way to know if an operator is achieving active \_\_\_\_\_

5957 With the limited time often available for conducting inspections, regulators must focus  
5958 their attention on those areas that clearly have the greatest impact on food safety—  
5959 foodborne illness risk factors. By knowing that there are only a few control measures that  
5960 are essential to food safety and focusing on these during the inspection, an inspector can  
5961 assess the operator's active managerial control of the foodborne illness risk factors.

5962 Regulators can provide invaluable feedback to an operator through their routine  
5963 inspections. This is especially useful when utilizing a risk-based approach. By  
5964 incorporating HACCP principles into routine inspections, an inspector can provide an  
5965 operator with the constructive input needed to establish the control system necessary to  
5966 bring the foodborne illness risk factors back under continuous control.

5967 **6. ~~Summary~~**

5968 In order to make a positive impact on foodborne illness, retail and food service operators must  
5969 achieve active managerial control of the risk factors contributing to foodborne illness. Combined  
5970 with basic sanitation, employee training, and other prerequisite programs, the principles of  
5971 HACCP provide an effective system for achieving this objective.

5972 The goal in applying HACCP principles in retail and food service is to have the operator take  
5973 purposeful actions to ensure safe food. The process approach simplifies HACCP principles for  
5974 use in retail and food service. This practical and effective method of hazard control embodies the  
5975 concept of active managerial control by providing an on-going system of simple control measures  
5976 that will reduce the occurrence of risk factors that lead to out-of-control hazards.

5977 The role of retail and food service regulatory professionals is to conduct risk-based inspections  
5978 using HACCP principles to assess the degree of control industry has over the foodborne illness  
5979 risk factors. Regulators can assist industry in achieving active managerial control of risk factors  
5980 by using a risk-based inspection approach to identify strengths and weaknesses and suggesting  
5981 possible solutions and improvements.

5982

5983

5984 **7. Acknowledgements**

5985 Much of this Appendix is adapted from the National Advisory Committee on Microbiological  
5986 Criteria for Foods, Hazard Analysis and Critical Control Point Principles and Guidelines, adopted  
5987 August 14, 1997.

5988 The physical hazards table (Table 3) was provided courtesy of "Overview of Biological,  
5989 Chemical, and Physical Hazards" in "HACCP Principles and Applications," Merle Pierson and  
5990 Donald A. Corlett, Jr. (Eds.), 1992. p. 8-28. Chapman and Hall, New York.

5991 Based on a recommendation from the Retail HACCP Committee of the Conference for Food  
5992 Protection, the two HACCP Manuals have been endorsed by the Conference.

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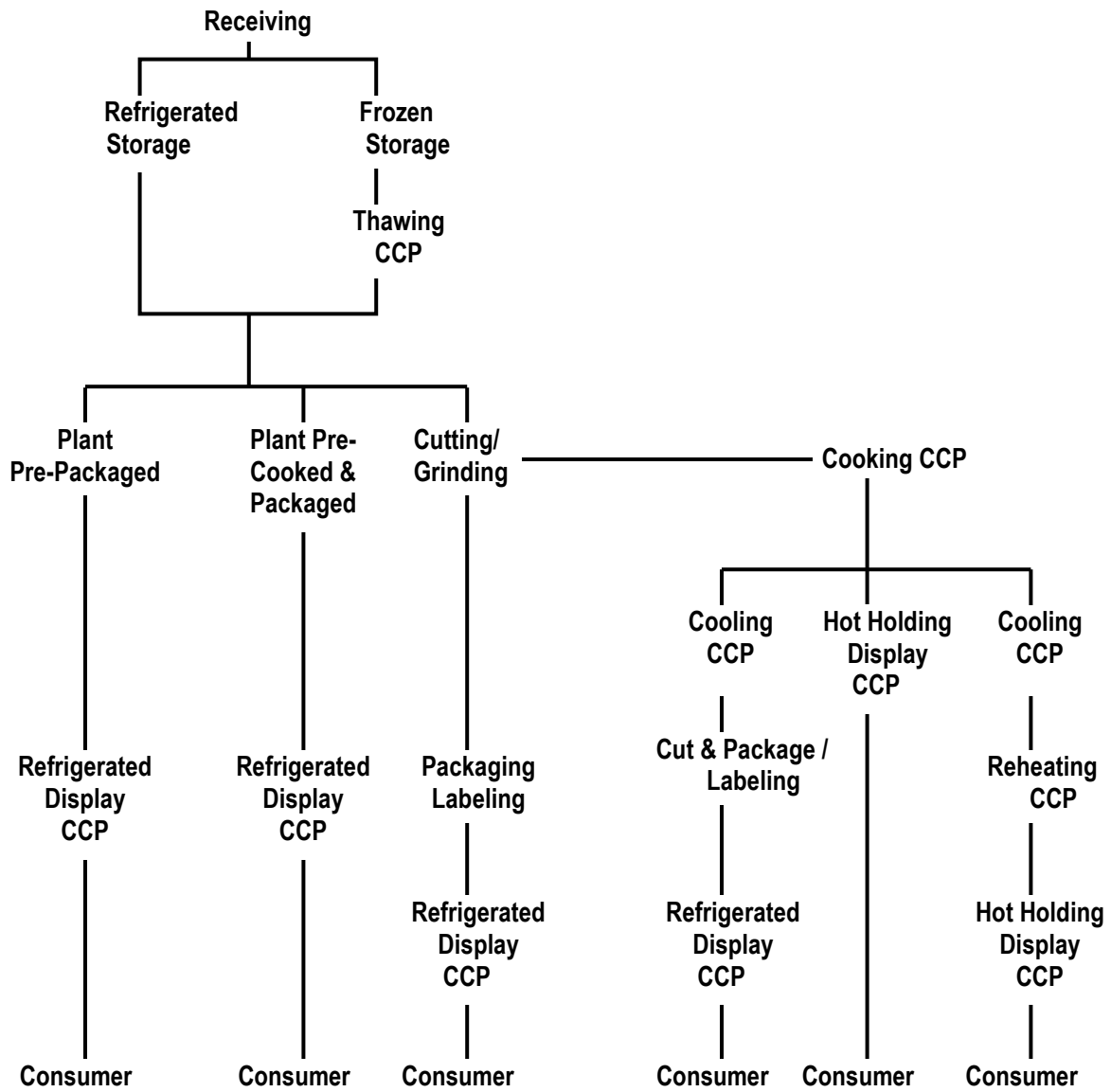
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6060 ~~703 487 4650.~~
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6062 ~~obtained as long as supplies last from FDA district offices and from:~~
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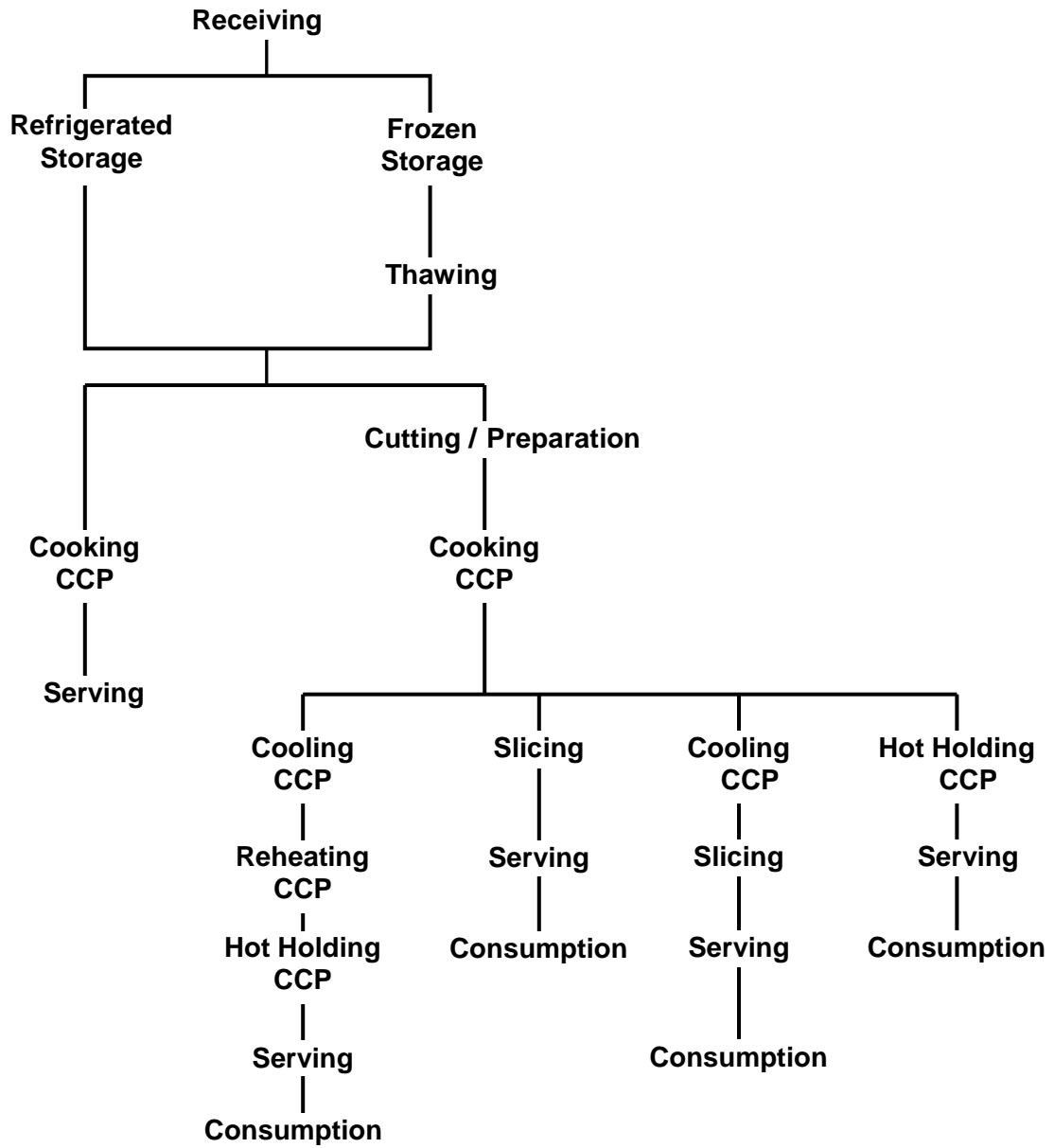
**Two Typical Flow Diagrams**

**Flow Chart 1**



6075

### Flow Chart 2





6076

***Appendix H – RETAIL FOOD STORE SANITATION ACT***

6077 ~~25-4-1301. Legislative declaration. The general assembly hereby declares that the sanitary protection of~~  
6078 ~~bulk foods and the sanitary maintenance of equipment used to display and dispense bulk foods are matters~~  
6079 ~~of statewide concern and are affected with a public interest and that the provisions of this part 13 are~~  
6080 ~~enacted in the exercise of the police powers of this state for the purpose of protecting the health, peace,~~  
6081 ~~safety, and general welfare of the people of this state.~~

6082 ~~25-4-1302. Definitions. As used in this part 13, unless the context otherwise requires:~~

6083 ~~(1) “Bulk foods” means unpackaged or unwrapped foods, either processed or unprocessed, in aggregate~~  
6084 ~~containers from which quantities desired by the consumer are withdrawn. “Bulk foods” does not include~~  
6085 ~~fresh fruits, fresh vegetables, nuts in the shell, salad bar, bulk pet foods, potentially hazardous foods, and~~  
6086 ~~bulk nonfood items.~~

6087 ~~(2) “Department” means the department of health.~~

6088 ~~(3) “Display area” means a location including physical facilities and equipment, where bulk foods are~~  
6089 ~~offered for customer self service.~~

6090 ~~(4) “Potentially hazardous foods” includes any food that consists in whole or in part, of milk or milk~~  
6091 ~~products, eggs, meat, poultry, fish, shellfish, edible crustacea, or other food products or ingredients,~~  
6092 ~~including synthetic ingredients, in a form capable of supporting rapid and progressive growth of~~  
6093 ~~infectious or toxigenic microorganisms. This term does not include refrigerated, clean, whole, uncracked,~~  
6094 ~~odor-free shell eggs.~~

6095 ~~(5) “Product module” means a food contact container (multiuse or single service) designed for customer~~  
6096 ~~self service of bulk foods by either direct or indirect means.~~

6097 ~~(6) “Servicing area” means a designated location equipped for cleaning, sanitizing drying, or refilling~~  
6098 ~~product modules or for preparing bulk foods.~~

6099 ~~25-4-1303. Labeling – product modules – take home containers. (1) product modules shall be labeled with~~  
6100 ~~either:~~

6101 ~~(a) The manufacturer's or processor's bulk food container labeling plainly in view; or~~

6102 ~~(b) A counter card, a counter sign, or any other appropriate device bearing prominently and conspicuously~~  
6103 ~~the common name of the product, a list of ingredients in their proper order of predominance, and a~~  
6104 ~~declaration of artificial color or flavor and chemical preservatives if contained in the product.~~

6105 ~~(2) any unpack aged bulk food need not comply with the labeling requirements of this section if the~~  
6106 ~~unpackaged bulk food is manufactured on the premises of a store or manufactured by the same store at the~~  
6107 ~~different location and if the manufactured bulk food is offered for retail sale on the store's premises and if~~  
6108 ~~there are no state requirements.~~

6109 ~~(3) Labels or marking pens shall be available to customers to identify their take home containers with the~~  
6110 ~~common name of the product unless the product is readily identifiable on sight.~~

6111 ~~25-4-1304. Bulk food protection. (1) Bulk foods and product modules shall be protected from~~  
6112 ~~contamination during , display, customer self service, refilling, and storage.~~

- 6113 ~~(2) Containers of bulk pet foods and bulk nonfood items shall be separated from product modules by a~~  
6114 ~~barrier or open space.~~
- 6115 ~~(3) Bulk foods returned to stores by customers shall not be offered for resale.~~
- 6116 ~~(4) Only containers provided by stores in their display areas shall be filled with bulk foods; except that~~  
6117 ~~any customer may fill or refill his own containers with vended or dispensed water; however, the risk that~~  
6118 ~~the customer's own container is unsafe, unpure, contaminated, or in a non-sterile condition when it is~~  
6119 ~~filled or refilled by the customer, shall be borne solely by the customer, and, except for warranties, no~~  
6120 ~~liability shall attach thereto to the manufacturer, seller, or dispenser of such container.~~
- 6121 ~~25-4-1305. Bulk food display. (1) Bulk foods shall be dispensed only from product modules which are~~  
6122 ~~protected by close fitting, individual covers. If any product module is to be opened by customers, the~~  
6123 ~~cover shall be self-closing and shall remain close when not in use.~~
- 6124 ~~(2) Customer access to bulk foods in product modules shall be limited and controlled to avoid the~~  
6125 ~~introduction of contaminants. All product modules shall have an access height of thirty inches or more~~  
6126 ~~above the floor and a depth of eighteen inches or less.~~
- 6127 ~~(3) Potentially hazardous foods shall not be made available for customer self-service.~~
- 6128 ~~25-4-1306. Dispensing utensils. (1) Manual handling of bulk foods by customers during dispensing shall~~  
6129 ~~be discouraged. Mechanical dispensing devices shall be used, including gravity dispensers, pumps,~~  
6130 ~~extruders, and augers. Manual dispensing utensils shall also be used, including tongs, scoops, ladles, and~~  
6131 ~~spatulas.~~
- 6132 ~~(2) If the dispensing devices and utensils listed in subsection (1) of this section do not discourage manual~~  
6133 ~~customer handling of bulk foods, such bulk foods must be wrapped or sacked prior to display.~~
- 6134 ~~(3) Manual dispensing utensils shall be protected against becoming contaminated and serving as vehicles~~  
6135 ~~for introducing contamination into bulk foods. A tether of easily cleanable material shall be attached to~~  
6136 ~~such a utensil and shall be of such length that the utensil cannot contact the floor. A sleeve or protective~~  
6137 ~~housing attached or adjacent to the display unit shall be available for storing a utensil when not in use.~~
- 6138 ~~(4) Ladles and spatulas shall be stored in bulk foods with handles extending to the outside of product~~  
6139 ~~modules. Handles shall not prevent lids from being self-closing.~~
- 6140 ~~25-4-1307. Materials. Product modules and utensils shall be constructed of safe materials and shall be~~  
6141 ~~corrosion resistant, nonabsorbent, smooth, easily cleanable, and durable under conditions of normal use.~~  
6142 ~~Wood shall not be used as a food-contact surface.~~
- 6143 ~~25-4-1308. Food contact surfaces. Product modules, lids, dispensing units, and utensils shall be designed~~  
6144 ~~and fabricated to meet the requirements for food-contact surfaces, as provided in section 25-4-1307.~~
- 6145 ~~25-4-1309. Non food contact surfaces. Surfaces of product module display units, tethers, and display~~  
6146 ~~equipment which are not intended for food contact but which are exposed to splash, food debris, or other~~  
6147 ~~soiling shall be designed and fabricated to be smooth, cleanable, durable under conditions of normal use,~~  
6148 ~~and free of unnecessary ledges, projections, and crevices. The materials for non-food contact surfaces~~  
6149 ~~shall be nonabsorbent or made nonabsorbent by being finished and sealed with a cleanable coating.~~
- 6150 ~~25-4-1310. Accessibility. Individual product modules shall be designed to be easily removable from a~~  
6151 ~~display unit for servicing unless the product modules are so designed and fabricated that they can be~~

6152 effectively cleaned and sanitized when necessary through a manual in place cleaning procedure that will  
6153 not contaminate or otherwise adversely affect bulk foods or equipment in any adjoining display areas.

6154 ~~25-4-1311. Equipment sanitization. (1) Tongs, scoops, ladles, spatulas, and other appropriate utensils and~~  
6155 ~~tethers used by customers shall be cleaned and sanitized at least daily or at more frequent intervals based~~  
6156 ~~on the type of bulk food and the amount of food particle accumulation or soiling.~~

6157 ~~(2) When soiled, product modules, lids, and other equipment shall be cleaned and sanitized prior to~~  
6158 ~~restocking or at intervals of a schedule based on the type of bulk food and the amount of food particle~~  
6159 ~~accumulation.~~

6160 ~~(3) Food contact surfaces shall be cleaned and sanitized immediately if contamination is observed or~~  
6161 ~~suspected.~~

6162 ~~(4) Facilities and equipment shall be available, either in a servicing area or in place, to provide for the~~  
6163 ~~proper cleaning and sanitizing of all food contact surfaces, including product modules, lids, and~~  
6164 ~~dispensing utensils.~~

6165 ~~(5) Take home containers, including but not limited to bags, cups, and lids, which are provided in a~~  
6166 ~~display area for customer use shall be stored and dispensed in a sanitary manner.~~

6167 ~~25-4-1312. Violation - Penalty. Any retail food store owner violating any of the provisions of this part 13~~  
6168 ~~is guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not more than five~~  
6169 ~~hundred dollars, or by imprisonment in the county jail for not more than ninety days, or by both such fine~~  
6170 ~~and imprisonment. It is the duty of the district attorneys of the several districts of this state to prosecute~~  
6171 ~~for violations of this part 13 as for other crimes and misdemeanors.~~

6172 ~~25-4-1313. Rules and regulations. The department has the power to promulgate rules and regulations for~~  
6173 ~~the implementation of this part 13.~~

6174 ~~25-4-1314. Limitation. The provisions of this part 13 shall be expressly limited to retail food store outlets.~~

***APPENDIX I - Equipment Investigation Report***

6175  
6176

6177 ~~Section 4-101 of the Colorado Retail Food Establishment Rules and Regulation specify all equipment,~~  
6178 ~~utensils and single service articles shall be fabricated with safe materials; be of commercial design, that is~~  
6179 ~~certified or classified by an American National Standards Institute (ANSI) accredited certification~~  
6180 ~~program, such as the National Sanitation Foundation (NSF), Underwriters Laboratories (UL) sanitation~~  
6181 ~~standards, Environmental Testing Laboratories, Inc. (ETL) sanitation standards, Baking Industry~~  
6182 ~~Sanitation Standards Committee (BISSC), or other comparable design criteria as approved by the~~  
6183 ~~Department during a standardized equipment review.~~

6184 ~~If a retail food establishment intends to have any equipment, utensils and single service articles approved~~  
6185 ~~by the Department, the approval will be based upon submission of the following information to be~~  
6186 ~~provided to the local public health agency and/or the Colorado Department of Public Health and~~  
6187 ~~Environment for evaluation.~~

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**COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT  
4300 CHERRY CREEK DRIVE SOUTH  
DENVER, CO 80246-1530**

| <b>EQUIPMENT INVESTIGATION REPORT</b>   |                          |
|---|--------------------------|
| 1. LOCATION (STATE AND COUNTY)  |                          |
| 2. RECOMMENDATION<br><br><input type="checkbox"/> ACCEPT<br><input type="checkbox"/> REJECT   |                          |
| 3. PREPARED BY<br><br>NAME _____<br><br>TITLE _____<br><br>AGENCY _____<br><br>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  |                          |
| <b>EQUIPMENT INFORMATION</b>  |                          |
| 9. TRADE NAME   | 10. MODEL NUMBER         |
| 11. DESCRIPTION OF EQUIPMENT (CHECK APPROPRIATE LINE AND DESCRIBE)<br><br><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)<br><br><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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## ~~Summary of Changes to the Colorado Retail Food Establishment Rules and Regulations~~

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~~This summary provides a synopsis of the textual changes from the 2007 Colorado Retail Food Establishment Rules and Regulations to the 2013 edition. The primary intent of this record is to capture the nature of the changes rather than to identify every word or editing change. This record should not be relied upon as an absolute comparison that identifies each and every change. Section numbers listed refer to the section as it appears in the 2013 edition.~~

6205

### ~~Chapter 1— Purpose and Definitions~~

6206

6207

~~This section was revised for clarity and consistency with the FDA Model Food Code.~~

6208

6209

6210

~~1-201 ————— Added language to clarify that this regulation is intended to be the standard for the department and its authorized agents and employees, to be applied uniformly by all parties.~~

6211

~~1-201(1) ————— Added definition of “Accredited Program”~~

6212

~~1-201(3) ————— Added definition of “Allergens”~~

6213

~~1-201(6) ————— Added definition of “Asymptomatic”~~

6214

~~1-201(7) ————— Added definition of “Aw”~~

6215

~~1-201(8) ————— Added definition of “Balut”~~

6216

~~1-201(10) ————— Added definition of “Catering Operation”~~

6217

~~1-201(11) ————— Added definition of “Certified Food Protection Manager”~~

6218

~~1-201(12) ————— Added definition of “CFR”~~

6219

6220

6221

~~1-201(14) ————— Amended definition of “Commercial Design” to specify that it is certified or classified by an American National Standards Institute (ANSI) accredited certification program~~

6222

~~1-201(15) ————— Added definition of “Commingle”~~

6223

6224

6225

~~1-201(17) ————— Amended definition of “Commissary” to include language that specifies it needs to be approved by the Department and serve as a base of operation for temporary, pushcart, or mobile food operations.~~

6226

~~1-201(18) ————— Added definition of “Conditional Employee”~~

6227

6228

~~1-201(19) ————— Amended definition of “Contamination” to include language that is consistent with USDA’s definition~~



- 6229 1-201(20) ~~Added definition of “Confirmed Disease Outbreak”~~
- 6230 1-201(21) ~~Amended definition of “Corrosion Resistant Materials” to be more clear~~  
6231 ~~and concise~~
- 6232 1-201(24) ~~Added definition of “Critical Limit”~~
- 6233 1-201(25) ~~Added definition of “Cross Connection”~~
- 6234 1-201(26) ~~Added definition of “Cross Contamination”~~
- 6235 1-201(27) ~~Added definition of “Cut Leafy Greens”~~
- 6236 1-201(29) ~~Added definition of “Drinking Water” to be more in line with terms used~~  
6237 ~~by Water Quality Control Division~~
- 6238 1-201(32) ~~Added definition of “Egg”~~
- 6239 1-201(33) ~~Added definition of “Egg Product”~~
- 6240 1-201(34) ~~Revised definition of "employee" to be consistent with the Model Food Code~~
- 6241 1-201(35) ~~Added definition of “Enterohemorrhagic Escherichia Coli”~~
- 6242 1-201(36) ~~Added definition of “EPA”~~
- 6243 1-201(38) ~~Added definition of “Exclude”~~
- 6244 1-201(40) ~~Amended definition of “Fish” to include finfish~~
- 6245 1-201(43) ~~Added definition of “Foodborne Illness Risk Factor”~~
- 6246 1-201(44) ~~Added definition of “Food Employee”~~
- 6247 1-201(45) ~~Added definition of “Food Preparation”~~
- 6248 1-201(47) ~~Added definition of “Game Animal”~~
- 6249 1-201(50) ~~Added definition of “Handwashing Sink”~~
- 6250 1-201(52) ~~Added definition of “Health Practitioner”~~
- 6251 1-201(57) ~~Added definition of “Injected”~~
- 6252 1-201(58) ~~Added definition of “Inspection”~~
- 6253 1-201(59) ~~Added definition of “Juice”~~
- 6254 1-201(62) ~~Amended definition of “License” to include the term licensee~~
- 6255 1-201(63) ~~Amended definition of “Licensee” to clarify a licensee is responsible for~~  
6256 ~~the lawful operation of a retail food establishment~~
- 6257 1-201(65) ~~Added definition of “Major Food Allergen”~~

- 6258 1-201(67) ~~Added definition of “Mechanically Tenderized”~~
- 6259 1-201(69) ~~Amended “Mobile Retail Food Establishment” to include that it is a~~  
6260 ~~wheeled vehicle or trailer that is readily moveable and intended to physically~~  
6261 ~~report to and operate out of a commissary each day.~~
- 6262 1-201(71) ~~Added definition of “New Retail Food Establishment”~~
- 6263 1-201(73) ~~Added definition of “Non-Continuous Cooking”~~
- 6264 1-201(74) ~~Added definition of “Non-Critical Item”~~
- 6265 1-201(82) ~~Amended definition of “Potentially Hazardous Food” to clarify the term~~  
6266 ~~time and temperature controlled for safety, and added several matrixes to~~  
6267 ~~explain time and temperature controlled for safety in accordance with the~~  
6268 ~~Model Food Code.~~
- 6269 1-201(85) ~~Revised definition of “primal meat cuts” in accordance with the Model Food~~  
6270 ~~Code~~
- 6271 1-201(88) ~~Added definition of “Ratite”~~
- 6272 1-201(91) ~~Added definition of “Reduced Oxygen Packaging” in accordance with the~~  
6273 ~~Model Food Code.~~
- 6274 1-201(92) ~~Added definition of “Refuse”~~
- 6275 1-201(93) ~~Added definition of “Re-service”~~
- 6276 1-201(94) ~~Added definition of “Restrict”~~
- 6277 1-201(96) ~~Added definition of “Risk”~~
- 6278 1-201(100) ~~Added definition of “Sealed”~~
- 6279 1-201(101) ~~Added definition of “Self-Contained Mobile Retail Food Establishment”~~
- 6280 1-201(102) ~~Added definition of “Service Animal” in accordance with ADA.~~
- 6281 1-201(103) ~~Added definition of “Sewage”~~
- 6282 1-201(105) ~~Added definition of “Shiga Toxin Producing Escherichia Coli”~~
- 6283 1-201(108) ~~Added definition of “Single Use Articles”~~
- 6284 1-201(109) ~~Added definition of “Slacking”~~
- 6285 1-201(112) ~~Added definition of “Temperature Measuring Device”~~
- 6286 1-201(113) ~~Added definition of “Temporary Event”~~
- 6287 1-201(115) ~~Added definition of “USDA”~~
- 6288 1-201(117) ~~Added definition of “Variance”~~

|      |   |   |
|------|---|---|
| 6289 | 1-201(120)                                  | <del>Added definition of “ Whole Muscle, Intact Beef”</del>                               |
| 6290 | <b>Chapter 2 – Management and Personnel</b> |   |
| 6291 | 2-102                                       | <del>Amended section describing how a person in charge can demonstrate</del>              |
| 6292 |   | <del>knowledge by adding a information on HACCP plans; the relationship</del>             |
| 6293 |   | <del>between potentially hazardous foods and maintaining time and temperature</del>       |
| 6294 |   | <del>controlled for safety; sick employee policy; and major food allergens in</del>       |
| 6295 |   | <del>accordance with the Model Food Code.</del>   |
| 6296 | 2-103                                       | <del>Amended section to clarify employee and conditional employees obligation</del>       |
| 6297 |   | <del>to report illness and infection to the person in charge; and added language to</del> |
| 6298 |   | <del>clarify a consumer warning on consuming raw or partially cooked ready to</del>       |
| 6299 |   | <del>eat foods in accordance with the Model Food Code.</del>                              |
| 6300 | 2-201                                       | <del>This section was amended to be consistent with the Model Food Code and</del>         |
| 6301 |   | <del>the Colorado Disease Control Manual, it requires persons in charge, food</del>       |
| 6302 |   | <del>and/or conditional employees to report specific symptom and illnesses.</del>         |
| 6303 | 2-202                                       | <del>This section was amended to be consistent with the Model Food Code and</del>         |
| 6304 |   | <del>the Colorado Disease Control Manual; it requires food employees be</del>             |
| 6305 |   | <del>excluded or restricted from specific activities when exhibiting specific</del>       |
| 6306 |   | <del>symptoms and/or illness.</del>   |
| 6307 | 2-203                                       | <del>This section was amended to be consistent with the Model Food Code and</del>         |
| 6308 |   | <del>the Colorado Disease Control Manual, it provides guidelines for removing,</del>      |
| 6309 |   | <del>adjusting, or retaining the exclusion or restriction of a food employee.</del>       |
| 6310 | 2-401                                       | <del>Added language to clarify that food employees shall keep their hands and</del>       |
| 6311 |   | <del>exposed portions of their arms clean.</del>  |
| 6312 | 2-402                                       | <del>Added language to address the requirement for food employees with</del>              |
| 6313 |   | <del>surrogate prosthetic hands or arms to clean such devices in accordance with</del>    |
| 6314 |   | <del>the Model Food Code.</del>   |
| 6315 | 2-403                                       | <del>Amended section describing to clarify when an employee shall wash hands.</del>       |
| 6316 |   | <del>Added language “ after returning to food preparation, food storage,</del>            |
| 6317 |   | <del>equipment storage and warewashing areas from using the restroom.”</del>              |
| 6318 | 2-406                                       | <del>Language was stricken which excluded employees such as counter staff who</del>       |
| 6319 |   | <del>only serve beverages and wrapped or packaged foods, or hosts and wait staff</del>    |
| 6320 |   | <del>who present a minimal risk of contaminating exposed foods and equipment</del>        |
| 6321 |   | <del>from fingernail care and the ability to wear artificial nails and nail polish.</del> |
| 6322 |   | <del>Food employee is now defined to mean "an individual working with</del>               |
| 6323 |   | <del>unpacked food, food equipment or utensils, or food contact surfaces"</del>           |
| 6324 |   | <del>therefore the stricken language was redundant. This change is consistent with</del>  |
| 6325 |   | <del>the Model Food Code.</del>   |

- 6326 2-408 ~~Amended section to clarify food employees shall only wear a single plain~~  
 6327 ~~band, such as a wedding band, while preparing food in accordance with the~~  
 6328 ~~Model Food Code.~~  
 6329
- 6330 **Chapter 3 – Food**
- 6331 3-101 ~~Added language “ food shall not contain unsafe or unapproved food or color~~  
 6332 ~~additives per 21 CFR 170-186” to be consistent with the Model Food Code.~~
- 6333 3-201 ~~Added language to section requiring molluscan shellfish be obtained from~~  
 6334 ~~approved sources as listed on the National Shellfish Sanitation Program~~  
 6335 ~~Guide in accordance with the Model Food Code.~~
- 6336 3-201(B) ~~Added language on the condition molluscan shellfish shall be received in~~  
 6337 ~~accordance with the Model Food Code.~~
- 6338 3-202(C) ~~Added language excluding molluscan shellfish that has been caught~~  
 6339 ~~recreationally from being sold in retail food establishments in accordance~~  
 6340 ~~with the Model Food Code.~~
- 6341 3-202(E) ~~Added section regarding how molluscan shellfish shall be received and~~  
 6342 ~~labeled in accordance with the Model Food Code.~~
- 6343 3-103 ~~Amended this section to be more in line with the Model Food Code verbiage~~
- 6344 3-202 ~~Added this section to clarify package integrity in accordance with the Model~~  
 6345 ~~Food Code.~~
- 6346 3-302 ~~Amended to include reference to “ A Guide to Can Defects and Basic~~  
 6347 ~~Components of Double Seam Containers” , November 2011, published by~~  
 6348 ~~the Association of Food and Drug Officials.~~
- 6349 3-305(C)(1-5) ~~Added this section to be consistent with the Colorado Raw Milk Rule.~~
- 6350 3-306(A)(1-6) ~~Added section to clarify stipulations to selling wild harvested mushrooms~~  
 6351 ~~and the qualifications for a mushroom expert in accordance with the Model~~  
 6352 ~~Food Code.~~
- 6353 3-307 ~~Expanded this section on meat, poultry, game animals and exotic species to~~  
 6354 ~~be consistent with the Model Food Code.~~
- 6355 3-308 ~~Expanded this section to address condition of egg cartons, labeling of eggs~~  
 6356 ~~and pooling of eggs.~~
- 6357 3-309 ~~Changed “ potable” to “ drinking” to be consistent with Water Quality~~  
 6358 ~~Control Division's rules and regulations. Removed previous language on~~  
 6359 ~~“ dispensing” of ice and moved it to 3-409(B).~~
- 6360 3-312 ~~Added section on requirements of whole muscle intact beef intended for~~  
 6361 ~~consumption in accordance with the Model Food Code.~~

|      |             |  |
|------|-------------|--|
| 6362 | 3-401       | <del>Amended to clarify that a confirmed foodborne illness serves as grounds for the suspension or revocation of a bare hand contact policy.</del>   |
| 6363 |             |  |
| 6364 | 3-402       | <del>Added section on requirements of gloves use and clarified slash resistant glove use in accordance with the Model Food Code.</del>   |
| 6365 |             |  |
| 6366 | 3-403       | <del>Added section to clarify tasting utensil use in accordance with the Model Food Code.</del>  |
| 6367 |             |  |
| 6368 | 3-406       | <del>Added section to clarify segregation of packaged and un-packaged food storage in accordance with the Model Food Code.</del>   |
| 6369 |             |  |
| 6370 | 3-407       | <del>Amended section to include language on pasteurized eggs that is consistent with the Model Food Code.</del>  |
| 6371 |             |  |
| 6372 | 3-408       | <del>Amended section on washing fruits and vegetables to be consistent with the Model Food Code.</del>   |
| 6373 |             |  |
| 6374 | 3-409(B)    | <del>Moved section from 3-309 to clarify acceptable storage of ice dispensing utensils.</del>  |
| 6375 | 3-412(C)    | <del>Added section to clarify that personal beverage cups can be refilled by employees in accordance with the Model Food Code.</del>   |
| 6376 |             |  |
| 6377 | 3-417(B)    | <del>Added section noting that self-service buffets temperatures shall be monitored by trained staff in accordance with the Model Food Code.</del>   |
| 6378 |             |  |
| 6379 | 3-501(D)    | <del>Added section indicating that food that is labeled frozen and shipped frozen shall be received frozen in accordance with the Model Food Code.</del>   |
| 6380 |             |  |
| 6381 | 3-501(E)    | <del>Added section clarifying that food shall be received free of evidence of previous temperature abuse in accordance with the Model Food Code.</del>   |
| 6382 |             |  |
| 6383 | 3-502(B)    | <del>Added language to include corned beef, lamb and cured roasts in cooking temperatures in accordance with the Model Food Code.</del>  |
| 6384 |             |  |
| 6385 | 3-502(B)(1) | <del>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.</del>  |
| 6386 |             |  |
| 6387 | 3-502(B)(2) | <del>Added chart from the Model Food Code on the time/temperature requirements for whole muscle intact beef.</del>   |
| 6388 |             |  |
| 6389 | 3-502(C)    | <del>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.</del> |
| 6390 |             |  |
| 6391 |             |  |
| 6392 | 3-502(E)    | <del>Added section stating that eggs that are not prepared to consumer order shall be cooked to 155F in accordance with the Model Food Code.</del>   |
| 6393 |             |  |
| 6394 | 3-502(H)    | <del>Amended section to include mechanically tenderized or injected beef in accordance with the Model Food Code.</del>   |
| 6395 |             |  |

|      |  |  |
|------|--|--|
| 6396 | <del>3-502(K)</del>  | <del>Added section to require a consumer advisory on all animal products that are</del>        |
| 6397 |  | <del>consumed raw, undercooked or partially cooked in accordance with the</del>                |
| 6398 |  | <del>Model Food Code.</del>  |
| 6399 | <del>3-503(A)</del>  | <del>Added section to address non-continuous cooking of raw animal foods in</del>              |
| 6400 |  | <del>accordance with the Model Food Code.</del>  |
| 6401 | <del>3-505</del>   | <del>Added section to clarify re-heating temperatures for cooked and refrigerated foods.</del> |
| 6402 | <del>3-601</del>   | <del>Amended section on thawing to be consistent with the Model Food Code.</del>               |
| 6403 | <del>3-602</del>   | <del>Added section to clarify temperature requirements of “slacked” food</del>                 |
| 6404 | <del>3-605</del>   | <del>Amended section on time as a public health control to make verbiage more</del>            |
| 6405 |  | <del>consistent with the Model Food Code.</del>  |
| 6406 | <del>3-606</del>   | <del>Added section on specialized processing methods to be consistent with the</del>           |
| 6407 |  | <del>Model Food Code.</del>  |
| 6408 | <del>3-607</del>   | <del>Amended and expanded section on reduced oxygen packaging to be more</del>                 |
| 6409 |  | <del>consistent with the Model Food Code.</del>  |
| 6410 | <del>3-508 &amp; 608</del>                                     | <del>Added section on date marking and disposition of ready-to-eat food that do</del>          |
| 6411 |  | <del>not meet the date marking requirements, then moved it to section 3-702 to</del>           |
| 6412 |  | <del>apply only to facilities serving only highly susceptible populations.</del>               |
| 6413 | <del>3-608</del>   | <del>Added requirements for breeding mixtures used with raw animal products.</del>             |
| 6414 | <del>3-702(A)</del>  | <del>Amended section to require date marking in facilities that serve highly</del>             |
| 6415 |  | <del>susceptible populations. The requirements are consistent with the Model</del>             |
| 6416 |  | <del>Food Code, though they only apply in these settings.</del>                                |
| 6417 | <del>3-702(B)</del>  | <del>Added the requirement that reduced oxygen packaging HACCP plans be pre-</del>             |
| 6418 |  | <del>approved for facilities serving highly susceptible populations.</del>                     |
| 6419 | <del>3-702(D)</del>  | <del>Added section to address the disposition of food that was not consumed by</del>           |
| 6420 |  | <del>patients in accordance with the Model Food Code.</del>                                    |
| 6421 | <del>3-801</del>   | <del>Added section requiring a consumer advisory warning consumers of the risk</del>           |
| 6422 |  | <del>of consuming raw and undercooked animal products to be consistent with the</del>          |
| 6423 |  | <del>Model Food Code.</del>  |
| 6424 |  |  |
| 6425 |  |  |
| 6426 | <b>Chapter 4 — Warewashing, Equipment, Utensils and Linens</b> |  |
| 6427 | <del>4-102(A)</del>  | <del>Added language to clarify that facilities that only sell pre-packaged food are</del>      |
| 6428 |  | <del>not required to meet the minimum requirements of these regulations.</del>                 |
| 6429 | <del>4-202(D)</del>  | <del>Amended language regarding enamelware to read “shall not be used for</del>                |
| 6430 |  | <del>storage or preparation of acidic foods (e.g. vinegar, tomato-based sauces,</del>          |
| 6431 |  | <del>juices, etc.)”:</del>   |

- 6432 4-202(F) — Amended section on use of linen as a food contact surface for clarity.
- 6433 4-202(H) — Specified that pewter containing in excess of 0.05% lead cannot be used as a  
6434 food contact surface, in accordance with the Model Food Code.
- 6435 4-202(L) — Section regarding newspaper, cloth, cardboard, etc. was stricken and  
6436 incorporated into section (M)
- 6437 4-203(E) — Added section to clarify acceptable material as liners for shelves, drawers or  
6438 drainboards.
- 6439 4-211 — Added section regarding molluscan shellfish tanks to be consistent with  
6440 Model Food Code.
- 6441 4-212(B-C) — Revised section regarding ventilation hood systems to be consistent with  
6442 Model Food Code.
- 6443 4-301(A)(8-9) — Added sections to clarify that items used in a retail food establishment cannot  
6444 be stored in a private home or under open stairwells to be more consistent  
6445 with the Model Food Code.
- 6446 4-401 — Revised section on temperature measuring devices for clarity and to be more  
6447 consistent with the Model Food Code.
- 6448 4-402(A-B) — Section regarding chemical testing devices was revised and now includes a  
6449 requirement for testing devices to measure the strength of chemicals used to  
6450 wash fruits and vegetables.
- 6451 4-402(C) — Added requirement for temperature testing devices for high temperature dish  
6452 machines to be consistent with the Model Food Code.
- 6453 4-403 — Added clarification that utensil washing sinks be installed in new or  
6454 remodeled establishments for utensil washing to be consistent with the Model  
6455 Food Code.
- 6456 4-403(E)(6) — Section regarding drain boards has been revised and moved to section 4-405  
6457 for clarity.
- 6458 4-403(G) — Clarified section regarding ware washing in a three compartment sink.
- 6459 4-403(I)(7-8) — Added language clarifying the use of alternate chemical sanitizes.
- 6460 4-404 — Removed section that is now covered in section 4-102(A).
- 6461 4-404(K) — Added section to clarify that utensils shall not be rinsed prior air drying.
- 6462 4-405 — Added section to clarify drainboard requirements.
- 6463 4-407(D) — Added section to clarify cleaning of in-use pans and equipment shall be done  
6464 at least every 24 hours.

6465 4-407(D) ~~Added section to clarify that buffet style pans shall be cleaned at least every~~  
6466 ~~24 hours in accordance with the Model Food Code.~~

6467 4-603 ~~Clarified section regarding preset tableware.~~

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6470 **Chapter 5 – Water, Plumbing and Waste**

6471 5-101(A)(1)(a-e) ~~Added sections to be consistent with Drinking Water Regulations.~~

6472 5-105 ~~Added section to specify the requirements for an alternative water supply in~~  
6473 ~~cases of emergency.~~

6474 5-201 ~~Clarified the role of the department and local public works with regards to~~  
6475 ~~plumbing violations.~~

6476 5-202 ~~Reworded section to be consistent with the Drinking Water Regulations.~~

6477 5-205(A-B) ~~Added section to clarify acceptable locations to install a food waste grinder.~~

6478 5-208(C) ~~Replaced “lavatory facility faucet” with “handwashing sink water~~  
6479 ~~temperatures” and increased the temperature requirement from 90°F to~~  
6480 ~~100°F in accordance with the Model Food Code.~~

6481 5-208(D) ~~Revised section to allow shared handwashing supplies for adjacent hands~~  
6482 ~~sinks in accordance with the Model Food Code.~~

6483 5-208(E) ~~Revised section to state that common towels cannot be used to dry hands.~~

6484 5-208(F) ~~Added section to clarify that unused handtowels shall be protected from~~  
6485 ~~contamination.~~

6486 5-208(G) ~~Added section to requiring a waste receptacle for disposal towels in~~  
6487 ~~accordance with the Model Food Code.~~

6488 5-208(H) ~~Added section requiring that handwashing supply dispensers be kept clean~~  
6489 ~~and in good repair.~~

6490 5-208(I) ~~Added section to address commonly seen automatic handwashing facilities in~~  
6491 ~~accordance with the Model Food Code.~~

6492 5-208(J) ~~Added section to clarify the installation requirements for handwashing sinks~~  
6493 ~~in new or extensively remodeled establishments.~~

6494 5-209(G) ~~Added section to clarify toilet rooms shall be enclosed and provided with a~~  
6495 ~~self-closing door, unless located outside of the establishment.~~

6496 5-209(I) ~~Added section to clarify requirement for the installation and emptying of~~  
6497 ~~female sanitary trash can receptacles.~~

6498 5-210(D) ~~Added section requiring dump sinks in new and remodeled establishments.~~



6499 5-301(C) — Clarified section to include drain plugs in waste handling units.

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## **Chapter 6—Physical Facilities**

6507 ~~6-202(C) — Added language clarifying acceptable surfaces in areas limited beverage~~  
6508 ~~service and the heating of pre-prepared foods.~~

6509 ~~6-401(D) — Moved and expanded section clarifying how often mop water shall be~~  
6510 ~~changed to prevent recontamination of cleaned surfaces.~~

6511 ~~6-402 — Added language stating that wet mops shall be allowed to air dry without risk~~  
6512 ~~of re-contamination in accordance with the Model Food Code.~~

6513 ~~6-503 — Added section regarding dressing rooms and lockers to maintain consistency~~  
6514 ~~with the Model Food Code.~~

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## **Chapter 7—Poisonous or Toxic Materials**

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6518

No significant changes

6519  
6520  
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## **Chapter 8—Insect, Rodent and Animal Control**

6523 ~~8-102 — Clarified section on the control of pests to be consistent with the Model Food~~  
6524 ~~Code.~~

6525 ~~8-106 — Added section to address service and other animals in retail food~~  
6526 ~~establishments. Language is consistent with the Model Food Code and the~~  
6527 ~~ADA.~~

6528  
6529

## **Chapter 9—Mobile Retail Food Establishments and Pushearts**

6531 ~~This section was revised based on the recommendations of a stakeholder working group~~  
6532 ~~comprised mostly of Local Public Health Agency Representatives.~~

6533 ~~9-101(B) — Added section to require all mobile unit equipment be installed and/or~~  
6534 ~~mounted and to require all foods be prepared, assembled and served from~~  
6535 ~~within the mobile unit.~~

6536 ~~9-101(C) — Added section to limit food preparation and storage on pushearts.~~

6537 ~~9-102 — Added language to exempt mobile retail food establishments and pushearts~~  
6538 ~~with limited food preparation from water or sewage system requirements.~~

6539 ~~9-104(C) — Added section to provide additional clarification on water system~~  
6540 ~~requirements for mobile retail food establishments.~~

- 6541 9-104 (D) — Added section to provide additional information on water tank supply  
6542 capacity for pushcarts.
- 6543 9-104 (E) — Added section to provide additional information on water pressure  
6544 requirements for mobile retail food establishments and pushcarts.
- 6545 9-104 (F) — Added section to provide additional information on hot water requirements  
6546 for mobile retail food establishments and pushcarts. Water temperature for  
6547 handwashing has been increased from 90F to 100F to be consistent with  
6548 section 5-208(C) as well as the Model Food Code.
- 6549 9-104(I) — Clarified requirement for using food grade hoses for transferring drinking water.
- 6550 9-104 (J) — Added reference to 25-1.5-2, C.R.S., *COLORADO PRIMARY DRINKING WATER*  
6551 *REGULATIONS* with regard to water system disinfection and flushing if the unit  
6552 is not used daily.
- 6553 9-104(K) — Section was removed because it is redundant with the term "drinking water".  
6554
- 6555 9-105 (A) — Added language to clarify the requirement for a water retention tank for  
6556 mobile retail food establishments and pushcarts.
- 6557 9-106 (F) — Changed the requirement of providing 90°F water to handsinks on mobile  
6558 retail food establishments and pushcarts to 100°F to be consistent with  
6559 sections 5-208(C), 9-104 (F) and the Model Food Code.
- 6560 9-107 (A) — Added language to the section to have requirements in place for a written  
6561 commissary agreement.
- 6562 9-107(B) — Section was revised for clarity.
- 6563 9-107 (D) — Provided clarification to the section to include what parameters must be met  
6564 for a self-contained mobile retail food establishment to not have to report to a  
6565 commissary.
- 6566 9-107 (E) — Added language which prohibits a mobile retail food establishment from  
6567 acting as a commissary for another retail food establishment.
- 6568 9-108 (B) — Added section to require screening for openable windows and doors, except  
6569 for service windows, in mobile retail food establishments and pushcarts.
- 6570 9-108 (C) — Added section to require employee restroom availability for mobile retail  
6571 food establishments and pushcarts.
- 6572 9-108 (D) — Added section to provide clarification on temperature holding equipment for  
6573 mobile retail food establishments and pushcarts.
- 6574 9-108 (E) — Added section to require an adequate number of clean utensils during  
6575 operating hours of a mobile retail food establishment and/or a pushcart.

6576 9-108 (F) ——— Added section to require protection from contamination at customer self  
 6577 service areas.  
 6578  
 6579

## 6580 ~~Chapter 10 Temporary Retail Food Establishments~~

6581 ~~This section was revised based on the recommendations of a stakeholder working group~~  
 6582 ~~comprised mostly of Local Public Health Agency Representatives.~~

6583 10-101 ——— Added language to require completion and submission of a temporary event  
 6584 vendor application. Ambiguous language was stricken which allowed the  
 6585 Department to impose additional requirements to protect against health  
 6586 hazards. Added language requiring mobile retail food establishments and  
 6587 pushcarts to operate in accordance with Chapter 9 of these Rules and  
 6588 Regulations.

6589 10-102 ——— Clarified section to include requirements for food preparation at the  
 6590 temporary event site location and at the temporary retail food establishments.  
 6591 ort to a co Clarified section to include equipment installation and use at  
 6592 temporary events.

6593 10-103 ——— Added section to include commissary requirements for a temporary retail  
 6594 food establishment.

6595 10-104 ——— Added section to include the minimum equipment required at an event site  
 6596 for a temporary retail food establishment.

6597 10-105 ——— Altered language regarding ice to be consistent with the Model Food Code.

6598 10-106 ——— Added language requiring temporary food establishments to provide only  
 6599 single-service articles for use by the consumer.

6600 10-108 ——— Added language to clarify that the storage of food or beverage in undrained  
 6601 ice is prohibited.

6602 10-109 ——— Added language to clarify that waste water shall not be discharged onto the  
 6603 ground or into a storm drainage system.

6604 10-110 ——— Added language to provide more detail on the requirements of handwashing  
 6605 on site at a temporary event. Language was stricken which required floors,  
 6606 walls and ceilings be made of approved materials.

6607 10-111 ——— Added section to require screening or other provisions to prevent the  
 6608 entrance of pests and debris. Language was stricken which required floors,  
 6609 walls and ceilings be made of approved materials.

6610 10-112 ——— Added section to clarify requirements for the temporary event grounds.

6611 10-113 ——— Added language to require overhead protection at a temporary food  
 6612 establishment.

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- 6616
- 6617 **Chapter 11 – Compliance Procedures**
- 6618 11-102 (D) — ~~Added language to clarify when existing retail food establishments must~~  
6619 ~~obtain a new retail food establishment license.~~
- 6620 11-102(A) — ~~Restrictive language was removed to allow risk-based inspection frequencies.~~
- 6621 11-201 (B) — ~~Added language clarifying the inspection frequency for low risk category~~  
6622 ~~establishments.~~
- 6623 11-203 — ~~Added language to clarify the requirement to clearly document observed~~  
6624 ~~violations or conditions and removed requirement for next day delivery of~~  
6625 ~~the inspection form to allow time for electronic delivery in remote locations.~~
- 6626 11-204(A) — ~~Clarified what constitutes an imminent health hazard and added "severe and~~  
6627 ~~active pest infestation". Imminent health hazards require immediate closure.~~
- 6628 11-204(B) — ~~Amended section to allow 30 days following the receipt of an inspection to~~  
6629 ~~request an administrative hearing to appeal the inspection findings.~~
- 6630 11-205 — ~~Revised the retail food establishment inspection form to match the revisions~~  
6631 ~~to these Rules and Regulations.~~
- 6632 11-403 — ~~Added section to clarify the required contents of a HACCP plan in~~  
6633 ~~accordance with the Model Food Code.~~
- 6634 11-601 (E) — ~~Added language to require documentation associated with variances be made~~  
6635 ~~available on site.~~
- 6636
- 6637
- 6638 **Appendices**
- 6639 Appendix A — ~~This section was revised to provide guidance and clarification on the new~~  
6640 ~~definition of potentially hazardous food.~~
- 6641 Appendix C — ~~This section was stricken. The plan review application will be available~~  
6642 ~~online rather than being included as an appendix in these Rules and~~  
6643 ~~Regulations.~~
- 6644 Appendix D — ~~This section was stricken. The worksheet for calculating minimum hot water~~  
6645 ~~requirements will be available online rather than being included as an~~  
6646 ~~appendix in these Rules and Regulations.~~
- 6647 Appendix H — ~~This section was revised to be consistent with the Model Food Code.~~
- 6648

6649

# Public Health Reasons/Administrative Guidelines

- 6650  
6651 **CHAPTER 1 – PURPOSE AND DEFINITIONS**  
6652 **CHAPTER 2 – MANAGEMENT AND PERSONNEL**  
6653 **CHAPTER 3 – FOOD**  
6654 **CHAPTER 4 – WAREWASHING, EQUIPMENT, UTENSILS, AND LINENS**  
6655 **CHAPTER 5 – WATER, PLUMBING, AND WASTE**  
6656 **CHAPTER 6 – PHYSICAL FACILITIES**  
6657 **CHAPTER 7 – POISONOUS OR TOXIC MATERIALS**  
6658 **CHAPTER 8 – INSECT, RODENT AND ANIMAL CONTROL**  
6659  
6660

## Chapter 1 – Purpose and Definitions

- 6661  
6662 **Applicability and Terms Defined**  
6663  
6664 **1-201**  
6665  
6666 **Accredited Program**  
6667 Food protection manager CERTIFICATION occurs when INDIVIDUALS demonstrate through a  
6668 certification program that they have met specified food safety knowledge standards.
- 6669 Food protection certification program ACCREDITATION occurs when CERTIFICATION  
6670 ORGANIZATIONS demonstrate through an accreditation program that they have met specified program  
6671 standards.
- 6672 Accreditation is a conformity assessment process through which organizations that certify individuals  
6673 may voluntarily seek independent evaluation and listing by an accrediting agency based upon the  
6674 certifying organizations meeting program accreditation standards. Such accreditation standards typically  
6675 relate to such factors as the certifying organization's structure, mission, policies, procedures, and the  
6676 defensibility of its examination processes. These standards are intended to affirm or enhance the quality  
6677 and credibility of the certification process, minimize the potential for conflicts of interest, ensure fairness  
6678 to candidates for certification and others, and thereby increase public health protection.
- 6679 Program accreditation standards known to be relevant to food protection manager certification programs  
6680 include those contained in the STANDARDS FOR ACCREDITATION OF FOOD PROTECTION  
6681 MANAGER CERTIFICATION PROGRAMS available from the Conference for Food Protection, 2792  
6682 Miramar Lane, Lincoln, CA 95648 and found at [Standards for Accreditation of Food Protection Manager  
6683 Certification Programs](#)<sup>8</sup>
- 6684 Allowing food protection managers to demonstrate their required food safety knowledge "through passing  
6685 a test that is part of an accredited program" is predicated on the fact that their credentials have been issued



6686 by certifying organizations that have demonstrated conformance with rigorous and nationally recognized  
6687 program standards.

6688 **Egg**

6689 The definition of egg includes avian species' shell eggs known to be commercially marketed in the United  
6690 States. Also included are the eggs of quail and ratites such as ostrich.

6691 Not included are baluts. Baluts are considered a delicacy among Philippine and Vietnamese populations.  
6692 They are derived from fertile eggs; typically duck eggs, subjected to incubation temperatures for a period  
6693 of time less than necessary for the embryo to hatch resulting in a partially formed embryo within the shell.  
6694 Under the Egg Products Inspection Act (EPIA), an egg is typically considered adulterated if it has been  
6695 subjected to incubation. However, in 9 CFR 590.5, baluts are specifically exempted from inspection as  
6696 eggs under the EPIA.

6697 In producing baluts, fertile duck eggs are incubated for approximately 18 days at a temperature of 42.5°C  
6698 (108.5°F) in incubators with a relatively high humidity. (Complete development and hatching would take  
6699 place in 28 days.) Under these conditions, the potential for growth of transovarian *Salmonella* organisms  
6700 such as *S. Enteritidis* within the shell, and the potential for an increase in pathogenic microflora on the  
6701 shell itself, are increased. Where chicken eggs are used in preparing baluts, the incubation period may  
6702 only be 14 days at an incubation temperature of 37°C (99°F). A balut is a potentially hazardous food  
6703 (time/temperature control for safety food) subject to time/temperature management including proper  
6704 cooking and hot and cold holding. Baluts are typically boiled and packed in salt before sale or service.

6705 Also, not included in this definition are the eggs of reptile species such as alligators and turtles. Alligator  
6706 eggs are available for sale in some parts of the southern United States. In restaurants, the menu item  
6707 "Alligator Eggs" is sometimes made of alligator egg, but other times is simply a fanciful name for a menu  
6708 item that may include seafood items such as shrimp, but contains no alligator egg.

6709 Sea turtle eggs have been consumed in Asian and Latin American Countries. However, turtle eggs are not  
6710 mentioned in the definitions section because sea turtles (Loggerhead, East Pacific Green, Leatherback,  
6711 Hawksbill, Kemp's Ridley, and Olive Ridley) are protected by The Endangered Species Act of 1973 and  
6712 therefore may not be sold or consumed. This Act, with respect to turtle eggs, is enforced by the United  
6713 States Department of Interior, U.S. Fish and Wildlife Service, Washington, DC.

6714 **Potentially Hazardous Food (Time/Temperature Control for Safety Food)**

6715 Potentially hazardous food (PHF/TCS food) is defined in terms of whether or not it requires  
6716 time/temperature control for safety to limit pathogen growth or toxin formation. The term does not  
6717 include foods that do not support growth but may contain a pathogenic microorganism or chemical or  
6718 physical food safety hazard at a level sufficient to cause foodborne illness or injury. The progressive  
6719 growth of all foodborne pathogens is considered whether slow or rapid.

6720 The definition of PHF/TCS food takes into consideration pH,  $a_w$ , pH and  $a_w$  interaction, heat treatment,  
6721 and packaging for a relatively simple determination of whether the food requires time/temperature control  
6722 for safety. If the food is heat treated to eliminate vegetative cells, it needs to be addressed differently than  
6723 a raw product with no, or inadequate, heat treatment. In addition, if the food is packaged after heat  
6724 treatment to destroy vegetative cells and subsequently packaged to prevent re-contamination, higher  
6725 ranges of pH and/or  $a_w$  can be tolerated because remaining spore-forming bacteria are the only microbial  
6726 hazards of concern. While foods will need to be cooled slightly to prevent condensation inside the  
6727 package, they must be protected from contamination in an area with limited access and packaged before  
6728 temperatures drop below 57°C (135°F). In some foods, it is possible that neither the pH value nor the  $a_w$   
6729 value is low enough by itself to control or eliminate pathogen growth; however, the interaction of pH and

6730 ~~a<sub>w</sub> may be able to accomplish it. This is an example of a hurdle technology. Hurdle technology involves~~  
6731 ~~several inhibitory factors being used together to control or eliminate pathogen growth, when they would~~  
6732 ~~otherwise be ineffective if used alone. When no other inhibitory factors are present and the pH and/or a<sub>w</sub>~~  
6733 ~~values are unable to control or eliminate bacterial pathogens which may be present, growth may occur~~  
6734 ~~and foodborne outbreaks result. Cut melons, cut tomatoes, and cut leafy greens are examples where~~  
6735 ~~intrinsic factors are unable to control bacterial growth once pathogens are exposed to the cellular fluids~~  
6736 ~~and nutrients after cutting.~~

6737 ~~In determining if time/temperature control is required, combination products present their own challenge.~~  
6738 ~~A combination product is one in which there are two or more distinct food components and an interface~~  
6739 ~~between the two components may have a different property than either of the individual components. A~~  
6740 ~~determination must be made about whether the food has distinct components such as pie with meringue~~  
6741 ~~topping, focaccia bread, meat salads, or fettuccine alfredo with chicken or whether it has a uniform~~  
6742 ~~consistency such as gravies, puddings, or sauces. In these products, the pH at the interface is important in~~  
6743 ~~determining if the item is a PHF/TCS food.~~

6744 ~~A well designed inoculation study or other published scientific research should be used to determine~~  
6745 ~~whether a food can be held without time/temperature control when:~~

6746 ~~• process technologies other than heat are applied to destroy foodborne pathogens (e.g., irradiation,~~  
6747 ~~high pressure processing, pulsed light, ozonation);~~

6748 ~~• combination products are prepared; or~~

6749 ~~• other extrinsic factors (e.g., packaging/atmospheres) or intrinsic factors (e.g., redox potential, salt~~  
6750 ~~content, antimicrobials) are used to control or eliminate pathogen growth.~~

6751 ~~Before using Tables A and B of the definition for "potentially hazardous food (time/temperature control~~  
6752 ~~for safety food)" in determining whether a food requires time/temperature control for safety (TCS),~~  
6753 ~~answers to the following questions should be considered:~~

6754 ~~• Is the intent to hold the food without using time or temperature control?~~

6755 ~~○ If the answer is No, no further action is required. The decision tree later in this Annex is~~  
6756 ~~not needed to determine if the item is a PHF/TCS food.~~

6757 ~~• Is the food raw, or is the food heat treated?~~

6758 ~~• Does the food already require time/temperature control for safety?~~

6759 ~~• Does a product history with sound scientific rationale exist indicating a safe history of use?~~

6760 ~~• Is the food processed and packaged so that it no longer requires TCS such as ultra high~~  
6761 ~~temperature (UHT) creamers or shelf stable canned goods?~~

6762 ~~• What is the pH and a<sub>w</sub> of the food in question using an independent laboratory and Association of~~  
6763 ~~Official Analytical Chemists (AOAC) methods of analysis?~~

6764 ~~A food designated as product assessment required (PA), in either table should be considered PHF/TCS~~  
6765 ~~Food until further study proves otherwise. The PA means that based on the food's pH and a<sub>w</sub> and whether~~  
6766 ~~it was raw or heat treated or packaged, it has to be considered PHF until inoculation studies or some other~~  
6767 ~~acceptable evidence shows that the food is a PHF/TCS food or not.~~

6768 The Regulation definition designates certain raw plant foods as PHF/TCS food because they have been  
6769 shown to support the growth of foodborne pathogens in the absence of temperature control and to lack  
6770 intrinsic factors that would inhibit pathogen growth. Unless product assessment shows otherwise, these  
6771 designations are supported by Tables A and B. For example:

6772 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  
6773 treated), and cut tomatoes (pH 4.23–5.04,  $a_w > 0.99$ , not heat treated), Table B indicates that they are  
6774 considered PHF/TCS Foods unless a product assessment shows otherwise. Maintaining these products  
6775 under the temperature control requirements prescribed in this Regulation for PHF/TCS food will limit the  
6776 growth of pathogens that may be present in or on the food and may help prevent foodborne illness.

6777 If a facility adjusts the pH of a food using vinegar, lemon juice, or citric acid for purposes other than  
6778 flavor enhancement, a standardized recipe validated by lab testing for pH and  $a_w$  would be requested to  
6779 verify compliance with the conditions of the food storage.

6780 More information can be found in the Institute of Food Technologists (IFT) Report, "[Evaluation and  
6781 Definition of Potentially Hazardous Foods](#)"<sup>9</sup>.

6782 **Instructions for using the following Decision Tree and Table A and Table B:**

6783 1. Does the operator want to hold the food without using time or temperature control?

6784 a. No—Continue holding the food at  $\leq 5^\circ\text{C}$  ( $41^\circ\text{F}$ ) or  $\geq 57^\circ\text{C}$  ( $135^\circ\text{F}$ ) for safety and/or  
6785 quality.

6786 b. Yes—Continue using the decision tree to identify which table to use to determine whether  
6787 time/temperature control for safety (TCS) is required.

6788 2. Is the food heat treated?

6789 a. No—The food is either raw, partially cooked or treated with some other method other  
6790 than heat. Proceed to step #3.

6791 b. Yes—If the food is heat treated to the required temperature for that food vegetative cells  
6792 will be destroyed although spores will survive. Proceed to step #4.

6793 3. Is the food treated using some other method?

6794 a. No—The food is raw or has only received a partial cook allowing vegetative cells and  
6795 spores to survive. Proceed to step #6.

6796 b. Yes—If a method other than heat is used to destroy pathogens such as irradiation, high  
6797 pressure processing, pulsed light, ultrasound, inductive heating, or ozonation, the  
6798 effectiveness of the process needs to be validated by inoculation studies or other means.  
6799 Proceed to step #5.

6800

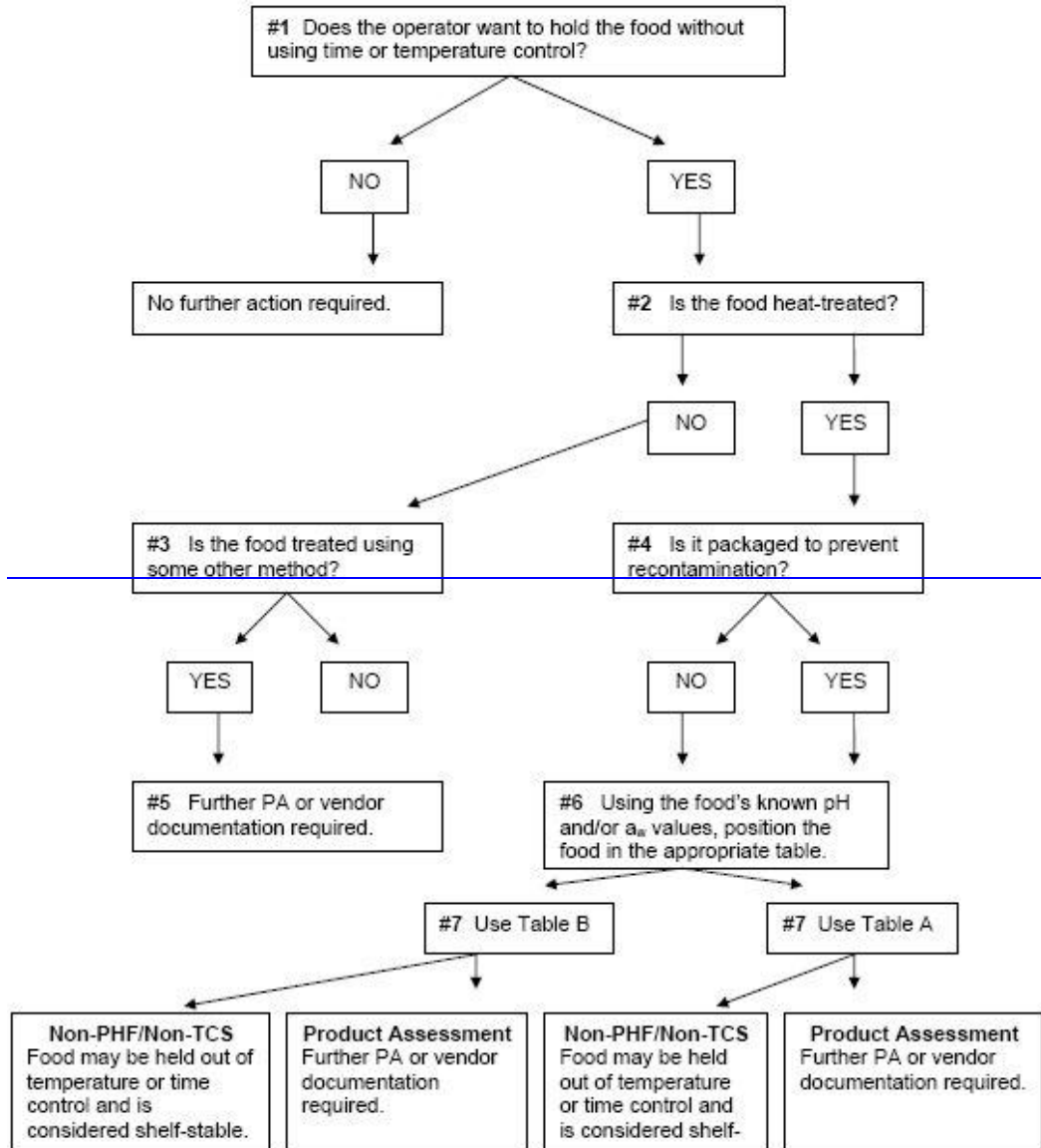
- 6801
- 6802 4. ~~Is it packaged to prevent re-contamination?~~
- 6803 a. ~~No—Re-contamination of the product can occur after heat treatment because it is not~~
- 6804 ~~packaged. Proceed to step #6.~~
- 6805 b. ~~Yes—If the food is packaged immediately after heat treatment to prevent re-~~
- 6806 ~~contamination, higher ranges of pH and/or  $a_w$  can be tolerated because spore-forming~~
- 6807 ~~bacteria are the only microbial hazard. Proceed to step #7.~~
- 6808 5. ~~Further product assessment or vendor documentation required.~~
- 6809 a. ~~The vendor of this product may be able to supply documentation that inoculation studies~~
- 6810 ~~indicate the food can be safely held without time/temperature control for safety.~~
- 6811 b. ~~Food prepared or processed using new technologies may be held without~~
- 6812 ~~time/temperature control provided the effectiveness of the use of such technologies is~~
- 6813 ~~based on a validated inoculation study.~~
- 6814 6. ~~Using the food's known pH and/or  $a_w$  values, position the food in the appropriate table.~~
- 6815 a. ~~Choose the column under "pH values" that contains the pH value of the food in question.~~
- 6816 b. ~~Choose the row under " $a_w$  values" that contains the  $a_w$  value of the food in question.~~
- 6817 c. ~~Note where the row and column intersect to identify whether the food is "non-PHF/non-~~
- 6818 ~~TCS food" and therefore does not require time/temperature control, or whether further~~
- 6819 ~~product assessment (PA) is required. Other factors such as redox potential, competitive~~
- 6820 ~~microorganisms, salt content, or processing methods may allow the product to be held~~
- 6821 ~~without time/temperature control but an inoculation study is required.~~
- 6822 7. ~~Use **Table A** for foods that are heat treated and packaged **OR** use **Table B** for foods that are not~~
- 6823 ~~heat treated or heat treated but not packaged.~~
- 6824 8. ~~Determine if the item is non-PHF/non-TCS or needs further product assessment (PA).~~
- 6825
- 6826

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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**

| <b>Table A. Interaction of pH and a<sub>w</sub> for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged</b> |                         |                       |                      |
|--|-------------------------|-----------------------|----------------------|
| <b>a<sub>w</sub> values</b>  | <b><u>pH values</u></b> |                       |                      |
|  | <b>4.6 or less</b>      | <b>&gt; 4.6 – 5.6</b> | <b>≥ 5.6</b>         |
| <b>≤ 0.92</b>  | non-PHF*/non-TCS FOOD** | non-PHF/non-TCS FOOD  | non-PHF/non-TCS FOOD |
| <b>&gt; 0.92 – .95</b>   | non-PHF/non-TCS FOOD    | non-PHF/non-TCS FOOD  | PA***                |
| <b>≥ 0.95</b>  | non-PHF/non-TCS FOOD    | PA                    | PA                   |

6838  
6839  
6840

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

| <b>Table B. Interaction of pH and a<sub>w</sub> for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged</b> |                         |                      |                       |                      |
|--|-------------------------|----------------------|-----------------------|----------------------|
| <b>a<sub>w</sub> values</b>  | <b><u>pH values</u></b> |                      |                       |                      |
|  | <b>&lt; 4.2</b>         | <b>4.2 – 4.6</b>     | <b>&gt; 4.6 – 5.0</b> | <b>≥ 5.0</b>         |
| <b>&lt; 0.88</b>   | non-PHF*/non-TCS food** | non-PHF/non-TCS food | non-PHF/non-TCS food  | non-PHF/non-TCS food |
| <b>0.88 – 0.90</b>   | non-PHF/non-TCS food    | non-PHF/non-TCS food | non-PHF/non-TCS food  | PA***                |
| <b>&gt; 0.90 – 0.92</b>  | non-PHF/non-TCS food    | non-PHF/non-TCS food | PA                    | PA                   |
| <b>≥ 0.92</b>  | non-PHF/non-TCS food    | PA                   | PA                    | PA                   |

6841 \* PHF means Potentially Hazardous Food  
6842 \*\* TCS food means Time/Temperature Control for Safety food  
6843 \*\*\* PA means Product Assessment required

## Chapter 2— Management and Personnel

6844

### 6845 *2-1— Supervision*

6846

#### 6847 **2-101— Responsibilities**

6848

6849 Designation of a person in charge during all hours of operations ensures the continuous presence of  
6850 someone who is responsible for monitoring and managing all retail food establishment operations and  
6851 who is authorized to take actions to ensure that the Regulation's objectives are fulfilled. During the day-  
6852 to-day operation of a retail food establishment, a person who is immediately available and knowledgeable  
6853 in both operational and Regulation requirements is needed to respond to questions and concerns and to  
6854 resolve problems.  
6855

#### 6856 **2-102— Demonstration**

6857

6858 The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard  
6859 Analysis and Critical Control Point (HACCP) principles, and Regulation requirements is prepared to  
6860 recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with  
6861 Regulation requirements, and to take appropriate preventive and corrective actions.  
6862

6863 There are many ways in which the person in charge can demonstrate competency. Many aspects of the  
6864 retail food operation itself will reflect the competency of that person. A dialogue with the person in  
6865 charge during the inspection process will also reveal whether or not that person is enabled by a clear  
6866 understanding of the Regulation and its public health principles to follow sound food safety practices and  
6867 to produce foods that are safe, wholesome, unadulterated, and accurately represented.  
6868

6869 The Regulation does not require reporting of uninfected cuts or reporting of covered, protected infected  
6870 cuts/lesions/boils since it requires no bare hand contact with ready-to-eat food.  
6871

#### 6872 **Status of "Universal Acceptance" of Food Protection Manager Certification**

6873 The increasing complexity of the food industry, the improved ability to identify/trace foodborne outbreaks  
6874 and other economic, staffing, cultural and behavioral challenges make it imperative that food protection  
6875 managers know and control the risk factors that impact the safety of the food they sell or serve. Food  
6876 protection managers have an important role in formulating policies, verifying food employees carry out  
6877 these policies, and communicating with these same employees to give information about recommended  
6878 practices to reduce the risk of foodborne illness. A Centers for Disease Control and Prevention  
6879 Environmental Health Specialist Network (EHS-Net) study suggests that the presence of a certified food  
6880 protection manager reduces the risk for a foodborne outbreak for an establishment and was a  
6881 distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had  
6882 not.

6883 FDA's Retail Food Risk Factor Studies suggest that the presence of a certified manager has a positive  
6884 correlation with more effective control of certain risk factors, such as poor personal hygiene, in different  
6885 facility types.

6886 There are a number of state and local agencies that currently mandate food protection manager  
6887 certification. For state and local agencies whose regulations do not mandate food protection manager  
6888 certification to establish criteria for assessing the food safety knowledge of food protection managers.

6889 Factors to consider when establishing such criteria include:

- 6890 • the size and scope of the operation;
- 6891 • the hours of operation;
- 6892 • the types of foods sold or served;
- 6893 • the extent to which food is prepared on site;
- 6894 • the number of staff;
- 6895 • type of population served, e.g. highly susceptible or not; and
- 6896 • the number of meals served.

### 6897 **2-103 Person in Charge**

6898  
6899 A primary responsibility of the person in charge is to ensure compliance with Regulation requirements.  
6900 Any individual present in areas of a retail food establishment where food and food-contact items are  
6901 exposed presents a potential contamination risk. By controlling who is allowed in those areas and when  
6902 visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery,  
6903 maintenance and service personnel, and pest control operators, comply with the Regulation requirements,  
6904 the person in charge establishes an important barrier to food contamination.

6905  
6906 Tours of food preparation areas serve educational and promotional purposes; however, the timing of such  
6907 visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the  
6908 disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for  
6909 contamination are reduced.

6910 When food and other purchased goods are delivered and placed into designated locations within the food  
6911 establishment during non-operating hours, the Person in Charge must make sure food employees inspect  
6912 such product and verify that it is from the appropriate supplier, is in the desired condition, and was  
6913 delivered to a proper storage location. Distributors deliver and place food and other goods in refrigeration  
6914 units, freezers, and dry storage areas for confirmation of receipt and inspection by employees immediately  
6915 upon arrival to the food establishment. Distributors contracted by the food establishment are often given  
6916 a key to allow access into the establishment outside of normal working hours. Upon delivery, all must be  
6917 appropriately stored in a safe and secure manner within the food establishment. For example, potentially  
6918 hazardous foods (time/temperature control for safety foods) must be stored within refrigeration units and  
6919 held at temperatures of 5°C (41°F) or below. Likewise, if the food product is frozen, it must be placed  
6920 into the freezer.

6921 To minimize the potential for access to the food establishment and the food by an unauthorized person,  
6922 precautions should be applied overall to the food establishment and especially when access to the facility  
6923 is made under key access deliveries. [Additional information on food defense](#)<sup>40</sup>.

6924 Food allergy is an increasing food safety and public health issue, affecting approximately 4% of the U.S.  
6925 population, or twelve million Americans. Restaurant and retail food service managers need to be aware  
6926 of the serious nature of food allergies, including allergic reactions, anaphylaxis, and death; to know the  
6927 eight major food allergens; to understand food allergen ingredient identities and labeling; and to avoid



6928 cross-contact during food preparation and service. The 2008 Conference of Food Protection (CFP) passed  
6929 Issue 2008-III-006 which provided that food allergy awareness should be a food safety training duty of  
6930 the Person in Charge. Accordingly, the Person in Charge's duties were amended to assure the food safety  
6931 training of employees includes food allergy awareness in order for them to safely perform duties related  
6932 to food allergies.

6933 The Person in Charge (PIC) has an important role in making sure employees properly report certain  
6934 information about their health status as it relates to diseases that are transmitted by food. In an effort to  
6935 reinforce dialogue between food employees and the PIC, there must be a way to verify that food  
6936 employees and conditional employees are informed of their responsibility to report such information.  
6937 Examples of ways to verify that employees have been appropriately informed include:

- 6938 • Implementation of an employee health policy that includes a system of employee notification  
6939 using a combination of training, signs, pocket cards or other means to convey all the required  
6940 information;
- 6941 • Other methods that satisfactorily demonstrate that all food employees and conditional employees  
6942 are informed of their responsibility to report to the PIC information about their health and  
6943 activities as it relates to diseases that are transmissible through food, as specified under Section 2-  
6944 201.

6945 Ultimately, responsibility for food safety at the retail level lies with retail and food service operators and  
6946 their ability to develop and maintain effective food safety management systems. There are many tools  
6947 that industry can use to develop an effective system to achieve active managerial control of foodborne  
6948 illness risk factors. An important tool in controlling risk factors inherent in a food establishment is the  
6949 development and implementation of written procedures or plans.

## 6950 **2-2 — Employee Health**

### 6951 6952 **2-201 — Restrictions Regarding Ill or Otherwise Infected Employees**

6953 A wide range of communicable diseases and infections may be transmitted by infected food employees to  
6954 consumers through food or food utensils. Proper management of a retail food establishment operation  
6955 begins with employing healthy people and instituting a system of identifying employees who present a  
6956 risk of transmitting foodborne pathogens to food or to other employees. In order to protect the health of  
6957 both consumers and employees, information concerning the health status of applicants and retail food  
6958 employees must be disclosed to the person in charge.  
6959

6961 Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and  
6962 inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of  
6963 employment. In order for the permit holder and the person in charge to be in compliance with this  
6964 particular aspect of the Regulation and the ADA, a conditional job offer must be made before making  
6965 inquiries about the applicant's health status.  
6966

6967 Furthermore, an applicant to whom an employment offer is conditionally made or a retail food employee  
6968 who meets the Regulation conditions that require restriction from certain duties or exclusion must be  
6969 accommodated to the extent provided under the ADA. That is, if there is an accommodation that will not  
6970 pose an undue hardship and that will prevent the transmission of the disease(s) of concern through food,  
6971 such accommodation, e.g., reassignment to duties that fulfill the intent of restriction or exclusion, must be  
6972 made. It should be noted that the information provided here about the ADA is intended to alert employers  
6973 to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA

6974 and its implications, consult the references listed in the References Annex that relate to this section of the  
6975 Regulation or contact the U. S. Equal Employment Opportunity Commission.

6976  
6977 The information required from applicants and retail food employees is designed to identify employees  
6978 who may be suffering from a disease, which can be transmitted through food. It is the responsibility of the  
6979 permit holder to convey to applicants and employees the importance of notifying the person in charge of  
6980 changes in their health status. Once notified, the person in charge can take action to prevent the likelihood  
6981 of the transmission of foodborne illness.

6982  
6983 Applicants, to whom a conditional offer of employment is extended, and retail food employees are  
6984 required to report specific high risk conditions, medical symptoms, and previous illnesses. The symptoms  
6985 listed may be indicative of a disease that is transmitted through the food supply by infected retail food  
6986 employees.

6987  
6988 As required by the ADA, the Centers for Disease Control and Prevention (CDC) published in the Federal  
6989 Register on September 27, 2000, (Volume 65, Number 188) a list of infectious and communicable  
6990 diseases that are transmitted through food. CDC updates the list annually. The list is divided into two  
6991 parts: pathogens often transmitted and pathogens occasionally transmitted by infected persons who handle  
6992 food.

6993  
6994 The Lists below summarize the CDC list by comparing the common symptoms of each pathogen.  
6995 Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. CDC has no  
6996 evidence that the HIV virus is transmissible via food. Therefore, a retail food employee positive for the  
6997 HIV virus is not of concern unless suffering secondary illness listed below. The Lists below include all  
6998 Shiga toxin producing *E. coli* likely to occur in foods in the United States.  
6999

7000

| <b>LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Persons.</b>        |          |          |          |          |          |
|---|----------|----------|----------|----------|----------|
|   | <b>D</b> | <b>F</b> | <b>V</b> | <b>J</b> | <b>S</b> |
| <b>1. Caliciviruses (Noroviruses)</b>   | ✓        | ✓        | ✓        | -        | -        |
| <b>2. Hepatitis A virus</b>   | -        | ✓        | -        | ✓        | -        |
| <b>3. Salmonella Typhi</b>  | -        | ✓        | -        | -        | -        |
| <b>4. Shigella species</b>  | ✓        | ✓        | ✓        | -        | -        |
| <b>5. Staphylococcus aureus</b>   | ✓        | -        | ✓        | -        | -        |
| <b>6. Streptococcus pyogenes</b>  | -        | ✓        | -        | -        | ✓        |
| <b>LIST II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons</b> |          |          |          |          |          |
|   | <b>D</b> | <b>F</b> | <b>V</b> | <b>J</b> | <b>S</b> |
| <b>1. Campylobacter jejuni</b>  | ✓        | ✓        | ✓        | -        | -        |
| <b>2. Cryptosporidium parvum</b>  | ✓        | -        | -        | -        | -        |
| <b>3. Entamoeba histolytica</b>   | ✓        | ✓        | -        | -        | -        |
| <b>4. Enterohemorrhagic Escherichia coli</b>  | ✓        | -        | -        | -        | -        |
| <b>5. Enterotoxigenic Escherichia coli</b>  | ✓        | -        | ✓        | -        | -        |
| <b>6. Giardia lamblia</b>   | ✓        | -        | -        | -        | -        |
| <b>7. Non-typhoidal Salmonella</b>  | ✓        | ✓        | ✓        | -        | -        |
| <b>8. Taenia solium</b>   | -        | -        | -        | -        | -        |
| <b>9. Vibrio cholerae 01</b>  | ✓        | -        | ✓        | -        | -        |
| <b>10. Yersinia enterocolitica</b>  | ✓        | ✓        | ✓        | -        | -        |

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**KEY: D = Diarrhea V = Vomiting S = Sore throat with fever F = Fever J = Jaundice**

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.

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.

7016 An employee suffering from any of the symptoms listed presents an increased risk of transmitting  
7017 foodborne illness.

7018  
7019 The high risk conditions that require reporting are designed to be used with the symptoms listed to  
7020 identify employees who may be suffering from an illness due to the following pathogens: *Salmonella*  
7021 *Typhi*, *Shigella* spp., Shiga toxin producing *Escherichia coli*, and hepatitis A virus. The specific  
7022 conditions requiring reporting were identified by CDC as significant contributing factors to the incidence  
7023 of foodborne illness.

7024  
7025 The 4 organisms listed have been designated by CDC as having high infectivity. This designation is based  
7026 on the number of confirmed cases reported that involved retail food employees infected with one of these  
7027 organisms and the severity of the medical consequences to those who become ill.

7028  
7029 The following information, taken from Control of Communicable Diseases Manual, is provided regarding  
7030 the period of communicability for the four pathogens of concern and the application of that information to  
7031 employees likely to be shedding certain pathogens:

7032  
7033 **Salmonella Typhi**—As long as the bacilli appear in the excreta, usually from the first week throughout  
7034 the convalescence; variable thereafter (commonly 1–2 weeks for paratyphoid). About 10% of untreated  
7035 typhoid fever patients will discharge bacilli for 3 months after onset of symptoms, and 2%–5% become  
7036 permanent carriers; considerable fewer persons affected with paratyphoid organisms may become  
7037 permanent gallbladder carriers.

7038  
7039 **Shigella spp.**—During acute infection and until the infectious agent is no longer present in feces, usually  
7040 within 4 weeks after illness. Asymptomatic carriers may transmit infection; rarely, the carrier state may  
7041 persist for months or longer. Appropriate antimicrobial treatment usually reduces duration of carriage to a  
7042 few days.

7043  
7044 **Shiga toxin**—producing serotypes of *Escherichia coli*, including *E. coli* O157:H7—The duration of  
7045 excretion of the pathogen, which is typically for a week or less in adults but 3 weeks in one third of  
7046 children. Prolonged carriage is uncommon.

7047  
7048 **Hepatitis A**—Evidence indicates maximum infectivity during the latter half of the incubation period,  
7049 continuing for a few days after onset of jaundice, although prolonged viral excretion (up to 6 months) has  
7050 been documented in infants born prematurely.—The infectious agent is found in feces, reaching peak  
7051 levels the week or two before onset of symptoms, and diminishing rapidly after liver dysfunction or  
7052 symptoms appear, which is concurrent with the appearance of circulating antibodies to HAV.

7053  
7054 Lesions containing pus that may occur on a retail food employee's hands, as opposed to such wounds on  
7055 other parts of the body, represent a direct threat for introducing *Staphylococcus aureus* into food.  
7056 Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms  
7057 are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is  
7058 allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with  
7059 food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other  
7060 parts of the body need to be covered; but, an impermeable bandage is not considered necessary for food  
7061 safety purposes. Retail food employees should be aware that hands and fingers that contact pustular  
7062 lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for  
7063 introducing *Staphylococcus aureus* into food.

7064

7065 If an employee has an infected cut and bandages it, plus puts on a glove, the employee does not have to  
7066 report the infected cut to the person in charge. However, if the employee does not bandage it, reporting is  
7067 required.

7068  
7069 A reporting requirement is an important component of any food safety program. A retail food employee  
7070 who suffers from any of the illnesses or medical symptoms or meets any of the high-risk conditions in  
7071 this Regulation may transmit disease through the food being prepared. The person in charge must first be  
7072 aware that an employee or prospective employee is suffering from a disease or symptom listed in the  
7073 Regulation before steps can be taken to reduce the chance of foodborne illness.

7074  
7075 Some of the symptoms that must be reported may be observed by the person in charge. However, retail  
7076 food employees and applicants share a responsibility for preventing foodborne illness and are obligated to  
7077 inform the person in charge if they are suffering from any of the symptoms, high-risk conditions, or  
7078 medical diagnoses listed in the Regulation and retail food employees must comply with restrictions or  
7079 exclusions imposed upon them.

7080

## 7081 **2-202—Exclusions and Restrictions**

7082

7083 Restriction or exclusion of retail food employees suffering from a disease or medical symptom listed in  
7084 the Regulation is necessary due to the increased risk that the food being prepared will be contaminated  
7085 with a pathogenic organism transmissible through food. A person suffering from any of the symptoms or  
7086 medical conditions listed may be suffering from a disease transmissible through food.

7087

7088 Because of the high infectivity (ability to invade and multiply) and virulence (ability to produce severe  
7089 disease) of *Salmonella Typhi*, *Shigella* spp., Shiga toxin-producing *Escherichia coli*, and hepatitis A  
7090 virus, a retail food employee diagnosed with an active case of illness caused by any of these four  
7091 pathogens must be excluded from retail food establishments. The exclusion is based on the severe medical  
7092 consequences to individuals infected with these organisms, i.e., hospitalization and even death.

7093

7094 Restrictions and exclusions vary according to the population served because highly susceptible  
7095 populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy  
7096 individual may be manifested by mild flu-like symptoms. The same foodborne illness may have serious  
7097 medical consequences in immunocompromised individuals. This point is reinforced by statistics  
7098 pertaining to deaths associated with foodborne illness caused by *Salmonella Enteritidis*. Over 70% of the  
7099 deaths attributed to this organism occurred among individuals who for one reason or another were  
7100 immunocompromised. This is why the restrictions and exclusions listed in the Regulation are especially  
7101 stringent for retail food employees serving highly susceptible populations.

7102

7103 The Regulation does not require restriction of a retail food employee with an unprotected, uninfected cut,  
7104 or a retail food employee with a covered, protected infected cut/lesion/boil since it requires no bare hand  
7105 contact with ready-to-eat food.

7106

7107 Periodic testing of retail food employees for the presence of diseases transmissible through food is not  
7108 cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active  
7109 symptoms and high-risk conditions listed. A high-risk condition alone does not trigger restriction or  
7110 exclusion. The employee must also suffer from one of the symptoms listed.

7111

7112 The use of high-risk conditions alone as the sole basis for restricting or excluding retail food employees is  
7113 difficult to justify. The high-risk conditions that must be reported apply only to the 4 organisms listed. Of  
7114 the 4 organisms listed, hepatitis A presents a different twist to this rationale. Retail food employees who

7115 meet a high risk condition involving hepatitis A may shed the virus before becoming symptomatic. In  
7116 fact, the infected employee could be shedding hepatitis A virus for up to a week before experiencing  
7117 symptoms of the infection. However, even in light of this fact, blanket exclusion or restriction of a retail  
7118 food employee solely because of a high risk condition involving hepatitis A is not justified.

7119

7120 The following summarize the rationale for not restricting or excluding an asymptomatic retail food  
7121 employee simply because the employee meets a high risk condition involving hepatitis A:

7122

7123 1. — Because hepatitis A virus infection can occur without clinical illness (i.e., without  
7124 symptoms), or because a person may shed hepatitis A virus in the stool for up to a week  
7125 before becoming symptomatic, it is possible that a person unknowingly may have been  
7126 exposed to an asymptomatic hepatitis A virus shedder or to an infected person who is in the  
7127 incubation stage. No restriction/exclusion routinely occurs under these — presumably much  
7128 more common — circumstances.

7129

7130 2. — Even though the asymptomatic retail food employee may be infected with hepatitis A virus  
7131 and may in fact be shedding virus in the stool, foodborne transmission of hepatitis A virus is  
7132 unlikely if the employee practices good personal hygiene, such as washing hands after going  
7133 to the bathroom.

7133

7134 3. — Exclusions from work for prolonged periods of time may involve economic hardship for the  
7135 retail food employee excluded.

7135

7136 Based on the information presented, exclusion or restriction solely on a high risk condition would be  
7137 potentially controversial and of questionable merit.

7138

7139 Because of the high infectivity of hepatitis A, the person in charge or regulatory authority should handle  
7140 employees and applicants who meet a high risk condition involving hepatitis A on a case-by-case basis.  
7141 With this approach in mind, the following criteria are offered as a guide. First, the following information  
7142 should be collected and analyzed:

7143

7144 1. — Clarify the type of contact the individual had with another person diagnosed with hepatitis A  
7145 virus infection. Keep in mind that the closer the contact (i.e., living in the same household as  
7146 the infected person), the more likely it is that a susceptible person may become infected.

7147

7148 2. — What job does the retail food employee perform at the retail food establishment, e.g., is the  
7149 employee involved in food preparation?

7149

3. — When did the employee begin work at the establishment?

7150

7151 4. — What level of personal hygiene does the individual exhibit? For example, does the individual  
7152 adhere to the handwashing requirements specified in the Regulation?

7152

7153 5. — Has the individual suffered from hepatitis A in the past? If the answer to this question is yes,  
7154 was blood testing done? If the individual did have hepatitis A in the past, the individual is  
7155 immune from re-infection.

7155

7156 6. — In terms of the current high risk condition, has the individual received immune globulin (IG)?  
7157 When?

7157

7158

- 7159  
7160 In addition, upon being notified of the high risk condition, the person in charge should immediately:  
7161  
7162 1. Discuss the traditional modes of transmission of hepatitis A virus infection with the retail  
7163 food employee involved.
- 7164 2. Advise the retail food employee to observe good hygienic practices both at home and at  
7165 work. This includes a discussion of proper handwashing, as described in the Regulation, after  
7166 going to the bathroom, changing diapers, or handling stool-soiled material.
- 7167 3. Review the symptoms listed in the Regulation that are caused by hepatitis A infection.
- 7168 4. Remind the employee of the employee's responsibility as specified in the Regulation to  
7169 inform the person in charge immediately upon the onset of any of the symptoms listed in the  
7170 Regulation.
- 7171 5. In light of the high infectivity of hepatitis A, ensure that the employee stops work  
7172 immediately if any of the symptoms described in the Regulation develop and reports to the  
7173 person in charge.

7174  
7175 If after consideration of all the information gathered, the person in charge feels that the employee in  
7176 question is likely to develop hepatitis A, restriction or exclusion of the individual's activities should be  
7177 considered.

7178  
7179 A restricted retail food employee may work in an area of the retail food establishment where there is  
7180 wrapped food, wrapped single-service or single-use articles, or soiled food equipment or utensils.  
7181 Examples of activities that a restricted person might do include working at the cash register, seating  
7182 patrons, bussing tables, stocking canned or other packaged foods, or working in a non-food cleaning or  
7183 maintenance capacity consistent with the criteria in the definition of the term "restricted." A retail food  
7184 employee who is restricted from working in one retail food establishment may not work in an unrestricted  
7185 capacity in another retail food establishment, but could work unrestricted in another retail store that is not  
7186 a retail food establishment. A restricted retail food employee may enter a retail food establishment as a  
7187 consumer or the same as any other member of the general public.

7188  
7189 An excluded individual may not work as a retail food employee on the premises of any retail food  
7190 establishment. In a facility that has different departments, such as a department store, school, or health  
7191 care facility, the regulatory authority, in concert with other infection control authorities, may consider  
7192 allowing an excluded retail food employee to work in an area or department that is separate and  
7193 segregated from the food preparation, service, and storage areas, and the food equipment and utensil  
7194 areas, such as the soiled linen/laundry area or exterior maintenance. An excluded person may enter the  
7195 retail food establishment as a customer or the same as any member of the general public.

## 7196 7197 **2-203—Removal of Exclusions**

7198  
7199 Chapter 2 provisions related to employee health are structured to recognize certain characteristics of each  
7200 of the four infectious agents, the risk of illness presented by asymptomatic shedders, the increased risk to  
7201 highly susceptible populations, and the need to provide extra protection to those high-risk populations.  
7202

7203 Asymptomatic shedders are retail food employees who do not exhibit the symptoms of foodborne illness  
7204 but who are identified through laboratory analysis of their stools to have any one of the three bacterial  
7205 pathogens identified in Chapter 2 in their gastrointestinal system.

7206  
7207 The duties that an asymptomatic shedder performs in a retail food establishment are restricted if the  
7208 establishment serves a general population or, if a highly susceptible population is involved, the shedder is  
7209 excluded. Several considerations factor into the need to preclude asymptomatic shedders from retail food  
7210 establishment functions that may result in the transmission of foodborne disease.

7211 •——— Outbreaks of foodborne illness involving *Salmonella Typhi* have been traced to  
7212 asymptomatic retail food employees who have transmitted the pathogen to food, causing  
7213 illness.

7214 •——— There is some epidemiological evidence of transmission of food via retail food  
7215 employees infected with *Shigella* spp.

7216 •——— Healthy consumers are at risk due to a low infectious dose of *Shigella* spp.

7217 •——— Despite lacking epidemiological evidence of transmission of food via retail food  
7218 employees infected with Shiga toxin producing *Escherichia coli*, the documented ease of  
7219 transmitting it from person to person in a day care setting, suggests a low infectious dose and  
7220 the potential for the organism to be transmitted through food.

7221 •——— The severity and consequences of one of the illnesses, Hemolytic Uremic Syndrome  
7222 (HUS), associated with Shiga toxin producing *Escherichia coli* warrant the institution of  
7223 disease interventions.

7224 •——— Restriction in a retail food establishment that does not serve a highly susceptible  
7225 population affords protection for the general population and the immune-suppressed subset of  
7226 the general population.

7227  
7228 The risk that a communicable disease will be transmitted by retail food employees who are asymptomatic  
7229 shedders varies depending upon the hygienic habits of the worker, the food itself and how it is prepared,  
7230 the susceptibility of the population served, and the infectivity of the organism.

7231  
7232 To minimize the risk in all retail food establishments of the transmission of foodborne disease by an  
7233 asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the  
7234 three bacterial pathogens are either restricted or excluded, depending on the population served. Requiring  
7235 restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion  
7236 and is consistent with APHA published recommendations in the "Control of Communicable Diseases in  
7237 Man."

7238  
7239 The Regulation requires medical clearance, based on criteria designed to detect the shedder state, before a  
7240 person who had a recent illness from, or is identified as a shedder of any of the three bacterial infectious  
7241 agents is allowed to resume the duties from which that person was restricted or, in the case of an  
7242 establishment that serves a highly susceptible population, before the person may return to work.

7243  
7244 With respect to a retail food employee in an establishment that serves an immunocompromised  
7245 population, more stringent provisions should be addressed. Specifically, exclusion may be required in 3  
7246 situations in which it is not required for retail food employees in other retail food establishments.

7247  
7248 Those 3 situations involve an employee who:



- 7249  
7250 1. ~~Meets a high risk condition and has a symptom of acute gastrointestinal illness~~
- 7251 2. ~~Is diagnosed as an asymptomatic shedder of *S. Typhi*, *Shigella* spp. or Shiga toxin producing~~  
7252 ~~*Escherichia coli*; or~~
- 7253 3. ~~Had a recent illness caused by *S. Typhi*, *Shigella* spp., or Shiga toxin producing *Escherichia*~~  
7254 ~~*coli*. The exclusion is in effect until a physician licensed to practice medicine or, if allowed~~  
7255 ~~by law, a nurse practitioner or physician assistant, provides the medical clearance, indicating~~  
7256 ~~that the infectious agent is not detected.~~

7257

7258 ~~**2-204 Discharges from the Eyes, Nose, and Mouth**~~

7259

7260 ~~Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by retail food~~  
7261 ~~employees can directly contaminate exposed food, equipment, utensils, linens, and single service and~~  
7262 ~~single use articles. When these poor hygienic practices cannot be controlled, the employee must be~~  
7263 ~~assigned to duties that minimize the potential for contaminating food and surrounding surfaces and~~  
7264 ~~objects.~~

7265

7266 ~~**2-3 Authorized Personnel**~~

7267

7268 ~~**2-4 Personal Cleanliness**~~

7269

7270 ~~**2-401**~~

7271

7272 ~~**2-402 and 2-403 Cleaning Procedure and When to Wash**~~

7273

7274 ~~The hands are particularly important in transmitting foodborne pathogens. Retail food employees with~~  
7275 ~~dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity, which~~  
7276 ~~may contaminate the hands, must be followed by thorough handwashing in accordance with the~~  
7277 ~~procedures outlined in the Regulation.~~

7278

7279 ~~Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are~~  
7280 ~~transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth,~~  
7281 ~~throat, and nose of many employees. The hands of employees can be contaminated by touching their nose~~  
7282 ~~or other body parts.~~

7283

7284 ~~Handwashing is a critical factor in reducing fecal-oral pathogens that can be transmitted from hands to~~  
7285 ~~ready to eat food as well as other pathogens that can be transmitted via cross contamination from raw~~  
7286 ~~foods to ready to eat foods. Many employees fail to wash their hands as often as necessary and even those~~  
7287 ~~who do may use flawed technique.~~

7288

7289 ~~In the case of a retail food worker with one hand or a hand like prosthesis, the EEOC has agreed that this~~  
7290 ~~requirement for thorough handwashing can be met through reasonable accommodation in accordance with~~  
7291 ~~the Americans with Disabilities Act. Devices are available which can be attached to a lavatory to enable~~  
7292 ~~the retail food worker with one hand to adequately generate the necessary friction to achieve the intent of~~  
7293 ~~this requirement without sacrificing public health concerns.~~

7294

7295 The greatest concentration of microbes exists around and under the fingernails of the hands. The area  
7296 under the fingernails, known as the "subungal space", has by far the largest concentration of microbes on  
7297 the hand and this is also the most difficult area of the hand to decontaminate.

7298  
7299 There are two different types of microbes on the hands, transient and resident microbes. Transient  
7300 microbes consist of contaminating pathogens which are loosely attached to the skin surface, do not  
7301 survive nor multiply, and a moderate number of organisms can be removed with adequate handwashing.  
7302 Resident microbes consist of a relatively stable population that survive and multiply on the skin, and are  
7303 not easily washed off the hands. Resident microbes on the hands are usually not a concern for potential  
7304 contamination in retail food service.

7305  
7306 All aspects of proper handwashing are important in reducing microbial transients on the hands. However,  
7307 friction and water have been found to play the most important role. This is why the amount of time spent  
7308 scrubbing the hands is critical in proper handwashing. It takes more than just the use of soap and running  
7309 water to remove the transient pathogens that may be present. It is the abrasive action obtained by  
7310 vigorously rubbing the surfaces being cleaned that loosens the transient microorganisms on the hands.

7311  
7312 Research has shown a minimum 10–15 second scrub is necessary to remove transient pathogens from the  
7313 hands, and when an antimicrobial soap is used, a minimum of 15 seconds is required.

7314  
7315 Every stage in handwashing is equally important and has an additive effect in transient microbial  
7316 reduction. Therefore, effective handwashing must include scrubbing, rinsing, and drying the hands. When  
7317 done properly, each stage of handwashing further decreases the transient microbial load on the hands.

7318  
7319 Handwashing done properly can result in a 2–3 logarithmic reduction in transient bacteria and a 2-log  
7320 reduction in transient viruses and protozoa. With heavy contamination of transient microbial pathogens,  
7321 (i.e.  $> 10^4$  microbes, as found on hands contaminated with bodily wastes and infected bodily fluids)  
7322 handwashing may be ineffective in completely decontaminating the hands. Therefore, a further  
7323 intervention such as a barrier between hands and ready-to-eat food is necessary.

7324  
7325 The hands may become contaminated when the retail food employee engages in specific activities. The  
7326 increased risk of contamination requires handwashing immediately after the activities listed. The specific  
7327 examples listed in this Regulation section are not intended to be all inclusive. Employees must wash their  
7328 hands after any activity, which may result in contamination of the hands.

## 7329 7330 **2-404—Hand Antiseptics**

7331  
7332 This provision is intended to ensure that an antimicrobial product applied to the hands is both, 1) safe and  
7333 effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will  
7334 come into direct contact with food. The prohibition against bare hand contact contained in Section 3-401  
7335 applies only to an exposed ready-to-eat food.

### 7336 7337 As a Drug Product

7338  
7339 There are three means by which a hand sanitizer is considered to be safe and effective when applied to  
7340 human skin:

7341  
7342 1. A hand sanitizer may be approved by FDA under a new drug application based on data  
7343 showing safety and effectiveness and may be listed in the publication **Approved Drug**  
7344 **Products with Therapeutic Equivalence Evaluations**. Also known as the "Orange Book,"  
7345 this document provides "product specific" listings rather than listings by compound. It is

7346 published annually with monthly supplements. These publications are available on the  
7347 Internet via the FDA Web Site and Center for Drug Evaluation and Research Home Page,  
7348 from the Superintendent of Documents/Government Printing Office, and from the National  
7349 Technical Information Service. However, as of the end of 1998, no hand sanitizers are listed  
7350 in this publication since no new drug applications have been submitted and approved for  
7351 these products.

7352 2.—A hand sanitizer active ingredient may be identified by FDA in the monograph for OTC  
7353 (over the counter) Health Care Antiseptic Drug Products under the antiseptic handwash  
7354 category. Since hand sanitizing products are intended and labeled for topical antimicrobial  
7355 use by retail food employees in the prevention of disease in humans, these products are  
7356 "drugs" under the Federal Food, Drug, and Cosmetic Act ¶ 201(g). As drugs, hand sanitizers  
7357 and dips must be manufactured by an establishment that is duly registered with the FDA as a  
7358 drug manufacturer; their manufacturing, processing, packaging, and labeling must be  
7359 performed in conformance with drug Good Manufacturing Practices (GMP's); and the  
7360 product must be listed with FDA as a drug product.

7361  
7362 Products having the same formulation, labeling, and dosage form as those that existed in the marketplace  
7363 on or before December 4, 1975 or that are authorized by USDA are being evaluated under the OTC (over-  
7364 the counter) Drug Review by FDA's Center for Drug Evaluation and Research. Otherwise, the far more  
7365 extensive FDA review process for a new drug application (NDA) is required before marketing.  
7366

7367 However, as of the end of 1998, no hand sanitizers have been shown to be acceptable through this process  
7368 since the monograph has not been finalized. FDA's Center for Drug Evaluation and Research is not  
7369 presently objecting to the use of "instant hand sanitizers" based on ethyl alcohol or isopropyl alcohol, or  
7370 certain chlorine "hand sanitizing dips" since these compounds are included in the OTC Drug Review. The  
7371 ultimate status of these products will not be known until the final monograph publishes.  
7372

7373 Acceptable antimicrobial ingredients for hand sanitizers will be identified in a future final monograph  
7374 issued under the OTC Drug Review for OTC Antiseptic Handwashes. Information about whether a  
7375 specific product has been accepted and included in the proposed monograph may be obtained from the  
7376 manufacturer. You may also refer to *Federal Register* (59) No. 116, June 17, 1994, Tentative Final  
7377 Monograph (TFM) for Health Care Antiseptic Drug Products; Proposed Rule. This TFM describes the  
7378 inclusion of hand sanitizers in this Review, on page 31440 under Comment 28 of Part II.  
7379

7380 Questions regarding acceptability of a hand sanitizer with respect to OTC compliance may be directed to  
7381 the OTC Compliance Team, HFD-312, Division of Labeling and Nonprescription Drug Compliance,  
7382 Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Place, Rockville, MD  
7383 20855-2737. Specific product label/promotional information and the formulation are required for  
7384 determining a product's regulatory status.  
7385

#### 7386 As a Food Additive

7387  
7388 To be regulated under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the  
7389 components of a hand care product must *reasonably* be expected to become a component of food based  
7390 upon the product's intended use.  
7391

7392 Where the components of a product are reasonably expected to become a component of food based upon  
7393 the product's intended use, there are three means by which they are considered by FDA to be safe:  
7394

- 7395 1. A substance may be exempted from the requirement of being listed in the federal food  
7396 additive regulations as specified in 21 CFR 170.39 Threshold of regulation for substances  
7397 used in food contact articles. A review by FDA's Center for Food Safety and Applied  
7398 Nutrition is required for such an exemption to be issued. The Center's Indirect Additives  
7399 Team has exempted ethyl alcohol and isopropyl alcohol from the requirement of being listed  
7400 in the federal food additive regulations. Therefore, there is no food additive prohibition  
7401 against using these substances as components of an instant hand sanitizer.
- 7402 2. A substance may be regulated for the intended use as a food additive as specified in 21 CFR  
7403 178—Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, and listed there  
7404 under with conditions of safe use. However, as of 1998, no petitions have been received for  
7405 the review and approval of substances for use as hand sanitizers, and therefore none are  
7406 listed.
- 7407 3. A substance may be "generally recognized as safe (GRAS)" for the intended use in contact  
7408 with food within the meaning of the Federal Food, Drug, and Cosmetic Act § 201(s).  
7409 Substances affirmed by FDA to be GRAS are listed in one of the following: 21 CFR 182—  
7410 Substances Generally Recognized as Safe, 21 CFR 184—Direct Food Substances Affirmed as  
7411 Generally Recognized as Safe, or 21 CFR 186—Indirect Food Substances Affirmed as  
7412 Generally Recognized as Safe. The law also provides for independent GRAS determinations.

7413  
7414 The Indirect Additives Team does not certify or provide approvals for specific products. However, if the  
7415 use of a product meets the regulations of 21 CFR 170.39 Threshold of regulation for substances used in  
7416 food contact articles, FDA may provide a letter to a firm stating that the use of this product is exempt  
7417 from the requirement of a food additive listing regulation. However, the product must be the subject of a  
7418 new drug application or under FDA's OTC Drug Review to be legally marketed.

7419  
7420 Questions regarding the regulatory status of hand sanitizer components as food additives may be directed  
7421 to the Indirect Additives Team, HFS-215, Office of Premarket Approval, Center for Food Safety and  
7422 Applied Nutrition, 200 C Street, SW, Washington, DC 20204. It may be helpful or necessary to provide  
7423 label/promotional information when inquiring about a specific component.

#### 7424 7425 **2-405—Where to Wash**

7426  
7427 Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross  
7428 contamination. It is important that handwashing be done only at a properly equipped handwashing facility  
7429 in order to help ensure that retail food employees effectively clean their hands. Handwashing facilities are  
7430 to be conveniently located, always accessible for handwashing, maintained so they provide proper water  
7431 temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels  
7432 and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since  
7433 this may result in avoidable contamination of the sink and the food prepared therein. Service sinks may  
7434 not be used for food employee handwashing since this practice may introduce additional hand  
7435 contaminants because these sinks may be used for the disposal of mop water, toxic chemicals, and a  
7436 variety of other liquid wastes. Such wastes may contain pathogens from cleaning the floors of food  
7437 preparation areas and toilet rooms and discharges from ill persons.

#### 7438 7439 **2-406—Fingernails**

7440  
7441 The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the  
7442 cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails

7443 may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails  
7444 after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability  
7445 concerns and may harbor pathogenic organisms.

7446

#### 7447 **2-407—Clothing**

7448

7449 Dirty clothing may harbor diseases that are transmissible through food. Retail food employees who  
7450 inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination  
7451 of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In  
7452 addition, employees wearing dirty clothes send a negative message to consumers about the level of  
7453 sanitation in the establishment.

7454

#### 7455 **2-408—Jewelry**

7456

7457 Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry  
7458 may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms  
7459 transmissible through food.

7460

7461 The term "jewelry" generally refers to the ornaments worn for personal adornment and medical alert  
7462 bracelets do not fit this definition. However, the wearing of such bracelets carries the same potential for  
7463 transmitting disease-causing organisms to food. In the case of a retail food worker who wears a medical  
7464 information or medical alert bracelet, the EEOC has agreed that this requirement can be met through  
7465 reasonable accommodation in accordance with the Americans with Disabilities Act by the person in  
7466 charge and the employee working out acceptable alternatives to the bracelet worn at the wrist. An  
7467 example would be wearing the bracelet high on the arm or secured in a manner that does not pose a risk to  
7468 the food but provides emergency medical information if it is needed.

7469

7470 An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item  
7471 itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for  
7472 consumers, such as chipped and/or broken teeth and internal cuts and lesions.

7473

#### 7474 **2-5—Hygienic Practice**

7475

#### 7476 **2-501—General**

7477

7478 Proper hygienic practices must be followed by retail food employees in performing assigned duties to  
7479 ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the  
7480 possibility of transmitting disease through food.

7481

#### 7482 **2-502—Eating, Drinking, or Using Tobacco**

7483

7484 Smoking or eating by employees in food preparation areas is prohibited because of the potential that the  
7485 hands, food, and food contact surfaces may become contaminated. Unsanitary personal practices such as  
7486 scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered  
7487 sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also  
7488 adversely affect consumer confidence in the establishment.

7489

7490 Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these  
7491 areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas  
7492 retail food employees are allowed to drink from closed containers that are carefully handled.

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## **2-503—Hair Restraints**

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Retail food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

## **Chapter 3—Food**

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### **3-1—Characteristics**

#### **3-101—General**

A primary line of defense in ensuring that food meets these requirements is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of *Clostridium botulinum*, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

#### **Labeling—General**

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in

7539 ~~dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In~~  
7540 ~~addition, consumers have a basic right to be protected from misbranding and fraud.~~  
7541

7542

**7543 Labeling for Raw Shell Eggs**

7544 The Code of Federal Regulations 21 CFR 101.17 ~~Food Labeling warning, notice, and safe handling~~  
7545 ~~statements~~, paragraph (h) *Shell eggs* state in subparagraph (1), "The label of all shell eggs, whether in  
7546 intrastate or interstate commerce, shall bear the following statement: 'SAFE HANDLING  
7547 INSTRUCTIONS: To prevent illness from bacteria; keep eggs refrigerated, cook eggs until yolks are  
7548 firm, and cook foods containing eggs thoroughly.'" Further, in subparagraph (4) it states, "Shell eggs that  
7549 have been, before distribution to consumers, specifically processed to destroy all viable *Salmonella* shall  
7550 be exempt from the requirements of paragraph (h) of this section."

**7551 3-2—Sources and Specifications**

7552

**7553 3-201—Shellfish and Fish**

7554

**7555 Shellfish**

7556

7557 Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or  
7558 in an undercooked state and thus receive neither heat nor any other process that would destroy or  
7559 inactivate microbial pathogens. For safety, these foods must be accompanied by certification that  
7560 documents that they have been harvested from waters that meet the water quality standards contained in  
7561 the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also  
7562 provides confidence that processing, packaging, and shipping have been conducted under sanitary  
7563 conditions.

7564

7565 Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers.  
7566 Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final  
7567 product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

7568

7569 Pathogens from the harvest area are of particular concern in molluscan shellfish because:

7570 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage,  
7571 which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2)  
7572 molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3)  
7573 molluscan shellfish are often consumed whole, either raw or partially cooked.

7574

7575 To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign  
7576 government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish  
7577 are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan  
7578 shellfish harvesting is allowed from some waters, not from others, and only at certain times or under  
7579 certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan  
7580 shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

7581

7582 Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan  
7583 shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag  
7584 that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a  
7585 requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck  
7586 molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that  
7587 containers of shucked molluscan shellfish bear a label with the name, address, and certification number of  
7588 the shucker packer or repacker.

7589

7590 Pathogens, such as *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, and *Listeria*  
7591 *monocytogenes* that may be present in low numbers at the time that molluscan shellfish are harvested,



7592 may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the  
7593 risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and  
7594 refrigeration. The length of time is dependant upon either the month of the year or the average monthly  
7595 maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control  
7596 Authority.

7597  
7598 Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as  
7599 dinoflagellates. In the U.S., PSP is generally associated with the consumption of molluscan shellfish from  
7600 the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated  
7601 with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the  
7602 U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, Dungeness crabs, tanner  
7603 crabs, and red rock crabs.

7604  
7605 Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of  
7606 molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern  
7607 Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and  
7608 some suggestions of occurrence elsewhere.

7609  
7610 For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However,  
7611 instances have been documented in Japan, Southeast Asia, Scandinavia, Western Europe, Chile, New  
7612 Zealand, and eastern Canada.

7613  
7614 Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish  
7615 from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of  
7616 Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been  
7617 identified as a problem in the viscera of Dungeness crab, tanner crab, red rock crab, and anchovies along  
7618 the west coast of the United States.

7619  
7620 Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However,  
7621 products such as roe on scallops and whole scallops do present a potential hazard for natural toxins.

7622  
7623 To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug  
7624 Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a  
7625 tripartite, cooperative action plan involving federal and state public health officials and the shellfish  
7626 industry. Those groups work together to improve shellfish safety. States regularly monitor waters to  
7627 ensure that they are safe before harvesting is permitted. FDA routinely audits the states' classification of  
7628 shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed  
7629 shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters.  
7630 Bootlegging is a criminal activity and a major factor in shellfish borne illnesses. Purchasing from  
7631 certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

7632  
7633 Plastic containers commonly used throughout the shellfish industry for shucked product bear specific  
7634 information regarding the source of the shellfish as required by the NSSP Guide for the Control of  
7635 Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their  
7636 subsequent reuse by shellfish packers, which could result in shucked product that is inaccurately  
7637 identified by the label. The reuse of these containers within the food establishment must be assessed on  
7638 the basis of the Regulation's criteria for multi-use containers and the likelihood that they will be properly  
7639 relabeled to reflect their new contents.

7640

7641 Accurate source identification of the harvesting area, harvester, and dealers must be contained on  
 7642 molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the  
 7643 information is available to expedite the epidemiological investigation and regulatory action.

7644  
 7645 Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to  
 7646 foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility  
 7647 continues throughout the distribution chain.

7648  
 7649 Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their  
 7650 source. Proper identification is needed for tracing the origin and determining conditions of shellfish  
 7651 processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of  
 7652 the problem may remain undetected. If no causative factors are identified in the food establishment,  
 7653 tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that  
 7654 may need to be closed to harvesting.

7655  
 7656 Accurate records that are maintained in a manner that allows them to be readily matched to each lot of  
 7657 shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak  
 7658 occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate  
 7659 actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus  
 7660 infections, which have an incubation period that is significantly longer than other shellfish-borne diseases,  
 7661 to come to light. The 90-day requirement is based on the following considerations:

7662

|                                    |         |
|------------------------------------|---------|
| 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 |

7663 In reality and as stated in the provision, the 90-day "clock" starts at the time the container of shellstock is  
 7664 emptied. Starting from the date of harvest is not correct because the shellstock may be sold/consumed in  
 7665 less than the 14 days of shelf life cited in the chart above. Therefore, the 90 days may expire and the tag  
 7666 discarded before an illness is reported and investigated.

7667 Shellstock could be frozen in the food establishment during the 14-day estimated shelf life period, which  
 7668 would effectively stop the clock on the shelf life. The shellstock could be thawed and consumed past the  
 7669 14-day shelf life. In this case, the 90 days would expire before consumption if the clock started 90 days  
 7670 from the harvest date.

7671 Freezing shellstock in the food establishment is not usually done because, although oysters in the shell  
 7672 can be frozen with fair results, they do not have the same texture and appearance of a fresh oyster when  
 7673 thawed. Commercially frozen oysters are frozen rapidly to retain product quality.

7674

7675

**7676 Fish**

7677

7678 After December 18, 1997, all processors of fish were required by 21 CFR 123 to have conducted a hazard  
7679 analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a  
7680 HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have  
7681 complied with this requirement. Hazards known to be associated with specific fish species are discussed  
7682 in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of  
7683 Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and  
7684 drugs.

7685

7686 The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21  
7687 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family  
7688 **Scombridae**, in which significant levels of histamine may be produced in the fish flesh by  
7689 decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow  
7690 the growth of mesophilic bacteria.

7691

7692 Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S.,  
7693 Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean  
7694 regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel,  
7695 large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large  
7696 predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and  
7697 snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and  
7698 barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

7699

**7700 3-202—Parasite Destruction**

7701

7702 Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or  
7703 perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service  
7704 as an alternative public health control to that which is provided by adequate cooking. Candling or other  
7705 visual inspection techniques are not adequate to avoid the risk of parasites from fish, which have not been  
7706 frozen.

7707

7708 The recommended control strategies refer to the ambient air temperature during freezing and to the length  
7709 of time that the fish is held at the appropriate freezer temperature, or the length of time that the fish is held  
7710 after it is solid frozen, whichever is appropriate. The parasite hazard is not considered to be reasonably  
7711 likely to occur if the finished product is fish eggs that have been removed from the skein (the tissue that  
7712 contains the egg mass) and rinsed.

7713

7714 Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw  
7715 consumption, they must be properly frozen before they are served. If this process is done off-premises,  
7716 purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be  
7717 provided. This is necessary because fish from natural bodies of water may carry parasitic worms that can  
7718 infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated)  
7719 herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough  
7720 freezing kills these worms if the fish are subjected to a low-enough temperature for a long-enough time.

7721

7722 In response to information provided to the FDA Office of Seafood, the [Fish and Fisheries Products](#)  
7723 [Hazards and Controls Guidance](#)<sup>33</sup> lists certain species of tuna as not being susceptible to parasites of  
7724 concern and therefore exempted from the freezing requirements that apply to other fish species that are  
consumed raw.

7725 The Fish and Fisheries Products Hazards and Controls Guidance states that species that normally have  
7726 parasites as a result of consuming infected prey, apparently do not have the same parasite hazard when  
7727 raised on pelleted food in an aquaculture operation. On the other hand, aquacultured fish that are fed  
7728 processing waste and by-catch fish may have a parasite hazard, even when wild caught fish of that species  
7729 do not normally have a parasite hazard. Feed must not contain any live parasites. For example, the use of  
7730 fresh fish meat in feed could transmit such parasites. Only heat treated feed or feed otherwise produced in  
7731 a manner that would kill parasite intermediate stages infective to the aquacultured fish, such as most  
7732 pelleted feeds, should be used.

7733 Additionally, it should be noted that the Fish and Fisheries Products Hazards and Controls Guidance,  
7734 Edition 3, Table 3.1 only lists fish with well documented parasite hazards. Fish species in Table 3.1 that  
7735 do not have specific parasite hazards listed are not necessarily safe when consumed raw or undercooked.  
7736 This is because fish species in Table 3.1 were not listed with a parasite hazard if the species were  
7737 generally cooked before consumption. In addition, in some cases, there is insufficient information or data  
7738 to be able to denote a specific parasite hazard or deem the species as naturally parasite free. The  
7739 exemptions to freezing as specified in Section 3-202 of the *REGULATION* are inclusive of and in  
7740 harmony with the information and recommendations provided in the Fish and Fisheries Products Hazards  
7741 and Controls Guidance.

### 7742 **3-3 — Sources and Specifications**

7743

#### 7744 **3-301 — Package Integrity**

7745 Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the  
7746 contained food. If the integrity of the packaging has been compromised, contaminants such as  
7747 *Clostridium botulinum* may find their way into the food. In anaerobic conditions (lack of oxygen),  
7748 botulism toxin may be formed.

7749 Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods.  
7750 Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many  
7751 cases, suspect packaging may have to be inspected by trained persons using magnifying equipment.  
7752 Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or  
7753 imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat  
7754 was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

#### 7755 **3-302 — Hermetically Sealed Food**

7756

7757 Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores  
7758 that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern  
7759 is the lethal toxin of *Clostridium botulinum*, an organism whose spores (i.e., survival stages for non-  
7760 growth conditions) are found throughout the environment. Even slight under processing of low acid food  
7761 which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn  
7762 consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these  
7763 foods are not processed to be commercially sterile, they must be received frozen or under proper  
7764 refrigeration.

7765

7766 Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the  
7767 contained food. If the integrity of the packaging has been compromised, contaminants such as  
7768 *Clostridium botulinum* may find their way into the food. In anaerobic conditions (lack of oxygen),  
7769 botulism toxin may be formed.

7770

7771 Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods.

7772 Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many

7773 cases, suspect packaging may have to be inspected by trained persons using magnifying equipment.  
7774 Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or  
7775 imperfections (lack of an airtight, i.e., hermetic seal). Swollen cans may also indicate that not enough heat  
7776 was applied during processing (under processing). Suspect cans must be returned and not offered for sale.  
7777

7778 Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may  
7779 become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment,  
7780 utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas  
7781 must be designated for storing unsaleable goods.  
7782

### 7783 **3-303—Dry Milk and Dry Milk Products**

### 7784 **3-304—Reconstitution of Dry Milk, Dry Milk Products and Non-Dairy Products**

### 7785 **3-305—Fluid Milk, Fluid Milk Products, and Frozen Dessert Mix**

7786  
7787  
7788  
7789 Milk, which is a staple for infants and very young children with incomplete immunity to infectious  
7790 diseases, is susceptible to contamination with a variety of microbial pathogens such as Shiga toxin-  
7791 producing *Escherichia coli*, *Salmonella* spp., and *Listeria monocytogenes*, and provides a rich medium  
7792 for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen  
7793 contamination in milk and products derived from milk. Dairy products are normally perishable and must  
7794 be received under proper refrigeration conditions.  
7795

7796 Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria  
7797 and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other  
7798 harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of  
7799 unpasteurized products will stop microbial growth and may reduce their bacterial populations; however,  
7800 some organisms will survive because neither process invariably kills bacteria. Under certain conditions,  
7801 freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain  
7802 cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.  
7803

### 7804 **3-306—Wild Mushrooms**

7805  
7806 Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never  
7807 been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans  
7808 whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous,  
7809 whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper  
7810 cooking.  
7811

7812 Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species.  
7813 In most parts of the country there is at least one organization that includes individuals who can provide  
7814 assistance with both identification and program design. Governmental agencies, universities, and  
7815 mycological societies are examples of such groups. If a food establishment chooses to sell wild  
7816 mushrooms, management must recognize and address the need for a sound identification program for  
7817 providing safe wild mushrooms.  
7818

7819 Regulatory authorities have expressed their difficulty in determining what constitutes a "wild mushroom  
7820 identification expert" and enforcing the Regulation provisions associated with it. In 1998, the Conference  
7821 for Food Protection (CFP) attempted to alleviate this problem through the formation of a committee that  
7822 was charged with determining what constitutes a wild mushroom expert. However, the committee was  
7823 unable to provide this information in a practical, useful manner for State and local regulators within the

7824 constraints of the Regulation. The 2000 CFP recommended and FDA accepted the committee's alternative  
7825 solution that a brochure be developed that will provide information on what constitutes a wild mushroom  
7826 expert, and to replace "identification by a wild mushroom expert" with "written buyer specifications."

7827  
7828 The CFP's recommendation attempts to provide the necessary information in a practical, useful manner  
7829 for all stakeholders, and yet still convey the highest level of public health protection. The CFP committee  
7830 suggested that written buyer specifications place more responsibility on the food establishment to ensure  
7831 that wild mushrooms are obtained from a safe source, and also provides state and local regulators a  
7832 template to use in ensuring wild mushrooms sold at retail are obtained from a safe source. The following  
7833 guidance is provided regarding the identification of wild mushrooms:

7834 A food establishment that sells or serves mushroom species picked in the wild shall have a written buyer  
7835 specification that requires identification of:

7836 1. The Latin binomial name, the author of the name, and the common name of the mushroom  
7837 species;

7838 2. That the mushroom was identified while in the fresh state;

7839 3. The name of the person who identified the mushroom;

7840 4. A statement as to the qualifications and training of the identifier, specifically related to mushroom  
7841 identification.

7842 Additional information can be found on the [California Poison Control](#)<sup>14</sup> web site.

### 7843 ~~3-307 Meat, Poultry, Game Animals and Exotic Species~~

7844  
7845 The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals  
7846 may be available as a source of food only if a regulatory inspection program is in place to ensure that wild  
7847 animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae,  
7848 bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the  
7849 human host. In addition to the risk posed to consumers of game that is not subject to an inspection  
7850 program, there is risk to those who harvest and prepare wild game because they may contract infectious  
7851 diseases such as rabies or tularemia.

### 7852 7853 **Labeling for Meat and Poultry**

7854  
7855 Retail food establishments that process and package meat or poultry in a form that is not ready to eat, are  
7856 obligated by federal regulation to label the product with safe food handling instructions. The intent of this  
7857 requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria  
7858 and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the  
7859 products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that  
7860 handles only prepackaged and pre-labeled products or if they obtain their meat or poultry at an operation  
7861 such as a supermarket with a meat processing operation or from a small neighborhood butcher.

7862  
7863

7864

7865 **3-308—Eggs**

7866

7867 Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria  
 7868 and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other  
 7869 harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of  
 7870 unpasteurized products will stop microbial growth and may reduce their bacterial populations; however,  
 7871 some organisms will survive because neither process invariably kills bacteria. Under certain conditions,  
 7872 freezing and drying may preserve microbes.

7873

7874 Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good  
 7875 growth medium for many types of bacteria. Damaged eggs must not be used as food.

7876

7877 The Definition of "Restricted Egg" contains several terms that are explained in this paragraph. An egg  
 7878 may be restricted because it is a/an:

7879

7880 (i) "Check" meaning an egg that has a broken shell or crack in the shell but has its shell  
 7881 membranes intact and contents not leaking.

7882 (ii) "Dirty egg or Dirties" meaning an egg that has a shell that is unbroken and has adhering dirt,  
 7883 foreign material, or prominent stains.

7884 (iii) "Incubator reject" meaning an egg that has been subjected to incubation and has been  
 7885 removed from incubation during the hatching operations as infertile or otherwise unhatchable.

7886 (iv) "Inedible" meaning eggs of the following descriptions: Black rots, yellow rots, white rots,  
 7887 mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs,  
 7888 eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

7889 (v) "Leaker" meaning an egg that has a crack or break in the shell and shell membranes to the  
 7890 extent that the egg contents are exposed or are exuding or free to exude through the shell.

7891 (vi) "Loss" meaning an egg that is unfit for human food because it is smashed or broken so that  
 7892 its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because  
 7893 it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

7894 On December 5, 2000 Federal regulations were amended to require that shell egg cartons bear safe  
 7895 handling instructions and be placed under refrigeration at 7.2°C (45°F) or lower upon delivery at retail  
 7896 establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of  
 7897 Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

7898 • 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5  
 7899 Inapplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or  
 7900 destruction of shell eggs.

7901 • 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling  
 7902 statements, (h) *Shell eggs*.

7903 • 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

7904 The labeling rule became effective September 4, 2001, and the refrigeration rule is effective June 4, 2001.  
 7905 This rule is one part of the larger Egg Safety Action Plan, a farm to table approach for ensuring the safety  
 7906 of our nation's egg supply, which was announced by the President on December 11, 1999. The Plan, a  
 7907 joint effort by the FDA and the USDA, seeks to reduce by 50 percent the number of *Salmonella*

7908 ~~Enteritidis, illnesses attributed to contaminated eggs by 2005 and eliminate egg-associated *Salmonella*~~  
7909 ~~Enteritidis illnesses by 2010.~~

7910

### 7911 ~~3-309—Ice~~

7912

7913 Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice  
7914 that comes into contact with food to cool it or that is used directly for consumption must be as safe as  
7915 drinking water that is periodically tested and approved for consumption.

7916

### 7917 ~~3-310—Ice Used as Exterior Coolant, Prohibited as Ingredient~~

7918

7919 Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and  
7920 other contaminants. For example, ice used to store or display fish or packaged foods could become  
7921 contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient,  
7922 it could contaminate the final product.

7923

### 7924 ~~3-311—Storage or Display of Food in Contact With Water or Ice~~

7925

7926 Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior  
7927 surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water  
7928 to the food that is unclaimed in the food's formulation and label.

7929

7930 Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing  
7931 the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by  
7932 water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

7933

### 7934 ~~3-312—Juice~~

7935

#### ~~Labeling for Juice~~

7936 On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling  
7937 regulations to require a warning statement on fruit and vegetable juice products that have not been  
7938 processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this  
7939 action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products.  
7940 FDA expects that providing this information to consumers will allow them to make informed decisions on  
7941 whether to purchase and consume such juice products, thereby reducing the incidence of foodborne  
7942 illnesses and deaths caused by the consumption of these juices.

7943 On July 18, 2001 FDA announced a final rule designed to improve the safety of fruit and vegetable juice  
7944 and juice products. Under the rule, juice processors must use Hazard Analysis and Critical Control Point  
7945 (HACCP) principles for juice processing. Processors making shelf-stable juices or concentrates that use a  
7946 single thermal processing step are exempt from the microbial hazard requirements of the HACCP  
7947 regulation. Retail establishments where packaged juice is made and only sold directly to consumers (such  
7948 as juice bars) are not required to comply with this rule.

7949 Rather, the rule requires fresh fruit or vegetable juices that are packaged at retail (untreated juices or  
7950 beverages containing untreated juices that are offered to consumers as prepackaged foods) to be processed  
7951 under HACCP with a 5 log reduction in pathogens of concern OR bear the warning statement as specified  
7952 in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and,  
7953 therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons  
7954 with weakened immune systems." Refer to Chapter 1 for the definition of juice. It is important to note that



7955 the definition of "juice" includes puréed fruits and vegetables, which are commonly prepared for service  
7956 to highly susceptible populations.

7957 Food establishments that serve a highly susceptible population (HSP) cannot serve prepackaged juice that  
7958 bears the warning label and they must serve only pasteurized juice. For juice only, this population  
7959 includes children who are age 9 or less and receive food in a school, day care setting, or similar facility  
7960 that provides custodial care.

7961 Unpackaged juice (glasses of juice prepared at a juice bar, for example) does not require the 5 log  
7962 reduction nor a warning statement or other consumer advisory (juice is not an animal food and therefore  
7963 not covered by section 3.801) when prepared and served at retail. Usually the juice is served by the glass  
7964 or in small batches compared to a commercial juice processor. The risk of using "drops" and damaged  
7965 fruits or vegetables is much less at retail because of buyer specs that provide higher quality produce,  
7966 meaning that fruits for juicing are less likely to be of a lower quality or damaged.

7967 Additional information is available in the document, "[Guidance for Industry: Exemptions from the  
7968 Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5 Log Pathogen  
7969 Reduction; Final Guidance](#)"<sup>8</sup>, October 7, 2002 or obtained from the FDA Office of Nutritional Products  
7970 Labeling and Dietary Supplements.

### 7971 **3-313—Whole Muscle, Intact Beef Steaks**

7972  
7973 In order for a food establishment operator to know that a steak is a whole muscle, intact cut of beef that  
7974 can therefore be undercooked and served without a consumer advisory, the incoming product must be  
7975 labeled. Processors can accommodate this need at the retail level by developing proposed labels,  
7976 obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately  
7977 affixing the labels to their products.

### 7978 7979 **3-4—Protection From Contamination After Receiving**

#### 7980 7981 **3-401—Preventing Contamination from Hands**

7982  
7983 In November, 1999, the National Advisory Committee for Microbiological Criteria for Foods  
7984 (NACMCF), concluded that bare hand contact with ready to eat foods can contribute to the transmission  
7985 of foodborne illness and agreed that the transmission could be interrupted. The NACMCF recommended  
7986 exclusion/restriction of ill food workers, as the first preventative strategy and recognized that this  
7987 intervention has limitations, such as trying to identify and manage asymptomatic food workers. When the  
7988 FDA reviewed and analyzed epidemiological data on foodborne illness outbreaks caused by fecal-oral  
7989 pathogens, 93% of the foodborne illnesses reported were caused by ill food workers preparing food. This  
7990 finding illustrates the problem caused by ill food workers who continue to prepare food. This is a  
7991 problem, which is exacerbated by an increasing global market place, a tight labor market and lack of  
7992 knowledge and understanding of food safety among food workers, and the economic need for food  
7993 workers to work even when ill.

7994  
7995 Depending on the microbial contamination level on the hands, handwashing with plain soap and water, as  
7996 specified in the Regulation, may not be an adequate intervention to prevent the transmission of pathogenic  
7997 microbes to ready to eat foods via hand contact with ready to eat foods. Handwashing as specified in the  
7998 Regulation will reduce microbial contamination of the hands by 2-3 logs.

7999  
8000 Food workers infected with fecal-oral pathogens can shed viral and protozoan pathogens in the feces at  
8001 levels up to 10<sup>8</sup> viral particles or oocysts per gram of feces. Having a high potential contamination level

8002 on the hands combined with a very low infectious dose necessary to cause infection are the reasons that  
8003 FDA believes that handwashing alone is not an effective single barrier in the transmission of these fecal-  
8004 oral pathogens. The infective dose for Giardia and Cryptosporidium is believed to be as low as 1-10  
8005 oocysts, and as few as 10 virus particles can infect an individual with hepatitis A. The infective dose for  
8006 Norwalk virus is also believed to be very small.

8007  
8008 The CDC now estimates that Norwalk-like viruses are the leading cause of foodborne illness in the United  
8009 States. The CDC has also reported that hands are the most important means by which enteric viruses are  
8010 transmitted. Further, contamination of food by an infected food worker is the most common mode of  
8011 transmission of hepatitis A in foodborne disease outbreaks. Research has shown the viral transfer rate  
8012 from contaminated hands to ready-to-eat food to be about 10% and that proper handwashing will  
8013 significantly reduce the chance of transmitting pathogenic viruses. However, with heavy initial  
8014 contamination of the hands, especially in the subungual space of the fingers, a basic 2-3 log reduction  
8015 handwash procedure may not be adequate to prevent the transmission of viral foodborne illness.

8016  
8017 The three interdependent critical factors in reducing foodborne illness transmitted through the fecal-oral  
8018 route, identified by the NACMCF, include exclusion/restriction of ill food workers; proper handwashing;  
8019 and no bare hand contact with ready-to-eat foods. Each of these factors is inadequate when utilized  
8020 independently and may not be effective. However, when all three factors are combined and utilized  
8021 properly, the transmission of fecal-oral pathogens can be controlled.

8022  
8023 Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is  
8024 important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the  
8025 food.

8026 If a ready-to-eat food is being added as an ingredient to a food item that is subsequently subjected to a  
8027 pathogen kill step (such as adding cheese or other ready-to-eat toppings to a pizza dough or adding  
8028 vegetables to a raw meat dish before cooking) then strict prohibition of bare hand contact is not necessary.  
8029 Cooking foods to the temperatures required in the Regulation will reduce the likelihood of survival of  
8030 pathogens that might be transferred from an employee's hands to the surface of the ready-to-eat foods.  
8031 The exception specifically targets bare hand contact with ready-to-eat food at the time it is added as an  
8032 ingredient to food that will be cooked in the food establishment to the minimum temperatures specified in  
8033 the Regulation. The exception does not apply when adding ready-to-eat foods as ingredients to foods that  
8034 will only be lightly heated, melted, or browned rather than cooked to the minimum temperatures specified  
8035 in this section. Nor does this exception apply when adding ready-to-eat foods as ingredients to foods that  
8036 are intended for preparation by the consumer offsite. When proper heat treatment is used in combination  
8037 with the exclusion/restriction of ill food workers and proper handwashing, the proper heat treatment  
8038 provides an additional means of interrupting disease transmission.

8039 Also refer to the public health reasons for Sections 2-401, 2-402, and 2-403.

8040

8041  
8042

**Clarification on accepting an alternative procedure to no bare hand contact**

8043

8044 **Background:**

8045

8046 Infected food employees are the source of contamination in approximately one in five foodborne disease  
8047 outbreaks reported in the United States with a bacterial or viral cause.<sup>1</sup> Most of these outbreaks involve  
8048 enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the  
8049 time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread  
8050 these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in  
8051 contamination of food. Viral, bacterial, and parasitic agents can be involved.

8052

8053 Traditionally, food regulations have required two methods of preventing the spread of foodborne disease  
8054 by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are  
8055 infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral  
8056 transmission interventions, the Regulation provides focused and specific guidance about ill workers and  
8057 when handwashing must occur. As a final barrier, bare hand contact with ready-to-eat food (i.e., food that  
8058 is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and  
8059 suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be  
8060 used. Any alternative to this requirement must convincingly address how food employees will be  
8061 managed to preclude food contamination and how management will ensure that thorough handwashing  
8062 occurs after employees use the toilet.

8063

8064 **Because highly susceptible populations include persons who are immunocompromised, the very**  
8065 **young and elderly, establishments serving these populations may not use alternatives to the no bare**  
8066 **hand contact with ready-to-eat food requirement.**

8066

**Objective:**

8067

8068 This guidance is provided to assist the regulatory authority in evaluating conformity with the principle of  
8069 no bare hand contact through alternative practices and procedures. In this guidance, "hazard" means  
8070 infected food workers spreading pathogens to food via the hands.

8071

8072

**Guidance:**

8073

8074 I. **Requirements prerequisite** to consideration of alternatives include compliance with all Regulation  
8075 provisions, particularly those related to:

8076

8077 1. **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of  
8078 handwashing that ensure food employees keep their hands and fingertips clean and handwashing  
8079 occurs at the times specified in Section 2.402—including after using the toilet and between tasks  
that may recontaminate the hands.

8080

2. **Hygienic Practices** as specified in Part 2.5.

8081

3. **Employee Health** regarding:

8082

1. **Reporting of diseases and medical conditions, and**

---

11 <sup>1</sup> 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, Guzewish, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

- 8083           2. ~~Exclusions and restrictions~~, i.e., that food employees (including applicants to whom a  
8084           conditional offer of employment has been made) report their health status as specified in  
8085           Section 2-202; ill food employees are restricted or excluded as specified in Section 2-202  
8086           and 2-205; and the exclusions and restrictions are removed as specified in Section 2-204.
- 8087           4. ~~Demonstration of Knowledge~~—Section 2-102.
- 8088           5. ~~Duties of the Person in Charge~~—Section 2-103.
- 8089           6. ~~How the alternative practices and procedures will control the hazard through an active~~  
8090           ~~managerial control program~~. Such a program includes monitoring and verifying the institution  
8091           of the provisions described in paragraphs A-C above and satisfies the following:
- 8092           1. ~~The public health hazard associated with bare hand contact specific to the food~~  
8093           ~~establishment operation is identified and understood. The regulatory authority needs~~  
8094           ~~assurance that the permit holder recognizes that the hazard being addressed is the~~  
8095           ~~possible contamination of ready-to-eat food by viral and parasitic as well as bacterial~~  
8096           ~~pathogens that are transferred from employees' hands.~~
- 8097           2. ~~The ready-to-eat foods that will be contacted with bare hands are identified and both~~  
8098           ~~procedures and practices are in place so that food employees wash their hands before~~  
8099           ~~returning to their work station and cross-contamination from touching raw and ready-to-~~  
8100           ~~eat food is precluded. For example, identifying the specific type of food to be prepared,~~  
8101           ~~such as tacos, and the specific location, such as a situation where a food employee is~~  
8102           ~~assigned solely to the designated taco work station. The work station is located~~  
8103           ~~immediately adjacent to the taco assembly unit and the employee will be preparing only~~  
8104           ~~the specified ready-to-eat food using bare hands. Another example could be a food~~  
8105           ~~employee who is responsible solely for assembling a variety of ready-to-eat foods.~~
- 8106           3. ~~Institution of an effective training program for food employees that emphasizes not~~  
8107           ~~working when ill with any of the gastrointestinal symptoms listed in the Regulation, and~~  
8108           ~~explains good hygienic practices, proper handwashing procedures, and safe food~~  
8109           ~~preparation procedures. This should include a documented training plan that specifies~~  
8110           ~~how management responsibility for training has been designated, training program~~  
8111           ~~content, and the frequency of administration including periodic refresher sessions.~~
- 8112           7. ~~The alternative procedure should clearly describe monitoring, documentation, and verification~~  
8113           ~~actions to ensure that the practices and procedures are followed. Corrective actions need to be~~  
8114           ~~predetermined for situations where the practices and procedures are not followed, e.g., an ill~~  
8115           ~~employee is found preparing foods.~~
- 8116           8. ~~Documentation of the practices, procedures, and corrective actions related to an alternative to no~~  
8117           ~~bare hand contact with ready-to-eat food must be maintained and readily available at the food~~  
8118           ~~establishment at all times for use by the person in charge and for review by the regulatory~~  
8119           ~~authority.~~
- 8120           H. ~~The regulatory authority should also consider industry's elective use, managerial control, and~~  
8121           ~~monitoring and verification of additional preventive measures used in tandem with the~~  
8122           ~~forementioned interventions, which could include one or more of the following:~~
- 8123           1. ~~Vaccination against hepatitis A for food employees including initial and booster shots or~~  
8124           ~~medical evidence that a food employee has had a previous illness from hepatitis A virus;~~

- 8125 2. ~~Double handwashing;~~
- 8126 3. ~~Use of nail brushes;~~
- 8127 4. ~~Use of an FDA-accepted hand sanitizer after handwashing, i.e., approved as safe for~~  
8128 ~~application to human skin and safe as an indirect food additive, or exempted as a food~~  
8129 ~~additive under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food~~  
8130 ~~Contact Articles; and~~
- 8131 5. ~~Motivation for food employees not to work when they are ill.~~

8132  
8133 **3-402—Glove Use**

8134  
8135 ~~Gloves used in touching ready-to-eat food are defined as a "utensil" and must meet the applicable~~  
8136 ~~requirements related to utensil construction, good repair, cleaning, and storage.~~

8137  
8138 ~~Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens~~  
8139 ~~that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat~~  
8140 ~~food or may indirectly contaminate food if stored with articles that will be used in contact with food.~~  
8141 ~~Multiuse gloves must be washed, rinsed, and sanitized between activities that contaminate the gloves.~~  
8142 ~~Hands must be washed before donning gloves. Gloves must be discarded when soil or other contaminants~~  
8143 ~~enter the inside of the glove.~~

8144  
8145 ~~Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could~~  
8146 ~~contaminate the food.~~

8147  
8148 ~~Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear~~  
8149 ~~latex gloves during food preparation, and even in individuals eating food prepared by food employees~~  
8150 ~~wearing latex gloves. This information should be taken into consideration when deciding whether single-~~  
8151 ~~use gloves made of latex will be used during food preparation.~~

8152  
8153 ~~Although many allergic reactions occur as a result of occupational exposure, CFSAN is actively~~  
8154 ~~reviewing its current policy on the use of disposable NRL gloves in food operations in light of the~~  
8155 ~~possible transmission of the latex protein via food. To gain additional information regarding allergic~~  
8156 ~~reactions allegedly due to the ingestion of food contaminated by NRL in retail settings, CFSAN has been~~  
8157 ~~collecting reports of such reactions from consumers who have contacted the Agency. Several offices~~  
8158 ~~within CFSAN will continue to collaborate in reviewing incoming data. The results of these activities and~~  
8159 ~~other related efforts will be used to determine if policy changes regarding the use of latex in food~~  
8160 ~~operations, based on food safety considerations, are warranted.~~

8161  
8162 ~~The FDA, Office of Premarket Approval, Indirect Additives, reviews gloves submitted for food contact~~  
8163 ~~use in the food industry on the basis of the glove's formulation or components.~~  
8164 ~~FDA regulates NRL gloves used for medical purposes only.~~

8165  
8166 ~~FDA is aware of the following information related to occupational hazards (not food safety hazards)~~  
8167 ~~associated with the use of NRL gloves:~~

- 8168 • ~~The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled~~  
8169 ~~"Preventing Allergic Reactions to Natural Rubber Latex in the Workplace" (NIOSH publication~~  
8170 ~~number 97-135) which is found at <http://www.cdc.gov/niosh/latexalt.html>.~~

8171 • The American College of Allergy, Asthma and Immunology (ACAAI) and the American  
 8172 Academy of Allergy Asthma and Immunology (AAAAI) issued a joint statement discouraging  
 8173 the routine use of NRL gloves by food handlers. (1997)  
 8174 <http://allergy.mcg.edu/physicians/joint.html>

8175 The AAAAI provides information on latex allergies on the web at  
 8176 <http://www.aaaai.org/patients/resources/fastfacts/latex.stm>

8177 The ACAAI provides information on latex allergies on the web at  
 8178 <http://allergy.mcg.edu/physicians/ltxhome.html>

8179 • An OSHA Technical Information Bulletin recommends reducing allergy potential by reducing  
 8180 unnecessary exposure to NRL. Stating "Food service workers ... do not need to use NRL gloves  
 8181 for food handling..." (1999) [http://www.osha-slc.gov/dts/tib/tib\\_data/tib19990412.html](http://www.osha-slc.gov/dts/tib/tib_data/tib19990412.html)

8182 OSHA addresses gloves in the following federal regulation, which can be found at  
 8183 [http://www.osha-slc.gov/OshStd\\_data/1910\\_0138.html](http://www.osha-slc.gov/OshStd_data/1910_0138.html):

8184 OSHA Regulations (Standards—29 CFR)

8185 Standard Number: 1910.138

8186 Standard Title: Hand Protection:

8187 SubPart Number: I

8188 SubPart Title: Personal Protective Equipment

8189 (a) General requirements. Employers shall select and require employees to use appropriate hand  
 8190 protection when employees' hands are exposed to hazards such as those from skin absorption of  
 8191 harmful substances; severe cuts or lacerations; severe abrasions; punctures; chemical burns;  
 8192 thermal burns; and harmful temperature extremes.

8193 (b) Selection. Employers shall base the selection of the appropriate hand protection on an  
 8194 evaluation of the performance characteristics of the hand protection relative to the task(s) to be  
 8195 performed, conditions present, duration of use, and the hazards and potential hazards identified.

8196

8197 For further information on the OSHA requirements, see [59 FR 16362, April 6, 1994].

8198

### 8199 **3-403—Preventing Contamination When Tasting**

8200

#### 8201 **3-404—General**

8202

8203 Food that is inadequately packaged or contained in damaged packaging could become contaminated by  
 8204 microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons  
 8205 delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing  
 8206 the entry of microbes and other contaminants such as chemicals. These contaminants may be present on  
 8207 the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when  
 8208 the packaging is opened. The removal of food product overwraps may also damage the package integrity  
 8209 of foods under the overwraps if proper care is not taken.

8210

8211 Pathogens can be transferred to food from utensils that have been stored on surfaces, which have not  
 8212 been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly  
 8213 from used tableware or food containers.

8214

8215 Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that  
 8216 comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such

8217 contamination. The handles of utensils, even if manipulated with gloved hands, are particularly  
8218 susceptible to contamination.

8219  
8220 Probe-type price or identification tags are defined as a utensil. Probe-type price or product identification  
8221 tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and  
8222 maintained.

8223  
8224 Food preparation activities may expose food to an environment that may lead to the food's contamination.  
8225 Just as food must be protected during storage, it must also be protected during preparation. Sources of  
8226 environmental contamination may include splash from cleaning operations, drips from overhead air  
8227 conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing  
8228 food in a building that is not constructed according to Regulation requirements.

8229  
8230 **3-405—Cross-Contamination Control**

8231  
8232 Cross contamination can be avoided by separating raw animal foods from ready-to-eat foods. Cross  
8233 contamination may also occur when raw unprepared vegetables contact ready-to-eat potentially hazardous  
8234 foods. Raw animal foods must also be separated from each other because required cooking temperatures  
8235 are based on thermal destruction data and anticipated microbial load. These parameters vary with  
8236 different types of raw animal foods.

8237  
8238 **3-406—Packaged and Unpackaged Food—Separation, Packaging, and Segregation**

8239 It is important to separate foods in a ready-to-eat form from raw animal foods during storage, preparation,  
8240 holding and display to prevent them from becoming contaminated by pathogens that may be present in or  
8241 on the raw animal foods. An exception is permitting the storage and display of frozen, commercially  
8242 packaged raw animal food adjacent to or above frozen, commercially packaged ready-to-eat food. The  
8243 freezer equipment should be designed and maintained to keep foods in the frozen state. Corrective action  
8244 should be taken if the storage or display unit loses power or otherwise fails. Raw or ready-to-eat foods or  
8245 commercially processed bulk-pack food that is packaged on-site presents a greater risk of cross-  
8246 contamination. Additional product handling, drippage during the freezing process, partial thawing or  
8247 incomplete seals on the package increase the risk of cross-contamination from these products packaged  
8248 in-house.

8249 With regard to the storage of different types of raw animal foods it is the intent of this Regulation to  
8250 require separation based on anticipated microbial load and raw animal food type (species). Separating  
8251 different types of raw animal foods from one another during storage, preparation, holding and display will  
8252 prevent cross-contamination from one to the other. The required separation is based on a succession of  
8253 cooking temperatures as specified under Section 3-502 which are based on thermal destruction data and  
8254 anticipated microbial load. For example, to prevent cross-contamination, fish and pork, which are  
8255 required to be cooked to an internal temperature of 62.8°C (145°F) for 15 seconds, shall be stored above  
8256 or away from raw poultry, which is required to be cooked to an internal temperature of 74°C (165°F) for  
8257 15 seconds due to its considerably higher anticipated microbial load. In addition, raw animal foods having  
8258 the same cooking temperature, such as pork and fish, shall be separated from one another during storage  
8259 and preparation by maintaining adequate spacing or by placing the food in separate containers because of  
8260 the potential for allergen cross-contamination or economic adulteration via inadvertent species  
8261 substitution.

8262 Storing or displaying comminuted or otherwise non-intact meats above whole-muscle intact cuts of meat  
8263 can also present a cross-contamination hazard unless they are packaged and displayed in a manner that  
8264 creates a barrier to prevent leakage of contents from one package to the other. Cooking recommendations  
8265 assume that lower levels of contamination will be present in whole-muscle products than in non-intact

8266 meats. If the whole muscle product is subject to cross contamination, the recommended cooking  
8267 temperature may not be sufficient to ensure the safety of the product.

8268 Food that is inadequately packaged or contained in damaged packaging could become contaminated by  
8269 microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons  
8270 delivering, stocking, or opening packages or overwraps. Packaging must be appropriate for preventing  
8271 the entry of microbes and other contaminants such as chemicals. These contaminants may be present on  
8272 the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when  
8273 the packaging is opened. The removal of food product overwraps may also damage the package integrity  
8274 of foods under the overwraps if proper care is not taken.

8275

### 8276 **3-407—Pasteurized Eggs, Substitute for Shell Eggs for Certain Recipes**

8277

8278 Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because  
8279 the virulent organism **Salmonella Enteritidis** may be present in raw shell eggs.

8280 Pasteurized eggs provide an egg product that is free of pathogens and is a ready to eat food. The  
8281 pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

8282

### 8283 **3-408—Washing Fruits and Vegetables/Additives/Sulfites**

8284 Pathogenic microorganisms, such as *Salmonella* spp., and chemicals such as pesticides, may be present  
8285 on the exterior surfaces of raw fruits and vegetables. It has been assumed that washing removes the  
8286 majority of organisms and/or chemicals present; however, more recent studies have demonstrated  
8287 washing to fall short of their complete removal. Biofilm development by *Salmonella* allows bacterial cells  
8288 to survive under adverse environmental conditions and also reduces the ability to remove pathogens by  
8289 washing, even with antimicrobial agents. All fresh produce, except commercially washed, pre-cut, and  
8290 bagged produce, must be thoroughly washed under running, potable water or with chemicals before  
8291 eating, cutting or cooking. Even if you plan to peel or otherwise alter the form of the produce, it is still  
8292 important to remove soil and debris first.

8293 Infiltration of microorganisms can occur through stem scars, cracks, cuts or bruises in certain fruits and  
8294 vegetables during washing. Once internalized, bacterial pathogens cannot be removed by further washing  
8295 or the use of sanitizing solutions. To reduce the likelihood of infiltration, wash water temperature should  
8296 be maintained at 10°F warmer than the pulp temperature of any produce being washed. Because certain  
8297 fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is  
8298 recommended that soaking or submerging produce during cleaning be avoided. It is important to follow  
8299 practices that minimize pathogens in the water or on the surface of produce. It is important that proper  
8300 handwashing procedures are followed before and after handling fresh produce.

8301 Scrubbing with a clean brush is only recommended for produce with a tough rind or peel, such as carrots,  
8302 cucumbers or citrus fruits, which will not be bruised easily or penetrated by brush bristles. Scrubbing firm  
8303 produce with a clean produce brush and drying with a clean cloth towel or fresh disposable towel can  
8304 further reduce bacteria that may be present. Washing fresh fruits and vegetables with soap, detergent or  
8305 other surfactants should be avoided as they facilitate infiltration and may not be approved for use on food.  
8306 Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes  
8307 are unapproved or applied in excessive concentrations. Unless otherwise stipulated in 21 CFR 173.315,  
8308 chemicals used to wash or peel fruits and vegetables should not exceed the minimum amount required to  
8309 accomplish the intended effect, need to be accurately tested for proper concentration, and must adhere to  
8310 any indications as dictated on the product label.

8311 Many pre-cut, bagged produce items are pre-washed. If so, these products will be identified as such on the  
8312 package label, and can be used as ready to eat without further washing. The label should also state if  
8313 further washing is recommended or necessary. Precut or prewashed produce in open bags should not be



8314 washed before use. After being cut, certain produce such as melons, leafy greens and tomatoes are  
8315 considered potentially hazardous food (PHF) requiring time/temperature control for safety (TCS) and  
8316 should be refrigerated at 5°C (41°F) or lower to prevent any pathogens that may be present from  
8317 multiplying. For more retail food guidance on the storage and handling of tomatoes, leafy greens, and  
8318 other produce, you may consult the FDA Program Information Manual, [Retail Food Protection Storage  
8319 and Handling of Tomatoes, dated October 5, 2007](#)<sup>41</sup>, the document, [Time as a Public Health Control for  
8320 Cut Tomatoes, dated June 8, 2010](#)<sup>42</sup> and the FDA Program Information Manual, [Recommendations for the  
8321 Temperature Control of Cut Leafy Greens during Storage and Display in Retail Food Establishments  
8322 dated July 7, 2010](#)<sup>43</sup>.

8323 On October 26, 1998 a voluntary guidance document that addresses practices commonly used by fresh  
8324 fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance  
8325 contains useful information related to washing fruits and vegetables as well as the application of  
8326 antimicrobial agents. The "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and  
8327 Vegetables" is available from FDA's Food Safety Initiative staff and also on the Internet at  
8328 <http://www.fda.gov>.

8329 Additionally, in February 2008, the FDA Center for Food Safety and Applied Nutrition (CFSAN) issued  
8330 ["Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and  
8331 Vegetables"](#)<sup>21</sup>, which covers fresh-cut fruits and vegetables that have been minimally processed (e.g. no  
8332 kill step) and altered in form, by peeling, slicing, chopping, shredding, coring, or trimming with or  
8333 without washing or other treatment, prior to being packaged for use by the consumer or a retail  
8334 establishment.

8335 On January 11, 2006 FDA/CFSAN published additional [safe handling advice](#)<sup>22</sup> on the purchase, storage,  
8336 and preparation of fresh produce, as well as Q & A's for consumers on their website. This document is  
8337 available in PDF (3.5 MB) format (also available in Spanish) and provides additional information on the  
8338 cleaning of fresh produce.

8339 Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by  
8340 food additive regulations could result in foodborne illness, including allergic reactions. For example,  
8341 many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning"  
8342 of fruits and vegetables or to cause ground meat to look "redder" or fresher.

8343  
8344 It is imperative for safety that food supplies come from sources that are in compliance with laws  
8345 regarding chemical additives and contaminants.

8346  
8347 Food additives are substances, which, by their intended use, become components of food, either directly  
8348 or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved  
8349 application, additives may be harmful to the consumer. Unintentional contaminants or residues also find  
8350 their way into the food supply. The tolerances or safe limits designated for these chemicals are  
8351 determined by risk assessment evaluations based on toxicity studies and consumption estimates.

8352 Food and Color additives must be used in compliance with a federal food, or color additive regulation, an  
8353 effective food contact notification, or a threshold of regulation exemption. Such regulations, notifications,  
8354 and exemptions are generally composed of three parts: the IDENTITY of the substance,  
8355 SPECIFICATIONS including purity or physical properties, and LIMITATIONS on the conditions of use.  
8356 In order for a food, or color additive use to be in compliance, the use must comply with all three criteria.

8357 Federal Food Additive regulations are found in Title 21 CFR, Parts 172-180. Color additive regulations  
8358 are found in Title 21 CFR Parts 73-Subpart A, 74-Subpart A, 81 and 82. Effective food contact  
8359 notifications are listed at [Inventory of Effective Food Contact Substance \(FCS\) Notifications](#)<sup>15</sup>, and  
8360 threshold of regulation exemptions are listed at [Threshold of Regulation Exemptions](#)<sup>16</sup>.

8361 Other substances that are added to food include those prior sanctioned for use in food by either the FDA  
8362 or USDA, or those generally recognized as safe for their intended use in food. Some of these are listed in  
8363 Title 21 CFR Parts 181–186, Title 9 CFR Section 424.21(b) and at [GRAS Notice Inventory](#)<sup>17</sup>. Tolerances  
8364 and exemptions from tolerance for pesticide chemical residues in or on food are found in Title 40 CFR  
8365 Part 180. Substances that are prohibited from use in human food are listed in Title 21 CFR Part 189.  
8366

### 8367 **3-409—In-Use Utensils, Between-Use Storage**

8368  
8369 Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously  
8370 cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or  
8371 intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that  
8372 precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils  
8373 may be safely stored in hot water maintained at 60°C (135°F) or above during intermittent use because  
8374 microbial growth is controlled at such temperatures.

8375 Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that  
8376 comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such  
8377 contamination. The handles of utensils, even if manipulated with gloved hands, are particularly  
8378 susceptible to contamination.

8379 A food utensil should be designed and used to prevent bare hand contact with ready-to-eat food or to  
8380 minimize contact with food that is not in a ready-to-eat form. On-site evaluations can be made to  
8381 determine if a utensil is improperly designed for the task or whether a food employee is misusing an  
8382 appropriately designed utensil.  
8383

8384 Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of  
8385 food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil  
8386 so that it may be used for another, use of soiled tableware to transfer food, and cross-contamination  
8387 between foods, including a raw food to a cooked potentially hazardous food.  
8388

### 8389 **3-410—Wiping Cloths**

8390 Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be  
8391 transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must  
8392 be stored in a sanitizer solution of adequate concentration between uses. Wiping cloths soiled with  
8393 organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution  
8394 must be changed as needed to minimize the accumulation of organic material and sustain proper  
8395 concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with  
8396 an appropriate chemical test kit.

8397 Wiping down a surface with a reusable wet cloth that has been properly stored in a sanitizer solution is an  
8398 acceptable practice for wiping up certain types of food spills and wiping down equipment surfaces.  
8399 However, this practice does not constitute cleaning and sanitizing of food contact surfaces where and  
8400 when such is required to satisfy the methods and frequency requirements in Section 4-4 of the Regulation.

8401 The same is true of the practice of wiping down a surface using dry disposable towels and a spray bottle  
8402 containing pre-mixed sanitizing solution. This practice is not prohibited, however it alone does not  
8403 constitute proper cleaning and sanitizing of food contact surfaces where and when such is required to  
8404 satisfy the methods and frequency requirements in Parts 4-4 of the Regulation.

8405 Further, for the purpose of wiping up food spills from surfaces in situations where full cleaning and  
8406 sanitizing is not required (such as when a soft drink overflows onto the side of a cup or onto a countertop)  
8407 the use of dry cloths and disposable towels is also acceptable as long as the cloth or towel is used for no

8408 other purpose. Again, this does not constitute a proper cleaning and sanitizing procedure for a food  
8409 contact surface, when such is called for in 4.4 of the Regulation.

8410 In order to effectively clean and sanitize food contact surfaces, where and when required to satisfy the  
8411 requirements in Parts 4.6 and 4.7 of the Regulation, the surface must be first cleaned properly to remove  
8412 organic material. In most cases this requires use of detergents or other cleaners. After the surface is clean  
8413 to sight and touch, a sanitizing solution of adequate temperature with the correct chemical concentration  
8414 should then be applied to the surface. The sanitizing solution must stay on the surface for a specific  
8415 contact time as specified in this Regulation and in accordance with the manufacturer's EPA registered  
8416 label, as applicable.

8417 Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and  
8418 contaminants that are found in the use environment. Because of their construction, sponges provide  
8419 harborage for any number and variety of microbiological organisms, many of which may be pathogenic.  
8420 Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use,  
8421 food contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

8422

### 8423 **3.411—Re-Use of Tableware**

8424

8425 Pathogens can be transferred to food from utensils that have been stored on surfaces, which have not been  
8426 cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly  
8427 from used tableware or food containers.

8428

### 8429 **3.412—Refilling Returnables**

8430

8431 Pathogens can be transferred to food from utensils that have been stored on surfaces, which have not been  
8432 cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly  
8433 from used tableware or food containers.

8434

8435 The refilling of consumer owned beverage containers introduces the possibility of contamination of the  
8436 filling equipment or product by improperly cleaned containers or the improper operation of the  
8437 equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of  
8438 consumer owned containers is limited to beverages that are not potentially hazardous. Equipment must be  
8439 designed to prevent the contamination of the equipment and means must be provided to clean the  
8440 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.

8490

8491 **3-418—Reservice**

8492

8493 Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus.

8494 Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous and that

8495 have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic

8496 microorganisms from the initial consumer to the next if the food is served again.

8497

8498 **3-5—Destruction of Organisms of Public Health Concern**

8499

8500 **3-501—Temperature**

8501

8502 Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all,

8503 types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant

8504 levels in properly refrigerated foods that are not out of date.

8505

8506 High temperatures for a long enough time, such as those associated with thorough cooking, kill or

8507 inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced

8508 in foods by certain bacteria (such as the enterotoxins of *Staphylococcus aureus*). Cooking or hot holding

8509 that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the

8510 Regulation prevents significant regrowth of heat-injured microorganisms and prevents recontamination

8511 with bacteria that are newly introduced.

8512

8513 Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the

8514 temperature "Danger Zone" of 5°C to 60°C (41°F to 135°F) too long. Up to a point, the rate of growth

8515 increases with an increase in temperature within this zone. Beyond the upper limit of the optimal

8516 temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or

8517 cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

8518

8519 The ability of equipment to cool, heat, and maintain potentially hazardous foods at Regulation-required

8520 temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major

8521 contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold

8522 holding equipment with enough capacity to meet the heating and cooling demands of the operation.

8523

8524 **Cold Holding**

8525

8526 Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most

8527 microbes. The growth of some bacteria, such as *Listeria monocytogenes*, is significantly slowed but not

8528 stopped by refrigeration. Over a period of time, this and similar organisms may increase their risk to

8529 public health in ready-to-eat foods.

8530

8531 Except for raw shell eggs, control of the growth of *Listeria monocytogenes* is the basis for the list of cold

8532 holding temperature and time combinations. The list addresses time, in addition to temperature, as a

8533 control for the growth of *Listeria monocytogenes* in refrigerated, ready-to-eat, potentially hazardous food.

8534 The Regulation provisions for cold holding focus on environmental conditions that allow 1 log of growth

8535 of *Listeria monocytogenes*, and do not set an acceptable number of Lm in food. Neither do they imply that8536 *Listeria monocytogenes* is in the product.

8537

8538 The times and temperatures in the 1999 FDA Model Food Code and the 1999 *Colorado Retail Food*8539 *Establishment Rules and Regulations* were based on the USDA Pathogen Modeling Program (PMP),8540 which is conservative in estimating how soon *Listeria monocytogenes* begins to grow and how fast. The

8541 PMP was based largely on observations of microbial growth in broth cultures, but some observations in  
8542 specific foods were also included. The PMP allows for some variation in temperature, pH, and water  
8543 activity, and gives a conservative estimate of safe times and temperatures for holding foods. The 1999  
8544 Regulation estimated safe times and temperatures that would allow 3 logs of growth, based on the PMP.

8545  
8546 During 2000, CFSAN researched published literature and compiled a listing of the growth potential of  
8547 Lm in various food commodities using real food data. Based on this information, the 1999 Food Code  
8548 times and temperatures of 5°C (41°F) for 7 days and 7.2°C (45°F) for 4 days were validated, but the  
8549 underlying performance standard changed for the commodities studied. The research based, food specific  
8550 times and temperatures allow no more than 1 log of growth instead of the 3 log growth predicted in the  
8551 PMP. This more stringent performance standard of 1 log is consistent with the USDA/FSIS performance  
8552 standard and the fact that the infectious dose of Lm remains unknown.

8553 FDA concluded that the 1999 Regulation time/temperature criteria hold true and provide both a greater  
8554 level of safety and a more realistic basis for regulatory requirements without compromising public health  
8555 protection.

8556 In October 2003, FDA, in cooperation with the USDA/FSIS and CDC, released the [Quantitative](#)  
8557 [Assessment of the Relative Risk to Public Health from Foodborne LISTERIA MONOCYTOGENES](#)  
8558 [Among Selected Categories of Ready-to-Eat Foods \(risk assessment\)](#)<sup>36</sup>. This initiative included the  
8559 development of 23 separate risk assessments and analysis of the relative risks of serious illness and death  
8560 associated with consumption of 23 categories of ready-to-eat foods. These categories included: seafood,  
8561 produce, meats, dairy products, and deli salads.

8562 The risk assessment identified several broad factors that affect consumer exposure to LM at the time of  
8563 food consumption. Two of these factors, refrigerated storage temperature and duration of refrigerated  
8564 storage before consumption, have a direct bearing on cold holding time/temperature combinations used in  
8565 food establishments.

8566 FDA continues to have concerns about the potential for growth of LM in refrigerated, ready-to-eat,  
8567 potentially hazardous food (time/temperature control for safety food), prepared and packaged in a food  
8568 processing plant and held in a food establishment. Data from the risk assessment show a significant  
8569 reduction in the projected cases of listeriosis when refrigerated storage is limited to 5°C (41°F). Based on  
8570 these data and conclusions from the risk assessment, FDA continues to recommend that food  
8571 establishments limit the cold storage of potentially hazardous (time/temperature control for safety), ready-  
8572 to-eat foods to a maximum temperature of 5°C (41°F).

8573

8574

| <b>Table 1. Estimated Reduction of Cases of Listeriosis from Limits on Refrigeration Temperatures*</b> |   |                                  |                                   |
|--|---|----------------------------------|-----------------------------------|
| <b>Maximum Refrigerator Temperature</b>  | <b>Cases of Listeriosis<sup>a</sup></b> |                                  |                                   |
|  | <b>Median</b>                           | <b>5<sup>th</sup> Percentile</b> | <b>95<sup>th</sup> Percentile</b> |
| <b>Baseline<sup>b</sup></b>  | 2105                                    | 3/4 <sup>e</sup>                 | 3/4 <sup>e</sup>                  |
| <b>7 °C (45 °F) maximum</b>  | 656                                     | 331                              | 761                               |
| <b>5 °C (41 °F) maximum</b>  | 28                                      | 1                                | 126                               |

8575 <sup>a</sup>Values for the median, upper and lower uncertainty levels.

8576 <sup>b</sup>The baseline uses the full empirical distribution of refrigerator temperatures from the Audits  
8577 International (1999) survey.

8578 <sup>c</sup>The baseline number of cases of listeriosis is fixed based on CDC surveillance data.

8579 <sup>\*</sup>The scenario assumed the distribution of storage times is the same for all three temperature sets.

8580 Source: [Quantitative Assessment of the Relative Risk to Public Health from Foodborne](#)  
8581 [LISTERIA MONOCYTOGENES Among Selected Categories of Ready-to-Eat Foods](#)<sup>37</sup>  
8582 September 2003. Table VI-1. Estimated Reduction of Cases of Listeriosis from Limits on  
8583 Refrigeration Temperatures.

8584 Regarding shell eggs, USDA published a final rule (63 FR 45663, August 27, 1998) to require that shell  
8585 eggs packed for consumer use be stored and transported at an ambient temperature not to exceed 7.2°C  
8586 (45°F). This regulation, however, does not apply to eggs while held at all retail establishments. FDA is  
8587 concerned that without continued refrigeration up until the time that the eggs are cooked, there would be  
8588 an opportunity for the egg's defenses to degrade and growth of *Salmonella Enteritidis* to occur. The  
8589 agency reviewed research indicating that *Salmonella Enteritidis* multiplies at temperatures of 10°C (50°F)  
8590 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).  
8591 Based on this research and USDA's temperature requirement during transport, FDA implemented  
8592 regulations that establish a maximum ambient air temperature of 7.2°C (45°F) for eggs stored and  
8593 displayed at retail establishments. Amended federal regulations 21 CFR Part 115, Eggs, Refrigeration  
8594 issued on December 5, 2000 and became effective on June 4, 2001.

8595  
8596 Although Congress did not expressly preempt State law in this area, FDA found preemption is needed  
8597 because State and local laws that are less stringent than the Federal requirements will significantly  
8598 interfere with the important public health goals of these regulations. FDA does not believe that  
8599 preemption of State and local refrigeration and labeling requirements that are the same as or more  
8600 stringent than the requirements of these regulations is necessary, as enforcement of such State and local  
8601 requirements will not interfere with the food safety goals of these regulations. Accordingly, the  
8602 preemptive effect of this rule is limited to State or local requirements that are not as stringent as the

8603 requirements of these regulations; requirements that are the same as or more stringent than FDA's  
8604 requirements remain in effect.

### 8605 **Hot Holding**

8606 In a January 2001 report, the National Advisory Committee on Microbiological Criteria for Foods  
8607 (NACMCF) recommended that the minimum hot holding temperature:

- 8608 • Be greater than the upper limit of the range of temperatures at which *Clostridium perfringens*  
8609 and *Bacillus cereus* may grow; and
- 8610 • Provide a margin of safety that accounts for variations in food matrices, variations in temperature  
8611 throughout a food product, and the capability of hot holding equipment to consistently maintain  
8612 product at a desired target temperature.

8613 *C. perfringens* has been reported to grow at temperatures up to 52°C (126°F). Growth at this upper limit  
8614 requires anaerobic conditions and follows a lag phase of at least several hours. The literature shows that  
8615 lag phase duration and generation times are shorter at incubation temperatures below 49°C (120°F) than  
8616 at 52°C (126°F). Studies also suggest that temperatures that preclude the growth of *C. perfringens* also  
8617 preclude the growth of *B. cereus*.

8618 CDC estimates that approximately 250,000 foodborne illness cases can be attributed to *C. perfringens*  
8619 and *B. cereus* each year in the United States. These spore-forming pathogens have been implicated in  
8620 foodborne illness outbreaks associated with foods held at improper temperatures. This suggests that  
8621 preventing the growth of these organisms in food by maintaining adequate hot holding temperatures is an  
8622 important public health intervention.

8623 Taking into consideration the recommendations of NACMCF and the 2002 Conference for Food  
8624 Protection meeting, FDA believes that maintaining food at a temperature of 57°C (135°F) or greater  
8625 during hot holding is sufficient to prevent the growth of pathogens and is therefore an effective measure  
8626 in the prevention of foodborne illness.

### 8628 **3-502—Cooking Potentially Hazardous Foods**

8629  
8630 Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include  
8631 the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the  
8632 food's bulk, which affects the time to achieve the needed internal product temperature. Other factors to be  
8633 considered include post-cooking heat rise and the time the food must be held at a specified internal  
8634 temperature.

8635  
8636 Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal  
8637 foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these  
8638 products.

8639  
8640 To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a  
8641 scheduled process in which each of a series of continuous time/temperature combinations can be equally  
8642 effective. For example, in cooking a beef roast, the microbial lethality achieved at 112 minutes after it has  
8643 reached 54.4°C (130°F) is the same lethality attained as if it were cooked for 4 minutes after it has  
8644 reached 62.8°C (145°F). The microbial lethality using these criteria will provide a 6.5-log<sub>10</sub> reduction of  
8645 Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of  
8646 each piece of meat for a least the stated time. The source of the time and temperature parameters is from  
8647 the USDA/FSIS [Appendix A. Compliance Guidelines For Meeting Lethality Performance Standards For](#)  
8648 [Certain Meat And Poultry Products](#)<sup>29</sup>.



8649  
8650 Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a  
8651 microorganism is determined by its ability to survive heat. Different species of microorganisms have  
8652 different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of  
8653 bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same  
8654 organism's survival form (the bacterial spore, protozoan cyst, or worm egg).  
8655  
8656 Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods  
8657 at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the  
8658 cooking vessel and the moisture content of food aid thermal destruction.

8659  
8660 Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a  
8661 layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food,  
8662 cooking must bring *all* parts of the food up to the required temperatures for the correct length of time.

8663  
8664 The temperature and time combination criteria specified in Part 3-5 of this Regulation are based on the  
8665 destruction of *Salmonellae*. This Part includes temperature and time parameters that provide "D" values  
8666 (decimal log reduction values) that may surpass 7D. For example, at 63°C (145°F), a time span of 15  
8667 seconds will provide a 3D reduction of *Salmonella Enteritidis* in eggs. This organism, if present in raw  
8668 shell eggs, is generally found in relatively low numbers. Other foods, uncomminuted fish and meats  
8669 including commercially raised game animal meat, specified as acceptable for cooking at this temperature  
8670 and time parameter are expected to have a low level of internal contamination. The parameters are  
8671 expected to provide destruction of the surface contaminants on these foods.

#### 8672 8673 **Slow-cooked roasts – Heating Deviations and Slow Come Up Time**

8674 (Source: USDA/FSIS [Appendix A Compliance Guidelines For Meeting Lethality Performance Standards](#)  
8675 [For Certain Meat And Poultry Products](#)<sup>30</sup>)

8676 Heating deviations, which most often involve slow come up time or an inordinate dwell time within the  
8677 optimum temperature range for microorganism growth can foster the multiplication of many pathogens.  
8678 This multiplication sometimes can be so prodigious that even additional cooking may be ineffective in  
8679 rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of  
8680 these toxins, such as those of **STAPHYLOCOCCUS AUREUS**, are extremely heat stable and are not  
8681 inactivated by normal cooking temperatures.

8682 Further, the sampling of product following a heating deviation may not yield sufficient information to  
8683 determine the safety of the product in question. Heating deviations can favor the multiplication of many  
8684 types of bacteria. It would be difficult and expensive to sample for all of them. Depending on the  
8685 circumstances, establishments may want to use computer modeling to estimate the relative multiplication  
8686 of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an  
8687 oven in which the temperature was inadvertently set to 35°C (95°F) for about 12 hours. Computer  
8688 modeling was easily applied in this case because much of the dwell time was at one temperature. The  
8689 USDA/FSIS determined that within a 6-hour time frame (with other growth conditions assumed to be  
8690 favorable), the relative multiplication of many pathogens of concern could have exceeded 5 logs. Clearly  
8691 the product could not be salvaged by reprocessing and was therefore destroyed. Under changing  
8692 conditions of temperature, however, computer modeling becomes more difficult. One approach is to  
8693 average lag/log times over small increments such as 5° and add these times to get an approximation of  
8694 possible total relative growth over a larger increment of time. Establishments must keep in mind that the  
8695 population of bacteria before processing is generally unknown and that assumptions in the high range  
8696 often are used as input parameters in the modeling.  
8697

**8698 ~~Seared Steak~~**

8699

8700 The provision for allowing seared steaks was reviewed by the National Advisory Committee for  
8701 Microbiological Criteria for Foods (NACMCF) and USDA.

8702

8703 USDA comments included, "For the purposes of this discussion, steak is a whole beef muscle. It does not  
8704 include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross  
8705 grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or  
8706 Chateaubriand. Other species, such as poultry, pork and lamb, are not included."

8707

8708 NACMCF comments included, "Due to the low probability of pathogenic organisms being present in or  
8709 migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be  
8710 safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In  
8711 addition, the cut (exposed) surfaces must receive additional heat to affect a complete sear across the cut  
8712 surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared  
8713 on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts  
8714 a temperature at the surface of the intact steak of at least 62.8°C (145°F) to achieve a cooked color change  
8715 on all external surfaces. The searing of all surfaces should be continuous until the desired degree of  
8716 doneness and appearance are attained. This is considered a ready-to-eat food."

8717

8718 As reflected in the definition of "whole muscle, intact beef steak," marinating is a food safety concern  
8719 when the fascia (exterior surface) of the steak is broken by scoring or other means, which allows the  
8720 marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Regulation  
8721 allowance for undercooking without a consumer advisory is negated.

8722

**8723 ~~Pork~~**

8724

8725 In pork, *Trichinella spiralis*, *Toxoplasma gondii*, and *Taenia solium*, parasites causing foodborne illness,  
8726 are inactivated at temperatures below 62.8°C (145°F). Therefore, pork roasts can be cooked like beef  
8727 roasts (e.g., 62.8°C (145°F) for 3 minutes) and pork chops cooked like steaks to achieve an internal  
8728 temperature of 62.8°C (145°F) for 15 seconds.

8729

8730 Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for  
8731 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals  
8732 commercially raised for food, and game animals that come under a USDA voluntary inspection program.  
8733 Ratites such as ostrich, emu, and rhea are included in this list of raw animal foods because when cooked  
8734 to a temperature greater than 68°C (155°F), ratites exhibit a (metallic) "off" taste.

8735

8736 When USDA established the time and temperature parameters, the Agency based the 5D for Salmonella  
8737 on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a  
8738 "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear  
8739 relationship between the patty rule and roast beef time and temperature parameters. The patty rule also  
8740 provided for an 8D reduction in the number of Shiga toxin-producing *Escherichia coli*. The time and  
8741 temperature requirements in the Regulation for comminuted meats are comparable to the USDA  
8742 requirements.

8743

**8744 ~~Temperature for Comminuted Meat at Less Than 1 Second~~**

8745

8746 In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee for  
8747 Microbiological Criteria for Foods' (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated  
8748 on page 7, in Option (A), that:

8749 ~~"Based on the 1998 research data ... and an assumption that instantaneous is defined as~~  
8750 ~~eight seconds, manufacturers would be required to process fully cooked meat patties at a~~  
8751 ~~temperature of 69°C (157°F). Given the lack of any significant margin of safety in this~~  
8752 ~~process, there should be no deviation below the 70°C (158°F) requirement."~~

8753  
8754 In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures  
8755 for cooking hamburger and advised FDA that cooking hamburger to 70°C (158°F) for less than one  
8756 second is an adequate cook based on the following:

- 8757
- 8758 1. ~~\_\_\_\_\_ The cooking recommendations contained in the Regulation and in USDA guidance~~  
8759 ~~provide a large margin of safety for killing vegetable enteric pathogens;~~
  - 8760 2. ~~\_\_\_\_\_ The concept of integrated lethality (the kill imparted during the entire heating and cooling~~  
8761 ~~process) adds to the margin of safety; and~~
  - 8762 3. ~~\_\_\_\_\_ The time component of the time and temperature requirement will be exceeded before the~~  
8763 ~~temperature can be determined.~~

8764  
8765 The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of 74°C (165°F)  
8766 or above for 15 seconds yield greater than a 7D reduction.

8767  
8768 **Microwave Cooking**

8769  
8770 The rapid increase in food temperature resulting from microwave heating does not provide the same  
8771 cumulative time and temperature relationship necessary for the destruction of microorganisms as do  
8772 conventional cooking methods. In order to achieve comparable lethality, the food must attain a  
8773 temperature of 74°C (165°F) in all parts of the food. Since cold spots may exist in food cooking in a  
8774 microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed  
8775 from the oven and then allow the food to stand covered for two minutes post microwave heating to allow  
8776 thermal equalization and exposure. Although some microwave ovens are designed and engineered to  
8777 deliver energy more evenly to the food than others, the important factor is to measure and ensure that the  
8778 final temperature reaches 74°C (165°F) throughout the food.

8779  
8780 "The factors that influence microwave thermal processes include many of the same factors that are  
8781 important in conventional processes (mass of objects, shape of objects, specific heat and thermal  
8782 conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of  
8783 the electric field involved in causing molecular friction. These factors are exemplified by moisture and  
8784 salt contents of foods, which play a far more important role in microwave than conventional heating."  
8785 (Reference: Hedderson and Doores)

8786  
8787

8788

**8789 Plant Food Cooking for Hot Holding**

8790

8791 Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be  
8792 cooked to the temperature required for hot holding. These foods do not require the same level of  
8793 microorganism destruction as do raw animal foods since these fruits and vegetables are ready to eat at  
8794 any temperature. Cooking to the hot holding temperature of 60°C (135°F) prevents the growth of  
8795 pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced  
8796 over time at the specified hot holding temperature.

8797

**8798 3-503—Non-Continuous Cooking of Raw Animal Foods**

8799 Close attention must be paid to control of biological hazards when a food establishment cooks raw animal  
8800 foods using a process in which the food is partially cooked then cooled with the expectation of fully  
8801 cooking the food at a later date or time. Section 3-503 requires that establishments wishing to use a non-  
8802 continuous process for the cooking of raw animal foods establish and follow a written plan that ensures  
8803 each stage of the process is completed within time and temperature parameters that adequately prevent  
8804 pathogen survival and growth. Section 3-503 also requires that establishments take special precautions to  
8805 ensure that raw animal foods that have only been initially heated to temperatures that are not lethal to the  
8806 pathogens of concern are clearly identified so that they will not be inadvertently sold or served to the  
8807 consumer in a partially cooked state.

8808 To ensure the food does not dwell for extended periods within temperature ranges that favor pathogen  
8809 growth, Section 3-503 establishes limits on the time permitted to initially heat the food (initial "come-up"  
8810 time) and the time permitted to cool the product to temperatures that are safe for refrigerated storage.  
8811 Together, these limits should prevent food from remaining at temperatures at which pathogen growth to  
8812 harmful levels may occur.

8813 The criteria in Section 3-503 were developed with consideration of the United States Department of  
8814 Agriculture/Food Safety and Inspection Service (USDA/FSIS) PERFORMANCE STANDARDS FOR  
8815 PARTIALLY COOKED AND CHAR-MARKED MEAT PATTIES AND PARTIALLY COOKED  
8816 POULTRY BREAKFAST STRIPS found in [9 CFR 318.23](#)<sup>31</sup> and [9 CFR 381.150](#)<sup>32</sup>.

8817 The maximum one-hour time limit for the initial heating stage was established based on estimates from  
8818 predictive microbial modeling. It is intended to limit the cumulative growth of **CLOSTRIDIUM**  
8819 **PERFRINGENS** that may occur during the come-up time and the subsequent cooling of the product.  
8820 Unless properly controlled, processes in which animal foods are heated to sub-lethal temperatures and  
8821 times and then cooled may create an environment for the growth of **CLOSTRIDIUM PERFRINGENS**,  
8822 **CLOSTRIDIUM BOTULINUM** and other spore-forming, toxigenic bacteria.

8823 The product temperature achieved during the initial heating process may not be sufficient to destroy  
8824 vegetative cells of **CLOSTRIDIUM BOTULINUM**, **CLOSTRIDIUM PERFRINGENS**, and  
8825 **BACILLUS CEREUS**, if present. The concern is the generation of a large number of vegetative cells of  
8826 **CLOSTRIDIUM PERFRINGENS** and/or **CLOSTRIDIUM BOTULINUM** before the final cooking  
8827 stage. For **CLOSTRIDIUM BOTULINUM**, if enough vegetative cells are produced, toxigenesis can  
8828 occur in the product before the product is fully cooked. The toxin is not destroyed at the minimum  
8829 required cooking temperatures. For **CLOSTRIDIUM PERFRINGENS**, if a large number of vegetative  
8830 cells are consumed, illness can result. In either case a high number of vegetative cells may challenge the  
8831 lethality step of the ultimate cooking process to the extent that it will be unable to completely eliminate all  
8832 of these vegetative cells. The cumulative growth of these bacterial pathogens must be taken into account  
8833 during both the initial heating and cooling steps. The hazard may be compounded with an extended initial

8834 "come up" time and/or a prolonged cooling stage. Hence the degree of hazard may be dependent upon the  
8835 ultimate effect of the initial heating and cooling, as well as the final cooking step.

8836 A full and adequate cook during the final cooking step is of critical importance to ensure destruction of  
8837 any pathogens that may have survived and proliferated during any initial heating and cooling stages of the  
8838 non-continuous cooking process. Section 3-503 requires that animal foods cooked by a non-continuous  
8839 cooking process achieve a minimum final cook temperature that heats all parts of the food to a  
8840 temperature of at least 74°C (165°F) for 15 seconds to ensure the destruction of vegetative microbial  
8841 pathogens, no matter the size of the product. This provides for an additional safeguard beyond the  
8842 minimum cooking temperature required for many types of animal foods that are cooked using a  
8843 continuous, uninterrupted process. This requirement also precludes serving animal foods that have  
8844 undergone non-continuous cooking in an undercooked or raw state. In other words, animal foods cooked  
8845 using a non-continuous process are not covered in the exceptions provided for in Section 3-503 that allow  
8846 for serving undercooked animal foods upon consumer request and with an adequate consumer advisory.

8847 Section 3-503 requires that an establishment using non-continuous cooking processes also establish  
8848 procedures for identifying foods that have only been partially cooked and cooled. This is necessary to  
8849 ensure these foods are not mistaken by food workers for foods that have been fully cooked and therefore  
8850 ready to eat without a full cook. Partially cooked foods may appear to be fully cooked.

8851 Requiring that food establishments obtain prior approval by the regulatory authority before employing  
8852 non-continuous cooking processes will help to ensure that the establishment has the proper procedures in  
8853 place, as well as the necessary facilities and capacity to monitor the appropriate cooling, cooking,  
8854 separation and product identification of the foods.

### 8855 8856 **3-504—Reheating**

8857  
8858 When food is held, cooled, and reheated in a food establishment, there is an increased risk from  
8859 contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper  
8860 temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper  
8861 reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective  
8862 in reducing the numbers of *Clostridium perfringens* that may grow in meat, poultry, or gravy if these  
8863 products were improperly cooled. Vegetative cells of *C. perfringens* can cause foodborne illness when  
8864 they grow to high numbers. Highly resistant *C. perfringens* spores will survive cooking and hot holding.  
8865 If food is abused by being held at improper holding temperatures or improperly cooled, spores can  
8866 germinate to become rapidly multiplying vegetative cells.

8867  
8868 Although proper reheating will kill most organisms of concern, some toxins such as that produced by  
8869 *Staphylococcus aureus*, cannot be inactivated through reheating of the food. It is imperative that food  
8870 contamination be minimized to avoid this risk.

8871  
8872 The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods.  
8873 This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product,  
8874 are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition  
8875 if temperature abuse occurs.

8876  
8877 Refer also to the public health reason for Section 3-502.

### 8878 8879 **3-505—Preparation for Immediate Service**

## 8880 8881 **3-6—Limitation of Growth of Organisms of Public Health Concern**

8882

8883 **3-601—Thawing**

8884

8885 Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper  
8886 thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce  
8887 toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are  
8888 preserved.

8889

8890 **3-602—Slacking**

8891

8892 Refer to the public health reason for Section 3-601.

8893

8894 **3-603—Cooling**

8895

8896 Safe cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive  
8897 time for cooling of potentially hazardous foods has been consistently identified as one of the leading  
8898 contributing factors to foodborne illness. During slow cooling, potentially hazardous foods are subject to  
8899 the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation  
8900 temperatures, 21°C–52°C (70°F–126°F), is to be avoided. If the food is not cooled in accordance with  
8901 this Regulation requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

8902 The Regulation provision for cooling provides for cooling from 57°C (135°F) to 5°C (41°F) or 7.2°C

8903 (45°F) in 6 hours, with cooling from 57°C (135°F) to 21°C (70°F) in 2 hours. The 6-hour cooling

8904 parameter, with an initial 2-hour rapid cool, allows for greater flexibility in meeting the Regulation. The

8905 initial 2-hour cool is a critical element of this cooling process. An example of proper cooling might

8906 involve cooling from 57°C (135°F) to 21°C (70°F) in 1 hour, in which case 5 hours remain for cooling

8907 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

8908 (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

8909 safety hazards may not be adequately controlled.

8910 If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming

8911 organisms such as *Clostridium perfringens* or *Bacillus cereus* should be killed or inactivated. However,

8912 under substandard sanitary conditions, other pathogens such as *Salmonella* or *Listeria monocytogenes*

8913 may be reintroduced. Thus, cooling requirements are based on growth characteristics of organisms that

8914 may survive or be a post-cook contaminate and grow rapidly under temperature abuse conditions.

8915

8916 **CFSAN/FSIS Joint Position Paper on Cooling**

8917

8918 The processing of most ready-to-eat products includes a heat treatment or cooking step to eliminate

8919 pathogenic and spoilage microorganisms. However, this heat treatment does not eliminate spores of

8920 *Clostridium botulinum* and *Clostridium perfringens* and other spore-forming bacteria. Furthermore,

8921 these organisms can thrive in the warm product since other competing organisms have been eliminated.

8922 Non-refrigerated, anaerobic conditions are conducive to their growth and multiplication.

8923

8924 To prevent the growth and multiplication of spore-forming organisms, product should be cooled rapidly

8925 after cooking. When there is inadequate cooling, spores can germinate and the resulting vegetative cells

8926 can multiply to hazardous levels. The presence of sufficient numbers of *C. botulinum* or other spore-

8927 forming organisms may lead to production of harmful toxins. Therefore, ensuring no growth of these

8928 organisms will provide the greatest amount of safety.

8929 The USDA/FSIS Performance Standards for the Production of Certain Meat and Poultry Products require

8930 a stabilization step (cooling) after the lethality step. The stabilization requirements allow for no growth of

8931 *C. botulinum* and no more than 1 log growth of *C. perfringens*. The performance standard of no more

8932 than 1 log growth of *C. perfringens* was based on the following reasons:

- 8933 1. The Centers for Disease Control and Prevention (CDC) suggested viable counts of  $10^5$  or greater  
8934 of *C. perfringens* per gram as one of the criteria for incriminating *C. perfringens* as a causative  
8935 agent of foodborne illness in finished product. However, foods responsible for *C. perfringens*  
8936 outbreaks were found usually to contain  $10^6$  vegetative *C. perfringens* cells per gram. In FSIS  
8937 microbiological raw product surveys, samples were found to contain more than 1000 *C.*  
8938 *perfringens* per gram. There is some probability that greater than  $10^4$  *C. perfringens* per gram  
8939 can occur in the raw product on rare occasions. It is a conservative assumption that the great  
8940 majority of *C. perfringens* in the raw product are spores.
- 8941 2. Heating activates spores that, during cooling, become vegetative cells that can multiply to  
8942 hazardous levels. If there are more than  $10^4$  *C. perfringens* (spores) per gram on raw product, it is  
8943 possible that there may be more than  $10^4$  vegetative *C. perfringens* per gram in the product if it is  
8944 improperly cooled after cooking.
- 8945 3. Based on the CDC recommended upper limit of  $10^5$  which should not be exceeded, it was  
8946 determined that a limit of no more than  $1 \log_{10}$  growth of *C. perfringens* would be appropriate to  
8947 ensure that there would be no more than  $10^5$  *C. perfringens* per gram on the finished product after  
8948 cooling.
- 8949 4. The performance standard was discussed with experts on clostridia research. The experts agreed  
8950 that limiting the relative growth of *C. perfringens* to no more than  $1 \log_{10}$  would be reasonable  
8951 and somewhat conservative with respect to product safety. (Federal Register 64: (3): 732-749)
- 8952 The FSIS compliance guideline for the cooling performance standards, which can be found at  
8953 <http://www.fsis.usda.gov/OA/fr/95033F-b.htm>, is that product must be cooled from 54.5°C (130°F) to  
8954 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  
8955 applied universally to cooked products like partially cooked or fully cooked, intact or non-intact meat and  
8956 poultry products. The guideline results in continuous and rapid cooling of the product in the temperature  
8957 range where the spore-forming organisms can grow rapidly.
- 8958  
8959 The former USDA guideline of cooling from 49°C (120°F) to 12.8°C (55°F) in no more than 6 hours is  
8960 also included in the new compliance guidelines. In using this guideline, chilling should begin within 90  
8961 minutes after the cooking cycle is completed, and cooling should continue until product reaches 4.4°C  
8962 (40°F). The 6 hour rule begins when the product reaches 49°C (120°F), and product should not be  
8963 shipped until the product reaches 4.4°C (40°F). This older cooling guideline results in a significantly  
8964 smaller margin of safety, especially if the product is non-intact. In using this older guideline, the  
8965 establishment has to ensure that cooling is as rapid as possible, especially between 49°C (120°F) and  
8966 27°C (80°F), and should monitor the cooling closely to prevent any deviation. If product remains between  
8967 these temperatures for more than an hour, compliance with the performance standard is less certain.
- 8968  
8969 The FSIS cooling guideline for meat and poultry products containing 100 ppm added nitrite is  
8970 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  
8971 hours cooling time. This cooling process provides a narrow margin of safety. In case of cooling  
8972 deviations, the establishment should assume that their process has exceeded the performance standard for  
8973 controlling the growth of *C. perfringens*, and should take corrective action. However, the presence of  
8974 nitrite should ensure compliance with the performance standard for *C. botulinum*.
- 8975  
8976 The Regulation provision for cooling is similar, though not identical to the FSIS cooling compliance  
8977 guidelines. It provides for cooling from 60°C (135°F) to 21°C (70°F) in 2 hours and from 60°C (135°F)  
8978 to 5°C (41°F) in 6 hours and is based on the same food safety concerns as FSIS' guidance. The Regulation  
8979 provides prescriptive cooling time/temperature combinations without a HACCP plan in place. Federally  
8980 inspected meat and poultry establishments are required to implement a HACCP plan for their operations.

8981  
8982 The Conference for Food Protection (CFP) at its 2000 meeting recommended that FSIS and FDA ask the  
8983 National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to review the data on  
8984 safe cooling times for cooked, potentially hazardous foods. The review would include data from a study,  
8985 submitted to the CFP, showing that cooling of a meat product from 54.4°C (130°F) to 7.2°C (45°F) can  
8986 safely take place in 15 hours based on a study by V.K. Juneja, et al., 1994. According to the authors of the  
8987 study, continuous cooling of a meat product from 54.4 °C (130°F) to 7.2°C (45°F) in 15 hours permitted  
8988 about 1 log growth of *C. perfringens*.

8989  
8990 In response to the CFP recommendation, the FSIS Administrator and CFSAN agreed that the data  
8991 referenced in the CFP recommendation do not support a change in the FSIS guidance or the Regulation §  
8992 3-503 and considered it inadvisable to ask the NACMCF to undertake the task requested for several  
8993 reasons:

- 8994 1. The study did not address growth of *C. botulinum*.
- 8995 2. The results are from a carefully controlled laboratory study in which cooling of the product was  
8996 steady and continuous, conditions difficult to maintain in most commercial processing or retail  
8997 environments even with data loggers and other control mechanisms in place.
- 8998 3. The study was done only on ground beef and may not be applicable to other meat and poultry or  
8999 to other potentially hazardous foods.

9000 As an alternative response, CFSAN and FSIS advised CFP that they would provide this written position  
9001 paper to clarify their joint position on the cooling issues.

9002  
9003 **Shell Eggs**

9004  
9005 FDA has approved the use of ionizing radiation for shell eggs. This approval means that FDA has not  
9006 found the ionizing radiation process to be unsafe for shell eggs. However, shell eggs that have been  
9007 subjected to the approved ionizing radiation process are not considered to have been pasteurized. Shell  
9008 egg pasteurization requires the egg to have been subjected to a 5 log kill process for *Salmonella*  
9009 *Enteritidis*, while the approved ionizing radiation process may deliver only 2 or 3 logs reduction.  
9010 Therefore, eggs treated by ionizing radiation process alone must be held under refrigeration, as it cannot  
9011 be guaranteed that *Salmonella Enteritidis* will be eliminated in all treated eggs. Further, irradiated eggs  
9012 must be labeled in accordance with 21 CFR 179.26 *Ionizing radiation for the treatment of food*.

9013  
9014 Hard-boiled eggs with shell intact may be cooled in ambient air and are not considered to be a potentially  
9015 hazardous food after cooling. Hard-boiled eggs may be cooled in drinking water but are considered to be  
9016 a potentially hazardous food after cooling because pathogens, which may be present in the water, may  
9017 pass through the egg shell during cooling.

9018  
9019 *Salmonella Enteritidis* has been shown to have an extended lag phase in shell eggs due to inhibitory  
9020 characteristics of the albumen. Research indicates that the organisms are physically located near the  
9021 exterior of the yolk membrane, in contact with the bacteriostatic components. Growth does not appear  
9022 until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron,  
9023 become available to the organisms.

9024 Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under  
9025 refrigeration at an ambient temperature not to exceed 7.2°C (45°F). Packed shell eggs must be labeled  
9026 indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to  
9027 include a certification that the eggs, at all times after packing, have been stored and transported at an  
9028 ambient temperature of no greater than 7.2°C (45°F).



9029 On December 5, 2000 federal regulations were amended to require that shell egg cartons bear safe  
9030 handling instructions and be placed under refrigeration at 7.2°C (45°F) or lower upon delivery at retail  
9031 establishments (65 FR 76091, December 5, 2000, Food Labeling, Safe Handling Statements, Labeling of  
9032 Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution). The amended provisions include:

9033 • 21 CFR Part 16 Regulatory Hearing before the Food and Drug Administration, § 16.5  
9034 Inapplicability and limited applicability, (4) A hearing on an order for re-labeling, diversion or  
9035 destruction of shell eggs...

9036 • 21 CFR Part 101 Food Labeling § 101.17 Food labeling warning, notice, and safe handling  
9037 statements, (h) *Shell eggs*.

9038 • 21 CFR Part 115 Shell Eggs, § 115.50 Refrigeration of shell eggs held for retail distribution.

9039 Shell eggs must be placed immediately after receipt in refrigerated equipment that is capable of  
9040 maintaining an ambient air temperature of 7.2°C (45°F). With the newly established federal requirement  
9041 for eggs to be in an ambient storage and transportation temperature of 7.2°C (45°F), and with  
9042 refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that  
9043 allow the growth of *Salmonella* spp. should be shortened. Additionally, this requirement negates the need  
9044 to "cool" shell eggs upon receipt, although food establishment operators should maximize the circulation  
9045 of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

9046

### 9047 **3-604—Cooling Methods**

9048

9049 Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool  
9050 because of the mass and volume from which heat must be removed. By reducing the volume of the food  
9051 in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen  
9052 growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e.,  
9053 the time required for cooling and the time the food is exposed to optimal temperatures for bacterial  
9054 multiplication or toxin production are increased.

9055

9056 Alternatives to conventional methods include avoiding the need to cool larger masses by preparing  
9057 smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice  
9058 water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool  
9059 large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures  
9060 quickly by using very low temperatures and high rates of air circulation.

9061

### 9062 **3-605—Time as a Public Health Control**

9063

9064 The 2000 Conference for Food Protection (CFP) recommended that FDA ask the National Advisory  
9065 Committee on Microbiological Criteria for Foods (NACMCF) to review the Regulation provision that  
9066 addresses using time alone as a public health control. In response to the CFP recommendation, FDA, in  
9067 consultation with USDA/FSIS, determined that there is sufficient scientific information available to  
9068 support the current provision in the Regulation without requesting consideration by the NACMCF. As an  
9069 alternative response, FDA informed CFP that it would provide the following position paper on using time  
9070 alone as a public health control.

9071

#### 9072 **Position Paper**

9073

9074 The Rules and Regulations allows potentially hazardous food (PHF) that is ready to eat (RTE) to be  
9075 stored without temperature control for up to 4 hours, after which it must be discarded or consumed. The  
9076 following information is provided to explain the reasoning in allowing time alone to be used as a public  
health control for food safety.

9077

**9078 Background information:**

9079

9080 Food kept without temperature control allows product to warm or cool as it equilibrates with the  
9081 environment. Each temperature scenario incurs different risks in regard to the type of foodborne  
9082 pathogens able to grow and the rate of growth likely to occur. For both cooling and warming conditions,  
9083 growth depends on the amount of time the food spends in an optimum growth temperature range during  
9084 its equilibration with its surroundings. Several factors influence the rate of temperature change in a food,  
9085 such as the type of food, thickness of the food, and temperature differential between the food and its  
9086 surroundings. When evaluating the safety of a 4-hour limit for food with no temperature control, products  
9087 and environmental parameters must be selected to create a worst-case scenario for pathogens growth and  
9088 possible toxin production.

9089

**9090 Holding Cold Food with Temperature Control**

9091

9092 When a food is removed from refrigerated storage and begins to warm to room temperature, *Listeria*  
9093 *monocytogenes* is a primary organism of concern. Even while food is held at refrigeration temperatures,  
9094 the growth potential of *L. monocytogenes* warrants concern for potentially hazardous RTE foods.

9095 Although the FDA and USDA have a zero tolerance for

9096 *L. monocytogenes* in RTE food, conditions are permitted in the Regulation that would allow *L.*

9097 *monocytogenes* cells 1 log of growth (3.3 generations). *Salmonella* is also a concern especially with

9098 products containing eggs. However *L. monocytogenes* grows more rapidly than *Salmonella* at

9099 refrigeration and room temperatures. By ensuring minimal *Listeria* growth in food, the threat from

9100 *Salmonella* would be negligible. Warming conditions will allow food to remain exposed to temperatures

9101 that allow *B. cereus* to produce emetic toxin. However the 4-hour time constraint in the Regulation is

9102 sufficient to prevent any toxin formation.

9103

9104 For food refrigerated at 5°C (41°F) or 7.2°C (45°F) then transferred to an ambient temperature of 23.9°C

9105 (75°F) for 4 hours, the growth rate of *L. monocytogenes* remains slow enough to ensure that the critical

9106 limit of 1 log growth is not reached. Published generation times at 23.9°C (75°F) for *L. monocytogenes* in

9107 food were not found, however published values at 20°C (68°F) and 21°C (70°F) in egg and milk products

9108 confirmed slow *L. monocytogenes* growth at room temperatures.

9109

9110 Using the USDA Pathogen Modeling Program (PMP) and assuming the optimum conditions of pH 6.8,

9111 0.5% NaCl, 0.0% nitrite, *L. monocytogenes* would require more than 4 hours to grow 1 log at 23.9°C

9112 (75°F). The PMP is based on broth studies and not on food products. Therefore, the growth rates reported

9113 at various temperatures by the PMP are faster than growth rates in most food products. Another factor

9114 exaggerating the growth rate in this warming scenario as predicted by the PMP is the assumption that the

9115 food product spent all 4 hours at 23.9°C (75°F). Obviously food equilibrates with the surrounding

9116 environment at a gradual rate and would not equilibrate instantly.

9117

9118 Unfortunately there are no models that take changing temperatures into consideration when predicting

9119 growth. Likewise there are very few published papers dealing with the growth of organisms in food

9120 during warming. The conservative nature of the 4-hour limit for keeping foods without temperature

9121 control allows for a needed margin of safety if the temperature of the environment is higher than 23.9°C

9122 (75°F).

9123

**9124 Holding Hot Food without Temperature Control**

9125

9126 The second scenario for food without temperature control exists when food is cooked according to

9127 Regulation recommendations, then kept at room temperature for 4 hours before discarding. Foodborne

9128 pathogens of concern for an uncontrolled temperature scenario are sporeformers including *Clostridium*  
9129 *perfringens* and *Bacillus cereus*. Food cooked according to Regulation guidelines should be free of  
9130 vegetative cells. However, the heat requirements are not sufficient to kill spores of *C. perfringens* or *B.*  
9131 *cereus* and may actually serve as a heat shock that activates the spores. *B. cereus* is found commonly in  
9132 outbreaks attributed to inadequate hot holding of starchy foods like rice, and has been isolated in a  
9133 multitude of food products. *C. perfringens* is found commonly in outbreaks attributed to inadequate hot  
9134 holding of beef and poultry. Despite the prevalence of both spores in nature, *C. perfringens* cases are  
9135 estimated to be more numerous than *B. cereus* cases by a factor of 10.

9136  
9137 *B. cereus* can produce emetic toxin in food, and the optimum temperature for the production of toxin is  
9138 between 25°C (77°F) and 30°C (86°F). However, the time needed to produce the toxin is longer than the  
9139 time the food will be exposed to any temperature range with a 4-hour holding limit. Both *C. perfringens*  
9140 and *B. cereus* produce enterotoxin inside the intestine of the infected host if substantial numbers of  
9141 vegetative cells are present in the food (10<sup>5-7</sup> CFU/g). Although the reported levels of both spores in raw  
9142 foods vary in the literature, generally the level expected in food can be assumed to be low (around 10-  
9143 1000 CFU/g). This implies that conditions allowing 1 log growth of either spore could be tolerated in  
9144 food.

9145  
9146 During the time without temperature control, the temperature of the food could decrease slowly enough to  
9147 expose spores of both organisms to optimal growth conditions for a significant length of time. Like  
9148 warming, several variables exist that determine the rate of heat transfer. Because of the wide variety of  
9149 foods prepared it would be impossible to generalize how fast a typical product loses temperature after  
9150 cooking. As with warming, it is prudent to imagine a worst case scenario where heat loss is slowed. A  
9151 beef roast slow cooked to 54.4°C (130°F) for the appropriate time according to the Regulation was used  
9152 as consideration for possible spore growth. Cooking roast beef to 54.4°C (130°F) can create an anaerobic  
9153 environment in both the meat and gravy. The low internal temperature creates a small temperature  
9154 differential with the environment (assumed at 23.9°C (75°F)), allowing for a slower decrease in the food's  
9155 temperature.

9156  
9157 After evaluating published studies as well as data collected at the FDA, the surface of a roast beef or  
9158 rolled meat product would lose heat quickly enough to discourage significant growth of either *C.*  
9159 *perfringens* or *B. cereus*. If all spores were distributed on the surface of the product by either pre- or  
9160 post-cooking contamination, storing this product for 4 hours at room conditions would be considered safe.  
9161 Likewise, products that are stirred or products that lose heat faster than a roast would also be considered  
9162 safe.

9163  
9164 ----- **End of position paper** -----

9165

9166 At the 2004 meeting of the CFP, a committee submitted and the Conference accepted a document that  
9167 examined scientific research related to the growth of **LISTERIA MONOCYTOGENES**, and the  
9168 influence of time and temperature on its growth.

9169 The 2004 CFP report stated that the USDA PMP program can be used as a tool to estimate time periods  
9170 for a 1-log increase in growth for **LISTERIA MONOCYTOGENES** in ideal (laboratory media) growth  
9171 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-  
9172 log increase was, 87.8, 53.9, and 34.7 hours, respectively. At room temperature (21°C (70°F)) a 1-log  
9173 increase was noted at 5.2 hours and at ideal growth temperatures (35°C (95°F)), the reported time for a 1-  
9174 log increase was 3.0 hours. In general, the data from the USDA PMP program provides very conservative  
9175 growth data and, in most cases, growth would be expected to be less rapid in a food system. This table

9176 does provide comparative information relative to growth rates at different holding temperatures in the  
9177 event that time was used as a factor in managing food safety.

9178 The report further recommended that food could safely be held for up to 6 hours without external  
9179 temperature control as long as the food temperature did not exceed 21°C (70°F). Based on that report and  
9180 data from the [Quantitative Assessment of the Relative Risk to Public Health from Foodborne LISTERIA  
9181 MONOCYTOGENES Among Selected Categories of Ready-to-Eat Foods](#)<sup>40</sup> September 2003, the Food  
9182 Code allows potentially hazardous food (time/temperature control for safety) to be stored up to 6 hours  
9183 without external temperature control provided that the food temperature does not exceed 21°C (70°F) and  
9184 the food is discarded or consumed at the end of the 6 hours.

9185 **The Safety of the Time as a Public Health Control Provision from Cooking Temperatures (135°F or  
9186 above) to Ambient**

9187 FDA conducted in-house laboratory experiments to test the safety of the existing TPHC provisions of 4  
9188 hours without temperature control starting with an initial temperature of 60°C (135°F) or above.  
9189 CLOSTRIDIUM PERFRINGENS was chosen to represent a worst case scenario pathogen for foods  
9190 allowed to cool from cooking temperatures to ambient without temperature control because its spores can  
9191 survive normal cooking procedures, it can grow at relatively high temperatures (>49°C (120°F)) and it  
9192 has a short lag period. C. PERFRINGENS spores were inoculated into foods that were cooked and then  
9193 cooled to yield a cooling curve that would promote outgrowth as quickly as possible. The growth data  
9194 suggest that the existing 4-hour TPHC provision will be safe for 6 hours after cooking, with the additional  
9195 2-hour margin of safety built in for consumer handling.

9196 **Consumer Handling Practices**

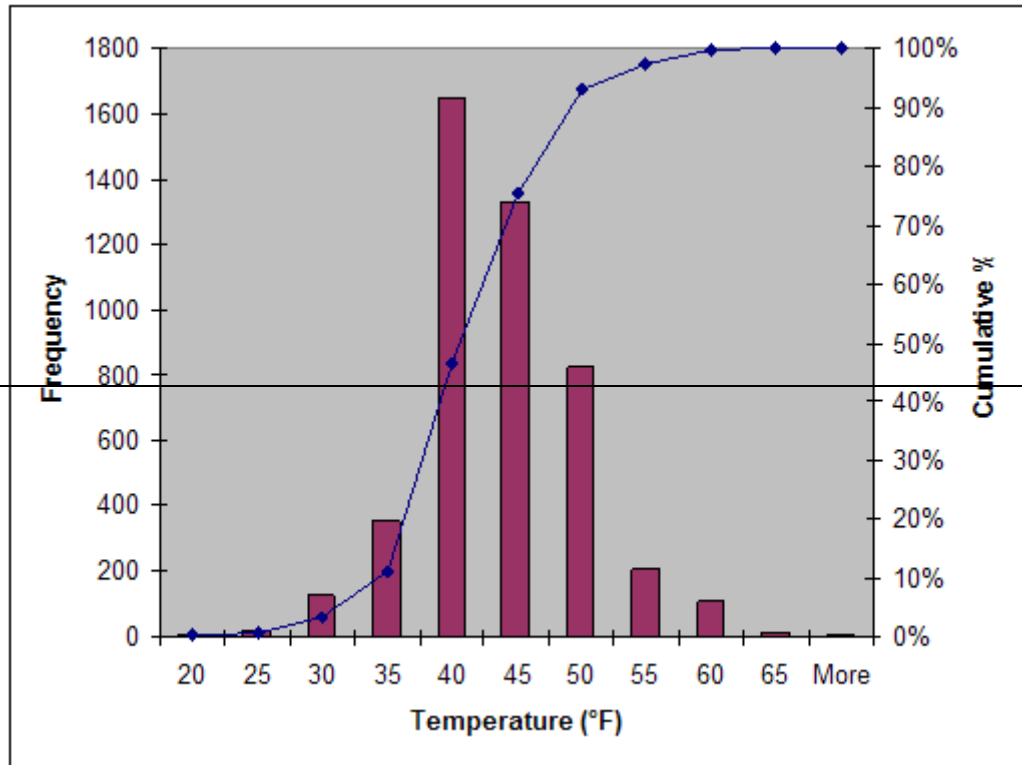
9197 An Audits International study was funded in 1999 by FDA to determine the food handling practices of  
9198 consumers purchasing food at retail and returning home to refrigerate their items. Forty-six (46) states are  
9199 represented, and the data comprises several food groups purchased from different grocery store types.  
9200 The food groups represented were: pre-packaged lunch meat, deli-counter products, seafood, fresh meat,  
9201 pre-packaged deli product, liquid dairy, semi-solid dairy product, ice cream, frozen entrées, frozen  
9202 novelties and whipped topping.

9203 The study evaluated information regarding time and food temperature at retail food stores, time to reach  
9204 home refrigeration, temperature after transport home, location and type of retail establishment where  
9205 purchase was made and type of product purchased.

9206 For product temperature at retail and after transportation, 5 product categories were used: pre-packaged  
9207 lunch meat, pre-packaged deli product, deli-counter products, seafood and fresh meat. These categories  
9208 were considered most applicable to the TPHC recommendations. The temperature ranges for these  
9209 products at retail and after transport to the home are summarized in Figures 1 and 2 respectively. The data  
9210 suggest that with current retail refrigeration practices, 25% of items are held above 7.2°C (45°F) (Figure  
9211 1). The data also show that by the time the product arrives at the home, 98% of products were at 18.3°C  
9212 (65°F) or less (Figure 2).

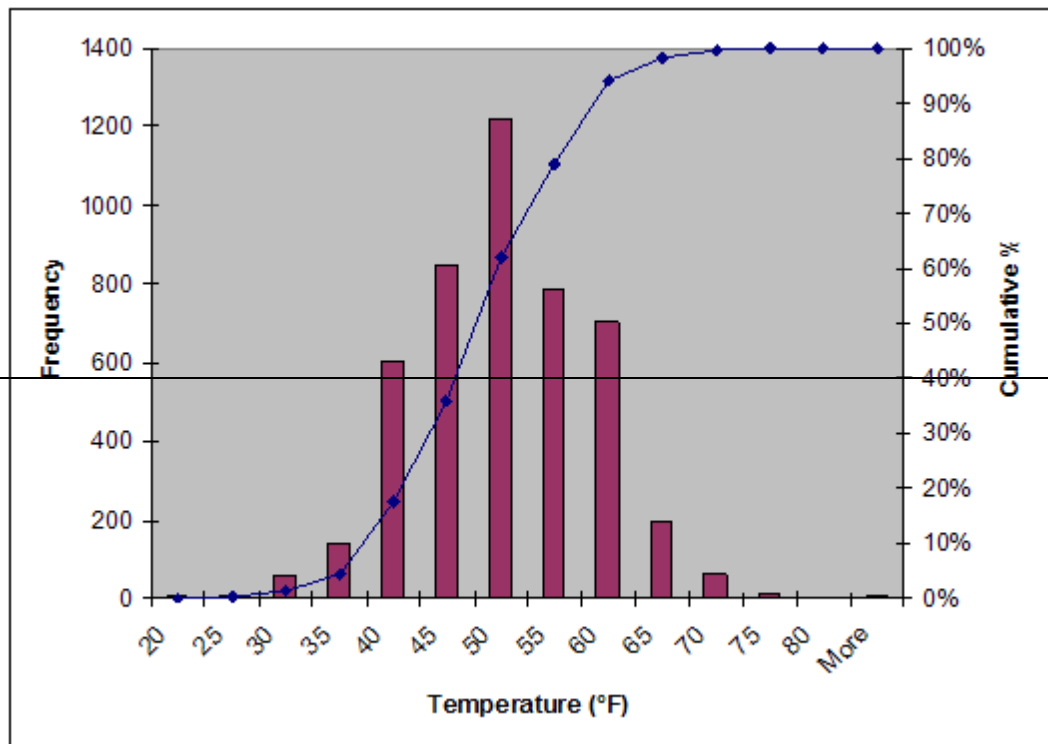
9213 The time of transport for all food categories from the retail establishment to home refrigeration was also  
9214 recorded. The data summarized in Figure 3 shows that over 97% of the foods purchased were ready to be  
9215 placed in refrigeration within 2 hours of purchase. For this histogram, all food categories except for  
9216 frozen entrées were included. Because all foods end up bagged and transported together, the time each  
9217 product was transported to the home was considered a valid data point and therefore used. Based on the  
9218 data, a benchmark was established that PHF/TCS foods purchased in a food establishment would be  
9219 either consumed, or placed under temperature control, within 2 hours.

9220 **Figure 1.** Temperatures of refrigerated products at retail (Audits International)-



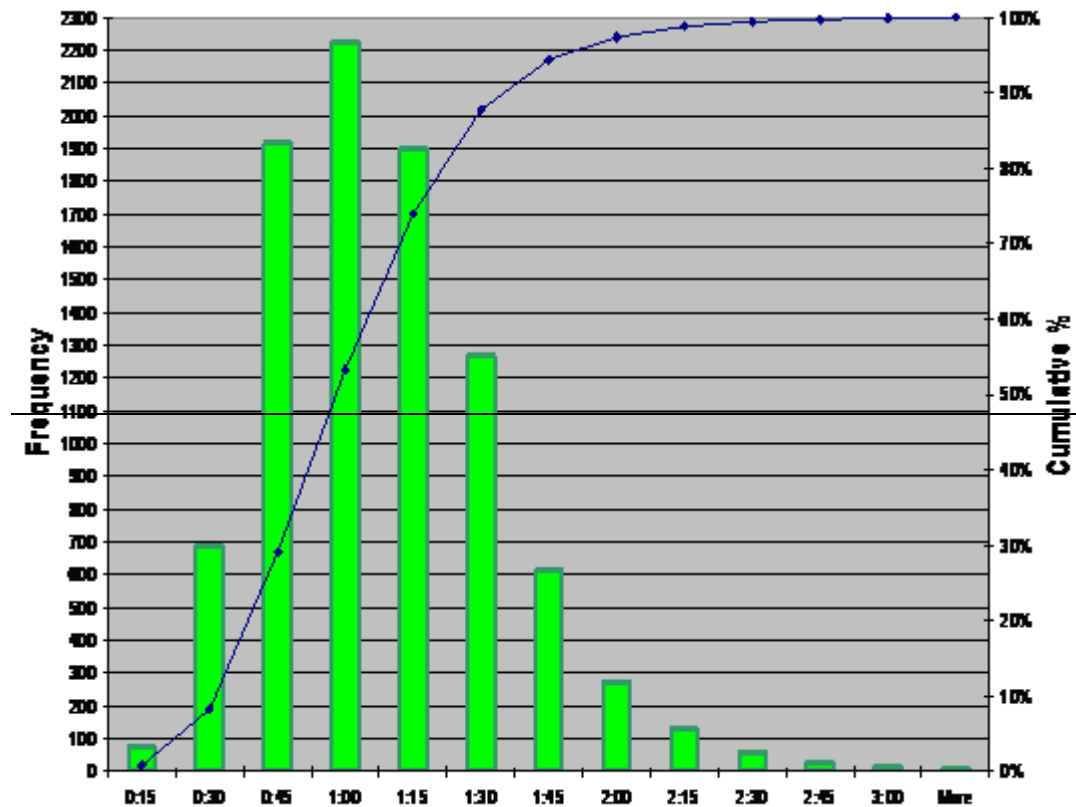
9221

9222 **Figure 2.** Product temperatures after transport to the home (Audits International)-



9223

9224 **Figure 3.** Times reported for transport of grocery items from the retail outlet to the home (Audits  
 9225 International).



9226

9227 **The Safety of the Time as a Public Health Control Provision from Refrigeration Temperatures (5°C**  
 9228 **(41°F) or less) to Ambient**

9229 As noted above, the current TPHC provision has two time provisions. Food can be kept with no  
 9230 temperature stipulations for 4 hours in a food establishment, at which time the food must be cooked and  
 9231 served, served if RTE, or discarded within the four hours. However, if food does not exceed 21°C (70°F),  
 9232 it may be held for 6 hours and cooked and served, served if RTE or discarded within the six hours. For  
 9233 foods warming from refrigeration to ambient temperatures, the data from the Audits International study  
 9234 outlined above, along with simulations from the USDA Pathogen Modeling Program (PMP), were used to  
 9235 determine the safety of the existing TPHC recommendations.

9236 Assuming pathogen growth in foods going from refrigeration (5°C (41°F) or less) to ambient temperature,  
 9237 the following parameters were used for the PMP simulation:

- 9238
- 18.3°C (65°F) was used as the temperature for the entire simulation;
- 9239
- 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);
- 9240
- The data were generated from PMP broth models (pH 6.8), with the minimal NaCl and no sodium nitrite.
- 9241
- 9242
- 9243

9244

9245 Table 1 summarizes the predicted growth of *BACILLUS CEREUS* (vegetative), *ESCHERICHIA COLI*,  
 9246 *LISTERIA MONOCYTOGENES*, *SALMONELLA* spp., *SHIGELLA FLEXNERI*, and  
 9247 *STAPHYLOCOCCUS AUREUS*, using the PMP and based on the assumptions discussed above. The  
 9248 data predicted that less than 1 log growth would be seen for each organism, during the 8 hour time period.  
 9249 Thus, the data show that the current 4 and 6 hour TPHC provisions from 5°C (41°F) or less to ambient,  
 9250 allow minimal growth of a number of pathogens of concern.

| <b>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.</b> |                |                |
|---|----------------|----------------|
| <b>Pathogens</b>  | <b>6 Hours</b> | <b>8 hours</b> |
| <b>B. CEREUS (vegetative cells)</b>   | 0.62           | 0.87           |
| <b>E. COLI</b>  | 0.35           | 0.52           |
| <b>L. MONOCYTOGENES</b>   | 0.47           | 0.71           |
| <b>SALMONELLA SPP.</b>  | 0.25           | 0.41           |
| <b>S. FLEXNERI</b>  | 0.26*          | 0.34*          |
| <b>S. AUREUS</b>  | 0.38*          | 0.51*          |

9251

9252

9253

\* Model predictions were in 5 hour increments, the 6 and 8 hour data was extrapolated between 5 hour and 10 hour predictions.

9254

#### **References**

9255

9256

U.S. Department of Agriculture. 1997. PATHOGEN MODELING PROGRAM. USDA Agricultural Research Service, Wyndmoor, PA.

9257

9258

Food and Drug Administration. 2006. Growth of *CLOSTRIDIUM PERFRINGENS* inoculated into beef roasts and meatloaf (unpublished data).

9259

-----End of Summary of Consumer Handling Practices study-----

9260

9261

9262 **Raw eggs**

9263 Recipes in which more than one egg is combined carry an increased risk of illness and possible serious  
9264 consequences for certain people. It is due to this increased risk, and documented occurrences of  
9265 foodborne illness and death among highly susceptible populations from temperature-abused raw shell  
9266 eggs contaminated with *Salmonella Enteritidis*, that the use of time as a public health control in  
9267 institutional settings is not allowed.

9268

9269 **3-606—Specialized Processing Methods**

9270 Specialized food processes have historically resulted in more foodborne illness than standard processes.  
9271 They present a significant health risk if not conducted under strict operational procedures. These types of  
9272 operations may require the person in charge and food employees to use specialized equipment and  
9273 demonstrate specific competencies. The requirement for Department approval is designed to ensure that  
9274 the proposed method of operation is carried out safely.

9275 **3-607—Reduced Oxygen Packaging**

9276 Reduced oxygen packaging (ROP) encompasses a large variety of packaging methods where the internal  
9277 environment of the package contains less than the normal ambient oxygen level (typically 21% at sea  
9278 level), including vacuum packaging (VP), modified atmosphere packaging (MAP), controlled atmosphere  
9279 packaging (CAP), cook chill processing (CC), and sous vide (SV). Using ROP methods in food  
9280 establishments has the advantage of providing extended shelf life to many foods because it inhibits  
9281 spoilage organisms that are typically aerobic.

9282 This state of reduced oxygen is achieved in different ways. Oxygen can be withdrawn from the package  
9283 (VP) with or without having another gas such as nitrogen or carbon dioxide replacing it (MAP). Fresh  
9284 produce and raw meat or poultry continue to respire and use oxygen after they are packaged. Bacterial  
9285 activity also plays a role here. Packaging materials that readily allow the transmission of oxygen is  
9286 usually designated by an Oxygen Transfer Rate of 10,000 cc/m<sup>2</sup>/24 hours at 24 °C. A reduced oxygen  
9287 atmosphere will result with an Oxygen Transmission rate of 10-100. The process of cooking drives off  
9288 oxygen (the bubbling is oxygen gas coming off) and leaves a reduced oxygen level in the food, thus,  
9289 microenvironments of reduced oxygen are possible even without packaging that has a barrier to oxygen  
9290 transmission.

9291 Most foodborne pathogens are anaerobes or facultative anaerobes able to multiply under either aerobic or  
9292 anaerobic conditions, therefore special controls are necessary to control their growth. Refrigerated storage  
9293 temperatures of 5°C (41°F) may be adequate to prevent growth and/or toxin production of some  
9294 pathogenic microorganisms but non-proteolytic *C. botulinum* and *L. monocytogenes* are able to multiply  
9295 well below 5°C (41°F). For this reason, *C. botulinum* and *L. monocytogenes* become the pathogens of  
9296 concern for ROP. Controlling their growth will control the growth of other foodborne pathogens as well.

9297 When followed as written, the ROP methods in this section all provide controls for the growth and/or  
9298 toxin production of *C. botulinum* and *L. monocytogenes*. Section 3-607 (A) identifies an ROP method  
9299 with secondary barriers that will control *C. botulinum* and *L. monocytogenes* when used in conjunction  
9300 with a food storage temperature of 5°C (41°F) or less. They include a<sub>w</sub> of 0.91 or less; pH of 4.6 or less;  
9301 cured, USDA inspected meat or poultry products using substances specified in 9 CFR 424.21; or high  
9302 levels of competing microorganisms. *C. botulinum* will not produce toxin below an a<sub>w</sub> of 0.91. Nitrite,  
9303 used in meat and poultry curing, inhibits the outgrowth of *C. botulinum* spores. Most foodborne  
9304 pathogens do not compete well with other microorganisms, therefore foods that have a high level of



9305 spoilage organisms or lactic acid bacteria can safely be packaged using ROP. Other intrinsic or extrinsic  
9306 factors can also control the growth and/or toxin production of *C. botulinum* and *L. monocytogenes*.

9307 Naturally fermented cheeses, as identified in Section 3-607(D), that meet the Standards of Identity for  
9308 hard, pasteurized process, and semisoft cheeses in 21 CFR 133.150, 21 CFR 133.169, or 21 CFR 133.187,  
9309 respectively, contain various intrinsic factors, often acting synergistically, that together act as a secondary  
9310 barrier to pathogen growth along with refrigerated storage at 5°C (41°F) or less. This combination of  
9311 factors could include some or all of the following: a lower pH, production of organic acids, and natural  
9312 antibiotics or bacteriocins such as nisin by lactic acid bacteria, salt (NaCl) added during processing, low  
9313 moisture content, added preservatives, and live competing cultures. Very few outbreaks have occurred  
9314 that were associated with cheese. The few outbreaks of foodborne illness associated with cheeses or  
9315 cheese products could be traced in large part to temperature abuse with storage at uncontrolled ambient  
9316 air temperatures. Examples of cheeses that may be packaged under ROP include Asiago medium, Asiago  
9317 old, Cheddar, Colby, Emmentaler, Gruyere, Parmesan, Reggiano, Romano, Sapsago, Swiss, pasteurized  
9318 process cheese, Asiago fresh and soft, Blue, Brick, Edam, Gorgonzola, Gouda, Limburger, Monterey,  
9319 Monterey Jack, Muenster, Provolone, and Roquefort. Soft cheeses such as Brie, Camembert, Cottage, and  
9320 Ricotta may not be packaged under reduced oxygen because of their ability to support the growth of *L.*  
9321 *monocytogenes* under modified atmosphere conditions.

9322 When the food to be packaged under reduced oxygen conditions cannot reliably depend on secondary  
9323 barriers such as a<sub>w</sub>, pH, nitrite in cured meat products, high levels of competing microorganisms or  
9324 intrinsic factors in certain cheeses, time/temperature becomes the critical controlling factor for growth of  
9325 *C. botulinum* and *L. monocytogenes*. Non proteolytic *C. botulinum* spores are able to germinate and  
9326 produce toxin at temperatures down to 3°C (38°F). Therefore, to control for toxin production by *C.*  
9327 *botulinum*, an anaerobe, ROP foods must be held at 3°C (38°F) or less. *Listeria monocytogenes* is able to  
9328 grow, although very slowly, at temperatures down to -1°C (30°F). The lag phase and generation time of  
9329 both pathogens becomes shorter as the storage temperature increases. In Section 3-607, cook-chill  
9330 processing where food is cooked then sealed in a barrier bag while still hot and sous vide processing  
9331 where food is sealed in a barrier bag and then cooked, both depend on time/temperature alone as the only  
9332 barrier to pathogenic growth. Therefore, monitoring critical limits including those established for cooking  
9333 to destroy vegetative cells, cooling to prevent outgrowth of spores/toxin production, and maintaining cold  
9334 storage temperatures to inhibit growth and/or toxin production of any surviving pathogens is essential.  
9335 Four separate options are provided in Section 3-607. These time-temperature combinations will provide  
9336 equivalent food safety protection without need for a variance. The first is cooling the bagged product to  
9337 1°C (34°F) and holding for up to 30 days after the product is sealed in the bag. The second is cooling  
9338 bagged product to 1°C (34°F), removing product to a different refrigeration unit and holding at any  
9339 temperature up to 5°C (41°F) for up to 72 hours with the total storage time not to exceed 30 days. This  
9340 situation is often encountered when a central kitchen prepares and stores the bagged product at 1°C  
9341 (34°F) then transports it to a satellite kitchen under their control where it can be held at 5°C (41°F) or  
9342 less. The third option is cooling to 3°C (38°F) and holding for no more than 72 hours from packaging.  
9343 The fourth option can be used without a restricted shelf life while the bagged product is held frozen until  
9344 thawed to be consumed or used in another preparation.

9345 Since there are no other controlling factors for *C. botulinum* and *L. monocytogenes* in a cook-chill or  
9346 sous vide packaging system, temperature control must be continuously monitored electronically and  
9347 visually examined twice daily to verify that refrigeration temperatures are adequate. New technology  
9348 makes it relatively easy to continuously and electronically monitor temperatures of refrigeration  
9349 equipment used to hold cook-chill and sous vide products at 1°C (34°F) or 3°C (38°F) or less.  
9350 Thermocouple data loggers can connect directly with commonly available thermocouple probes.  
9351 Recording charts are also commonly used. Temperature monitors and alarm systems will activate an  
9352 alarm or dialer if temperatures rise above preset limits. Nickel-sized data loggers are available to record

9353 temperatures which can be displayed using computer software. Since surveys have shown that  
9354 temperature control in home kitchens is not always adequate, food packaged using cook chill or sous vide  
9355 processing methods cannot be distributed outside the control of the food establishment doing the  
9356 packaging.

9357 Time is also a factor that must be considered in ROP. The 14 day "use by" date is required label  
9358 information for VP, MAP, and CAP products and cannot exceed the manufacturer's "sell by" or "use by"  
9359 date. This is considered a safe time period because two barriers to growth are required to be present.  
9360 When these ROP products are frozen, there is no longer a restricted 14 day shelf life. The 30 day shelf life  
9361 for cook chill and sous vide is based on killing all vegetative cells in the cooking process, preventing  
9362 recontamination, and then refrigerating at 1°C (34°F) or less with an option of 3°C (38°F) for up to 72  
9363 hours after packaging with stringent temperature monitoring and recording requirements. These criteria  
9364 allow both institutional sized cook chill operations that may feed thousands daily, often including  
9365 transportation to their satellite locations, and individual restaurants without ice banks and tumble or blast  
9366 chillers to safely use cook chill and sous vide processes.

9367 The extended shelf life for vacuum packaged hard and semisoft cheeses is based on many intrinsic factors  
9368 in these cheeses plus the normal refrigeration temperature of 5°C (41°F) or less to maintain safety.

9369 A Hazard Analysis Critical Control Point (HACCP) plan is essential when using ROP processing  
9370 procedures. *C. botulinum* and *L. monocytogenes* are potential hazards which must be controlled in most  
9371 foods unless the food is a low acid canned food produced under 21 CFR Part 108 or 113 or an acidified  
9372 food produced under 21 CFR 114. Critical control points, critical limits, monitoring, record keeping,  
9373 corrective actions, and verification procedures will vary based on the type of food and type of ROP  
9374 technology used.

9375 Unfrozen raw fish and other seafood are specifically excluded from ROP because of these products'  
9376 natural association with *C. botulinum* type E which grows at or above 3°C (37-38°F). Fish and seafood  
9377 that are frozen before, during and after the ROP packaging process are allowed.

### 9378 **3-608—Breading Mixtures**

9379

### 9380 **3-7—On-Premises Labeling**

9381

### 9382 **3-701—Labeling**

9383

9384 Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows  
9385 consumers to make informed decisions about what they eat. Many consumers, as a result of an existing  
9386 medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in  
9387 dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In  
9388 addition, consumers have a basic right to be protected from misbranding and fraud.

9389

9390 Certain foods may be difficult to identify after they are removed from their original packaging.

9391 Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the  
9392 consumer has specifically requested that it not be used, may result in severe medical consequences.

9393

9394 The mistaken use of food from unlabeled containers could result in chemical poisoning. For example,  
9395 foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant  
9396 formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble  
9397 cleaning compounds are also of particular concern.

9398 The identity of a food in terms of origin and composition is important for instances when a food may be  
9399 implicated in a foodborne illness and for nutritional information requirements. Ingredient information is

9400 needed by consumers who have allergies to certain food or ingredients. The appearance of a food should  
9401 not be altered or disguised because it is a cue to the consumer of the food's identity and condition.

9402 Recent illnesses and deaths from Shiga toxin-producing *Escherichia coli* have occurred across the United  
9403 States as a result of people eating hamburgers that were contaminated and then undercooked. USDA  
9404 issued final rules on August 8, 1994 requiring all raw meat or poultry products have a safe handling label  
9405 or sticker or be accompanied by a leaflet that contains information on proper handling and cooking  
9406 procedures.

9407 Certain requirements in the CFR relating to aspects of nutrition labeling became effective in May, 1997.  
9408 The following attempts to provide guidance regarding those requirements and exemptions as they relate to  
9409 the retail environment and to alert regulators to authority that has been given to them by the Nutrition  
9410 Labeling and Education Act (NLEA) of 1990. The statute and the CFR should be reviewed to ensure a  
9411 comprehensive understanding of the labeling requirements.

9412 I.—The following foods need not comply with nutrition labeling in the CFR if they do not bear a  
9413 nutrient claim, health claim, or other nutrition information:

9414 (A)—Foods packaged in a food establishment if:

9415 (1)—The food establishment has total annual sales to consumers of no more than  
9416 \$500,000 (or no more than \$50,000 in food sales alone), and

9417 (2)—The label of the food does not bear a reference to the manufacturer or processor  
9418 other than the food establishment;

9419 (B)—Low volume food products if:

9420 (1)—The annual sales are less than 100,000 units for which a notification claiming  
9421 exemption has been filed with FDA's Office of Nutritional Products Labeling and  
9422 Dietary Supplements Food Labeling by a small business with less than 100 full-  
9423 time equivalent employees, or

9424 (2)—The annual sales are less than 10,000 units by a small business with less than 10  
9425 full time equivalent employees;

9426 (C)—Foods served in food establishments with facilities for immediate consumption such as  
9427 restaurants, cafeterias, and mobile food establishments, and foods sold only in those  
9428 establishments;

9429 (D)—Foods similar to those specified in the preceding bullet but that are sold by food  
9430 establishments without facilities for immediate consumption such as bakeries and grocery  
9431 stores if the food is:

9432 (1)—Ready to eat but not necessarily for immediate consumption;

9433 (2)—Prepared primarily in the food establishment from which it is sold, and

9434 (3)—Not offered for sale outside the food establishment;

9435 (E)—Foods of no nutritional significance such as coffee;

9436 (F)—Bulk food for further manufacturing or repacking; and

- 9437 (G) — Raw fruits, vegetables, and fish.
- 9438 H. — Game animal meats shall provide nutrition information which may be provided by labeling  
9439 displayed at the point of purchase such as on a counter card, sign, tag affixed to the food, or some  
9440 other appropriate device.
- 9441 III. — Food packaged in a food processing plant or another food establishment, shall meet the  
9442 requirements specified in § 3-602.11 and enforcement by the regulatory authority is authorized in  
9443 the NLEA, Section 4. State Enforcement.
- 9444 In 1998, 21 CFR Part 73, Section 73.75 was amended to address canthaxanthin as a color additive for  
9445 salmonid fish. According to the FDA Regulatory Fish Encyclopedia, the family Salmonidae includes pink  
9446 salmon, coho salmon, sockeye salmon, chinook salmon, Atlantic salmon, chum salmon, rainbow trout,  
9447 cutthroat trout, and brown trout. This color additive may be in the feed that is fed to aquacultured fish,  
9448 and when those fish are placed into a bulk container for shipment, the bulk container must bear a label  
9449 declaring the presence of canthaxanthin. That same label information must be displayed at retail when  
9450 those fish are offered for sale.
- 9451 The 21 CFR Section 73.75(d)(4) requires that the presence of the color additive in salmonid fish that have  
9452 been fed feeds containing canthaxanthin be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2)  
9453 and 101.100(a)(2). For additional information, see the Federal Register announcement 63 FR 14814,  
9454 March 27, 1998, Listing of Color Additives Exempt from Certification; Canthaxanthin.
- 9455 On August 2, 2004, President Bush signed into law the Food Allergen Labeling and Consumer Protection  
9456 Act of 2004 (Public Law 108-282). This new law amended Sections 201 and 403 of the Federal Food,  
9457 Drug, and Cosmetic Act to establish food allergen labeling requirements for all packaged foods regulated  
9458 by FDA. The new provisions require that all affected packages of food labeled on or after January 1, 2006  
9459 must identify on the label the names of the food sources of any major food allergens (i.e., the following  
9460 eight foods and any protein derived from them: milk, egg, fish, crustacean shellfish, tree nuts, wheat,  
9461 peanuts, and soybeans) used as ingredients in the food. The names of the food sources are the same as the  
9462 names of the eight foods that are major food allergens, with the exception that for fish, crustacean  
9463 shellfish, and tree nuts, their respective food source names are the specific species of fish (e.g., bass,  
9464 flounder, or cod), the specific species of crustacean shellfish (e.g., crab, lobster, or shrimp), and the  
9465 specific types of tree nuts (e.g., almonds, pecans, or walnuts).
- 9466 **3-702—Special Requirements for Highly Susceptible Populations**
- 9467
- 9468 The Regulation provisions that relate to highly susceptible populations are combined in this section for  
9469 ease of reference and to add emphasis to special food safety precautions that are necessary to protect  
9470 those who are particularly vulnerable to foodborne illness and for whom the implications of such illness  
9471 can be dire.  
9472
- 9473 **Date Marking**
- 9474 Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most  
9475 microbes. The growth of some bacteria, such as **LISTERIA MONOCYTOGENES**, is significantly  
9476 slowed but not stopped by refrigeration. Over a period of time, this and similar organisms may increase  
9477 their risk to public health in ready-to-eat foods.
- 9478 Based on a predictive growth curve modeling program for **LISTERIA MONOCYTOGENES**, ready-to-  
9479 eat, potentially hazardous food (time/temperature control for safety food) may be kept at 5°C (41°F) a  
9480 total of 7 days. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by

9481 date marking to ensure its safety based on the total amount of time it was held at refrigeration  
9482 temperature, and the opportunity for **LISTERIA MONOCYTOGENES** to multiply, before freezing and  
9483 after thawing. Potentially hazardous (time/temperature control for safety) refrigerated foods must be  
9484 consumed, sold or discarded by the expiration date.

9485 Date marking is the mechanism by which the Regulation requires active managerial control of the  
9486 temperature and time combinations for cold holding. Industry serving a highly susceptible population  
9487 must implement a system of identifying the date or day by which the food must be consumed, sold, or  
9488 discarded. Date marking requirements apply to containers of processed food that have been opened and to  
9489 food prepared by a food establishment, in both cases if held for more than 24 hours, and while the food is  
9490 under the control of the food establishment. This provision applies to both bulk and display containers. It  
9491 is not the intent of the Regulation to require date marking on the labels of consumer size packages.

9492 A date marking system may be used which places information on the food, such as on an overwrap or on  
9493 the food container, which identifies the first day of preparation, or alternatively, may identify the last day  
9494 that the food may be sold or consumed on the premises. A date marking system may use calendar dates,  
9495 days of the week, color-coded marks, or other effective means, provided the system is disclosed to the  
9496 Regulatory Authority upon request, during inspections.

#### 9497 **FDA/USDA/CDC LISTERIA MONOCYTOGENES Risk Assessment**

9498 In September, 2003, FDA, in cooperation with USDA/FSIS and CDC, released the [Quantitative](#)  
9499 [Assessment of the Relative Risk to Public Health from Foodborne LISTERIA MONOCYTOGENES](#)  
9500 [Among Selected Categories of Ready-to-Eat Foods](#)<sup>38</sup>. This initiative included the development of 23  
9501 separate risk assessments and analysis of the relative risks of serious illness and death associated with  
9502 consumption of 23 categories of ready-to-eat foods. These categories included: seafood, produce, meats,  
9503 dairy products, and deli salads.

9504 In examining these closely, FDA showed that 5 factors are important in measuring the public health  
9505 impact to consumers from foodborne listeriosis. These factors are: (1) amounts and frequency of  
9506 consumption of a ready-to-eat food; (2) frequency and levels of **L. MONOCYTOGENES** in a ready-to-  
9507 eat food; (3) potential of the food to support growth of the bacterium during refrigeration; (4) refrigerated  
9508 storage temperature; and (5) duration of refrigerated storage before consumption.

9509 Based on these 5 factors, the 23 categories of ready-to-eat foods were ranked according to their relative  
9510 risk of contamination and growth of **LISTERIA MONOCYTOGENES**. The risk categories used were:  
9511 very high risk; high risk; moderate risk; low risk; and very low risk.

#### 9512 **IMPACT OF THE LISTERIA MONOCYTOGENES RISK ASSESSMENT ON DATE MARKING**

9513 Based on the results of the risk assessment and the recommendations from the 2004 Conference for Food  
9514 Protection meeting, it was necessary to re-evaluate date marking in an effort to focus the provision on  
9515 very high and high risk foods, while at the same time, exempting foods that present a very low, or low  
9516 risk of contamination and growth of **LISTERIA MONOCYTOGENES**. Based on this evaluation, date  
9517 marking provisions of the Regulation do not apply to the following foods:

9518

9519

9520

**DELI SALADS PREPARED AND PACKAGED IN A FOOD PROCESSING PLANT**

9521 Examples of deli salads include ham salad, chicken salad, egg salad, seafood salad, pasta salad, potato  
 9522 salad, and macaroni salad, manufactured according to 21 CFR 110. According to data from the risk  
 9523 assessment, deli salads prepared and packaged by a food processing plant contain sufficient acidity, along  
 9524 with the addition of preservatives (e.g., sorbate, benzoates), to prevent the growth of **LISTERIA**  
 9525 **MONOCYTOGENES**. There are estimates that 85% of all deli salads are prepared and packaged in a  
 9526 food processing plant and do not support growth. Based on discussions with deli salad manufacturers and  
 9527 trade associations, it is a nearly universal practice for food processing plants preparing and packaging deli  
 9528 salads to add one or more preservatives that inhibit the growth of **LISTERIA MONOCYTOGENES**.  
 9529 Based on their wide use within this segment of the industry and their effectiveness at inhibiting the  
 9530 growth of **LISTERIA MONOCYTOGENES**, all deli salads prepared and packaged in a food processing  
 9531 plant are exempt from date marking. However, all deli salads prepared in a food establishment require  
 9532 date marking.

9533

**HARD AND SEMI-SOFT CHEESES**

9534 In December, 1999, FDA issued an [exemption from date marking](#)<sup>39</sup> for certain types of hard and semi-soft  
 9535 cheeses, based on the presence of several factors that may control the growth of **LISTERIA**  
 9536 **MONOCYTOGENES**. These factors may include organic acids, preservatives, competing  
 9537 microorganisms, pH, water activity, or salt concentration. The results of the risk assessment support this  
 9538 interpretation and therefore, hard and semi-soft cheeses each manufactured according to 21 CFR 133 are  
 9539 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                  | Brick                    | 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       |                           |

9540 **CULTURED DAIRY PRODUCTS**

9541 Cultured dairy products include yogurt, sour cream, and buttermilk, each manufactured according to 21  
9542 CFR 131. Many of these products often are low pH foods manufactured with lactic acid fermentation.  
9543 Data from the risk assessment show that **LISTERIA MONOCYTOGENES** does not grow in these  
9544 foods and therefore, these products are exempt from date marking.

9545 **PRESERVED FISH PRODUCTS**

9546 Preserved fish products include pickled herring and dried, or salted cod, and other acidified fish products,  
9547 manufactured according to 21 CFR 114. Data from the risk assessment show that the high salt and/or  
9548 acidity of these products does not allow for the growth of **LISTERIA MONOCYTOGENES** and  
9549 therefore, these products are exempt from date marking. This exemption does not apply to hot or cold  
9550 smoked fish products, nor does it apply to fish products that are dried, marinated, or otherwise preserved  
9551 on-site, in a food establishment, such as ceviche.

9552 **USDA-regulated products**

9553 Date marking provisions of the Regulation do not apply to shelf-stable ready-to-eat meat and poultry  
9554 products. Shelf-stable ready-to-eat meat and poultry products are not required by USDA to be labeled  
9555 "Keep Refrigerated." For these products, the nitrite and salt in the cure and the lower pH resulting from  
9556 fermentation give additional protection against microbial growth. Some fermented sausages and salt-  
9557 cured products are shelf-stable, do not require refrigeration, and do not bear the label "Keep  
9558 Refrigerated." To be shelf-stable, a product manufactured under USDA inspection must have a process  
9559 that results in a product that meets one of the recognized objective criteria for shelf stability, such as  
9560 water activity, moisture-protein ratio (MPR), or combination of MPR and pH (acidity). Therefore they are  
9561 exempt from the Regulation date marking requirements.

9562 Shelf-stable fermented sausages such as pepperoni and dry salami do not have to be refrigerated or date  
9563 marked. Shelf-stable salt-cured products such as prosciutto, country cured ham, or Parma ham do not  
9564 require refrigeration or Regulation date marking. Other salt-cured products include basturma, breasaola,  
9565 coppa, and capocollo.

9566 Some ready-to-eat fermented sausages and salt-cured products must be refrigerated and therefore bear the  
9567 USDA required label "Keep Refrigerated." Examples of these products are cooked bologna, cooked  
9568 salami, and sliced country ham which are ready-to-eat fermented products that need refrigeration.  
9569 Bologna is a cooked, perishable sausage and there are other salamis, e.g., cotto that are perishable.

9570 Regarding the exemption from date marking for shelf-stable sausages in a casing, the exemption does not  
9571 apply if the casing is removed. The intact casing on shelf-stable sausages may be overwrapped to protect  
9572 the cut face of the sausage. With shelf-stable (not potentially hazardous (time/temperature control safety))  
9573 sausages, the intact casing provides a barrier to contamination (although not an absolute one), the exposed  
9574 face is likely to be sliced again within 4 or 7 days, and contamination is minimized because only the face  
9575 is exposed. The coagulated protein that occurs on the surface of some nonshelf-stable cooked sausages is  
9576 not a casing.

9577 Slices of cured and fermented sausages that require refrigeration and are kept for 24 hours or longer do  
9578 need to be date marked.

9579 If open dating information is applied to lunchmeats at a federally inspected meat or poultry establishment,  
9580 the information must comply with the requirements in 9 CFR 317.8 and 381.129. However, such dating is  
9581 not required by USDA/FSIS and if applied, would not supercede or replace date marking requirements  
9582 established by the Regulation that apply after the food is opened in a retail establishment.

9583

**Manufacturer's use-by dates**

9584 It is not the intent of this provision to give a product an extended shelf life beyond that intended by the  
9585 manufacturer. Manufacturers assign a date to products for various reasons, and spoilage may or may not  
9586 occur before pathogen growth renders the product unsafe. Most, but not all, sell-by or use-by dates are  
9587 voluntarily placed on food packages.

9588 Although most use-by and sell-by dates are not enforceable by regulators, the manufacturer's use-by date  
9589 is its recommendation for using the product while its quality is at its best. Although it is a guide for  
9590 quality, it could be based on food safety reasons. It is recommended that food establishments consider the  
9591 manufacturer's information as good guidance to follow to maintain the quality (taste, smell, and  
9592 appearance) and salability of the product. If the product becomes inferior quality-wise due to time in  
9593 storage, it is possible that safety concerns are not far behind.

9594 It is not the intention of this provision that either the manufacturer's date or the date marked by the food  
9595 establishment be placed on consumer packages.

**Juice**

9596

9597

9598 As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from  
9599 juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable  
9600 form in a hermetically sealed container. It is important to note that the definition of "juice" includes  
9601 puréed fruits and vegetables, which is commonly prepared for service to highly susceptible populations.  
9602 There are documented cases of foodborne illness throughout the United States that were associated with  
9603 the consumption of various juice products contaminated with microorganisms such as *Cryptosporidium*,  
9604 Shiga toxin-producing *Escherichia coli*, *Salmonella* spp., and *Vibrio cholera*. As new information  
9605 becomes available, the Regulation will be modified or interim interpretive guidance will be issued  
9606 regarding foodborne illness interventions for on-site juicing and puréeing.

9607

9608 The 21 CFR 120 regulation applies to products sold as juice or used as an ingredient in beverages. This  
9609 includes fruit and vegetable purees that are used in juices and beverages, but is not intended to include  
9610 freshly prepared fruit or vegetable purees that are prepared on-site in a facility for service to a highly  
9611 susceptible population.

9612

9613 In lieu of meeting the requirements of 21 CFR 120, juices that are produced as commercially sterile  
9614 products (canned juices) are acceptable for service to a highly susceptible population. Persons providing  
9615 pureed meals to highly susceptible populations may also wish to use fruit and vegetables that are  
9616 produced as commercially sterile products (canned fruit or vegetables) as a means of enhancing food  
9617 safety.

9618

**Eggs**

9619

9620

9621 *Salmonella* often survives traditional preparation techniques. It survives in a lightly cooked omelet,  
9622 French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of  
9623 ***Salmonella* Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs  
9624 remain a major source of these infections, causing large outbreaks when they are combined and  
9625 undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added  
9626 precautions need to be in place with those most susceptible to foodborne illness.

9627

9628 Operators of food establishments serving highly susceptible populations may wish to discuss buyer  
9629 specifications with their suppliers. Such specifications could stipulate eggs that are produced only by  
9630 flocks managed under a ***Salmonella* Enteritidis** control program that is recognized by a regulatory



9631 agency that has animal health jurisdiction. Such programs are designed to reduce the presence of  
9632 ~~*Salmonella Enteritidis*~~ in raw shell eggs. In any case, the food establishment operator must use adequate  
9633 time and temperature controls within the establishment to minimize the risk of a foodborne illness  
9634 outbreak relating to ~~*Salmonella Enteritidis*~~.

9635

### 9636 **Raw Seed Sprouts**

9637

9638 Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United  
9639 States. The FDA and CDC have issued health advisories that persons who are at a greater risk for  
9640 foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in  
9641 place to improve the safety of these products. For further information, see the FDA Talk Paper entitled,  
9642 "Interim Advisory on Alfalfa Sprouts" issued on August 31, 1998 and available on the FDA web site  
9643 ([www.fda.gov](http://www.fda.gov)). Since this issue continues to be under investigation, FDA recommends that interested  
9644 persons check the FDA web site periodically for more recent, updated information.

9645

### 9646 **3-8 — Consumer Advisory**

9647

### 9648 **3-801 — Consumption of Animal Foods That Are Raw, Undercooked, or Not Otherwise Processed** 9649 **to Eliminate Pathogens**

#### 9650 **Purpose:**

9651 At issue is the role of government agencies, the regulated industry, and others in providing notice to  
9652 consumers that animal derived foods that are not subjected to adequate heat treatment pose a risk because  
9653 they may contain biological agents that cause foodborne disease. The deliverance of a balanced message  
9654 that communicates fairly to all consumers and, where epidemiologically supported, attempts to place risk  
9655 in perspective based on the consumer's health status and the food being consumed is part of the challenge.  
9656 Notification of risk must be achieved via a meaningful message and in a manner that is likely to affect  
9657 behavior. The following information is to alert the reader to the options available to food establishments  
9658 in advising consumers of the increased possibility of foodborne illness when animal derived foods are  
9659 eaten raw or undercooked.

#### 9660 **Background:**

9661 Although no specific advisory language was recommended, beginning with the 1993 Food Code, FDA  
9662 included a codified provision for a point of purchase consumer advisory:

9663 "FDA has requested comments and will consider the responses as well as other information that  
9664 is available related to the risks involved and methods of risk communication to determine what  
9665 action may be necessary by FDA to effectively inform consumers."

9666

9667

**9668 Consumer Focus Groups:**

9669 During 1996—1998, FDA conducted two different consumer focus group studies. Because the first set of  
9670 focus groups (conducted before the 1997 Food Code) were not receptive to the language recommended at  
9671 the 1996 Conference for Food Protection (CFP) meeting, that language was not included in the 1997 Food  
9672 Code. Before the 1998 CFP meeting, the Agency convened a second set of focus groups with a modified  
9673 approach. The latter set expressed similar thoughts as those in the earlier set and a pattern for consumer  
9674 acceptance and receptiveness to menu-based advisories emerged.

9675 It became apparent that there is a general appreciation for "**disclosure**" of what consumers view as  
9676 "hidden ingredients," for example, whether a particular menu item contains raw egg. In addition to  
9677 disclosure being viewed as helpful, consumers are accepting, if not appreciative, of a "**reminder**" that  
9678 consuming raw or undercooked animal-derived foods carries an increased risk of foodborne illness. In the  
9679 food establishment venue, consumers are less willing to accept a message that extends beyond a reminder  
9680 and becomes a lesson or an educational message.

**9681 Satisfactory Compliance:**

9682 FDA submitted to the 1998 CFP meeting an Issue that asked the Conference to discuss an approach that  
9683 incorporated the knowledge obtained from the consumer testing. It was the consensus of the CFP that  
9684 **satisfactory compliance with the Code's consumer advisory provision is fulfilled when both a**  
9685 **disclosure and reminder are provided**, as described in Section 3-801 of the Regulation. **Disclosure** is  
9686 achieved when there is clear identification of animal-derived foods that are sold or served raw or  
9687 undercooked, and of items that either contain or may contain (to allow for ingredient substitution) such  
9688 raw or undercooked ingredients. A third option for the consumer "reminder" was added later. The  
9689 **reminder** is a notice about the relationship between thorough cooking and food safety.

9690 Two options were endorsed for disclosure and two for the reminder. One of the reminder options is a  
9691 menu statement that advises consumers that food safety information about the disclosed items is available  
9692 upon request. Essential criteria for such written information are available from FDA through the Retail  
9693 Food Protection Team by writing to: FDA/CFSAN, 5100 Paint Branch Parkway, (HFS-320) College  
9694 Park, Maryland 20740. All brochures must meet these essential criteria. The other option is a short notice  
9695 alerting consumers to the increased risk of consuming the disclosed menu items.

9696 In response to concerns raised by the Interstate Shellfish Sanitation Conference (ISSC) in an October 8,  
9697 1998 letter to FDA, a third option has been added to allow for a statement that links an increased risk of  
9698 illness to consumption of raw or undercooked animal foods by persons with certain medical conditions.

9699 The information contained in both the disclosure and reminder should be publicly available and readable  
9700 so that consumers have benefit of the total message (disclosure and reminder) before making their order  
9701 selections.

9702 It is not possible to anticipate all conceivable situations. Therefore, there will always be need for  
9703 discussion between the food establishment and the Regulatory Authority as to the most effective way to  
9704 meet the objectives of satisfactory compliance.

**9705 Locating the Advisory:**

9706 Disclosure of raw or undercooked animal-derived foods or ingredients and reminders about the risk of  
9707 consuming such foods belong at the point where the food is selected by the consumer. Both the disclosure  
9708 and the reminder need to accompany the information from which the consumer makes a selection. That

9709 information could appear in many forms such as a menu, a placarded listing of available choices, or a  
9710 table tent.

9711 **Educational Messages:**

9712 Educational messages are usually longer, more didactic in nature, and targeted to consumers who have  
9713 been alerted to the food safety concern and take the initiative to obtain more detailed information. It is  
9714 expected that, in most cases, educational messages that are provided pursuant to Section 3-801 (i.e., in  
9715 situations where the option for referring the consumer to additional information is chosen), will be  
9716 embodied in brochures that will not be read at the site where the immediate food choice is being made.  
9717 Nonetheless, such messages are viewed as an important facet of arming consumers with the information  
9718 needed to make informed decisions and, because the information is being requested by the consumer, it  
9719 would be expected to play a role in subsequent choices.

9720 **Applicability:**

9721 **FOOD ESTABLISHMENTS:**

9722 The consumer advisory is intended to apply to all food establishments where raw or undercooked animal  
9723 foods or ingredients are sold or served for human consumption in a raw or undercooked form. This  
9724 includes ~~all types of food establishments whenever there is a reasonable likelihood that the food will be~~  
9725 ~~consumed without subsequent, thorough cooking~~ such as restaurants, raw bars, quick service operations,  
9726 carry-outs, and sites where groceries are obtained that have operations such as delicatessens or seafood  
9727 departments.

9728 ~~"... OTHERWISE PROCESSED TO ELIMINATE PATHOGENS...":~~

9729 This phrase is included in Section 3-801 to encompass new technologies and pathogen control/reduction  
9730 regimens ~~as they are developed and validated~~ as fulfilling a specific performance standard for pathogens  
9731 of concern. Pasteurization of milk is an example of a long-standing validated process. For purposes of the  
9732 Regulation, the level of pathogen reduction that is required before a raw or undercooked animal food is  
9733 allowed to be offered without a consumer advisory must be equivalent to the levels provided by Section  
9734 3-502 for the type of food being prepared.

9735 The absorbed dose levels of radiation approved by FDA on December 3, 1997 for red meat are  
9736 insufficient to reduce the level of most vegetative pathogens to a point that is equivalent to the reductions  
9737 achieved in Section 3-502. Irradiated poultry provides a 3D kill which does not provide the level of  
9738 protection of the 7D kill that results from the cooking regimen in the Regulation. Therefore, irradiated  
9739 meat and poultry are not allowed to be offered in a ready-to-eat form without a consumer advisory. It is  
9740 intended that future Regulation revisions will address time/temperature requirements that take into  
9741 consideration the pathogen reduction that occurs with irradiated foods.

9742 **RECOGNITION OF OTHER PROCESSES:**

9743 Animal derived foods may undergo validated processes that target a specific pathogen. In such instances,  
9744 along with the required consumer advisory may appear additional language that accurately describes the  
9745 process and what it achieves. For example, a technology for reducing **VIBRIO VULNIFICUS** in oysters  
9746 to nondetectable levels has been validated. FDA concurs that shellfish subjected to that process can be  
9747 labeled with a truthful claim that appropriately describes the product. That is, a statement could be made  
9748 such as, "pasteurized to reduce **VIBRIO VULNIFICUS**" or "temperature treated to reduce **VIBRIO**  
9749 **VULNIFICUS**." Such a claim must be in accordance with labeling laws and regulations, accurate, and  
9750 not misleading. The claim would not, however, negate the need for a consumer advisory because the  
9751 treatment only reduces the level of one pathogenic organism.

9752 **PRODUCT SPECIFIC ADVISORIES:**

9753 Consumer advisories may be tailored to be product specific if a food establishment either has a limited  
9754 menu or offers only certain animal derived foods in a raw or undercooked ready to eat form. For  
9755 example, a raw bar serving molluscan shellfish on the half shell, but no other raw or undercooked animal  
9756 food, could elect to confine its consumer advisory to shellfish. The raw bar could also choose reminder,  
9757 option #3, which would highlight the increased risk incurred when persons with certain medical  
9758 conditions ingest shellfish that has not been adequately heat treated.

9759 **MILK:**

9760 In addition, "milk" is not mentioned in the actual on-site advisory language. The sale or transportation of  
9761 final packaged form of unpasteurized milk into interstate commerce is specifically prohibited by 21 CFR  
9762 1240.61. Also the consumption of raw milk is not recommended by FDA (this statement is in the form of  
9763 an official [FDA position statement](#)<sup>42</sup>). Nonetheless, approximately 25 states allow unpasteurized milk in  
9764 intrastate commerce which usually involves direct dairy farm to consumer procurement.

9765 **MOLLUSCAN SHELLSTOCK:**

9766 In addition to areas of retail food stores such as delis in supermarkets, the consumer advisory is to be  
9767 provided when a seafood department or seafood market offers raw molluscan shellstock for sale or  
9768 service. There is a risk of death from **VIBRIO** infections from consuming raw molluscan shellstock for  
9769 persons who have certain medical conditions.

**Chapter 4 – Warewashing, Equipment, Utensils, and Linens**

9770

9771 **4-1 — Materials For Construction and Repair**

9772

9773 **4-101 — General**

9774

9775 Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has  
9776 been stipulated that: "For food equipment programs, standards that establish sanitation requirements shall  
9777 be specified government standards or standards that have been ratified by a public health approval step.  
9778 ANSI shall verify that this requirement has been met by communicating with appropriate standards  
9779 developing organizations and governmental public health bodies."

9780

9781 The term "certified" is used when an item of food equipment has been evaluated against an organization's  
9782 own standard. The term classified is used when one organization evaluates an item of food equipment  
9783 against a standard developed by another organization.

9784

9785 Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended  
9786 period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared  
9787 which could lead to foodborne illness. In addition, some materials can affect the taste of the food being  
9788 prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used  
9789 could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit  
9790 adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes  
9791 contaminated.

9792

9793 Equipment and utensils must be designed and constructed to be durable and capable of retaining their  
9794 original characteristics so that such items can continue to fulfill their intended purpose for the duration of

9795 their life expectancy and to maintain their easy cleanability. If they cannot maintain their original  
9796 characteristics, they may become difficult to clean, allowing for the harborage of pathogenic  
9797 microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that  
9798 parts do not break and end up in food as foreign objects or present injury hazards to consumers. A  
9799 common example of presenting an injury hazard is the tendency for tines of poorly designed single  
9800 service forks to break during use.

9801  
9802 Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to  
9803 operate as designed. Failure to properly maintain equipment could lead to violations of the associated  
9804 requirements of the Regulation that place the health of the consumer at risk. For example, refrigeration  
9805 units in disrepair may no longer be capable of properly cooling or holding potentially hazardous foods at  
9806 safe temperatures.

9807  
9808 The safety and quality of food can be adversely affected through single service and single use articles that  
9809 are not constructed of acceptable materials. The migration of components of those materials to food they  
9810 contact could result in chemical contamination and illness to the consumer. In addition, the use of  
9811 unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors  
9812 transferred to the food.

## 9813 9814 **4-102—Equipment Requirements**

### 9815 9816 **4-2—Design and Construction**

#### 9817 9818 **4-201—Food Contact Surfaces**

9819  
9820 The purpose of the requirements for multiuse food contact surfaces is to ensure that such surfaces are  
9821 capable of being easily cleaned and accessible for cleaning. Food contact surfaces that do not meet these  
9822 requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have  
9823 imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once  
9824 established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and  
9825 sanitizing efforts. *The requirement for easy disassembly recognizes the reluctance of food employees to*  
9826 *disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.*

9827  
9828 Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of  
9829 pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms  
9830 from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

9831  
9832 Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced  
9833 because they can no longer be adequately cleaned and sanitized. Can openers must be designed to  
9834 facilitate replacement. The cutting or piercing parts of can openers may accumulate metal fragments that  
9835 could lead to food containing foreign objects and, possibly, result in consumer injury.

9836  
9837 Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to  
9838 clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or  
9839 accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

#### 9840 9841 **4-202—Use Limitations**

9842  
9843 Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended  
9844 period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared

9845 which could lead to foodborne illness. In addition, some materials can affect the taste of the food being  
9846 prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used  
9847 could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit  
9848 adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes  
9849 contaminated.

9850  
9851 Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of  
9852 pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms  
9853 from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

9854  
9855 Equipment and utensils constructed of cast iron meet the requirement of durability as intended in Sections  
9856 4-101 and 4-201. However, the surface characteristics of cast iron tend to be somewhat porous which  
9857 renders the material difficult to clean. On the other hand, when cast iron use is limited to cooking surfaces  
9858 the residues in the porous surface are not of significant concern as heat destroys potential pathogens that  
9859 may be present.

9860 **Lead**—

9861

9862 Historically, lead has been used in the formulation and/or decoration of these types of utensils.  
9863 Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused  
9864 high concentrations of lead to leach into the food they contain.

9865

9866 Lead poisoning continues to be an important public health concern due to the seriousness of associated  
9867 medical problems. Lead poisoning is particularly harmful to the young and has caused learning  
9868 disabilities and medical problems among individuals who have consumed high levels. The allowable  
9869 levels of lead are specific to the type of utensil, based on the average contact time and properties of the  
9870 foods routinely stored in each item listed.

9871

9872 FDA has established maximum levels (see FDA Compliance Policy Guide Section 545.450 Pottery  
9873 (Ceramics); Imported and Domestic—Lead Contamination (CPG 7117.07) for leachable lead in  
9874 ceramieware, and pieces that exceed these levels are subject to recall or other agency enforcement action.  
9875 The levels are based on how frequently a piece of ceramieware is used, the type and temperature of the  
9876 food it holds, and how long the food stays in contact with the piece. For example, cups, mugs and pitchers  
9877 have the most stringent action level, 0.5 parts per million, because they can be expected to hold food  
9878 longer, allowing more time for lead to leach. Also, a pitcher may be used to hold fruit juice. And a coffee  
9879 mug is generally used every day to hold a hot acidic beverage, often several times a day.

9880

9881 The FDA allows use of lead glazes because they're the most durable, but regulates them tightly to ensure  
9882 their safety. Commercial manufacturers employ extremely strict and effective manufacturing controls that  
9883 keep the lead from leaching during use. Small potters often can't control the firing of lead glazes as well  
9884 so their ceramics are more likely to leach illegal lead levels, although many do use lead-free glazes.

9885

9886 In 21 CFR 109.16, FDA requires high lead leaching decorative ceramicware to be permanently labeled  
9887 that it's not for food use and may poison food. Such items bought outside the United States may not be so  
9888 labeled, potentially posing serious risk if used for food.

9889

9890 Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals.  
9891 Solder may be composed of tin and lead alloys. Lead has been linked to many health problems especially  
9892 among the young. Consequently, the amount of lead allowed in food equipment is subject to limitation.

9893

9894 **Copper**

9895

9896 High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper  
9897 alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released  
9898 into a water supply because of an ineffective or nonexistent backflow prevention device between a  
9899 carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide  
9900 leaches copper from the plumbing components and the leachate is then transferred to beverages, causing  
9901 copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and  
9902 have resulted in, the leaching of both copper and lead into carbonated beverages.

9903  
9904 Brass is an alloy of copper and zinc and contains lead, which is used to combine the two elements.  
9905 Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are  
9906 subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.  
9907

9908 Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast  
9909 during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal  
9910 to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of  
9911 copper poisoning in humans. Therefore, the levels of copper necessary for successful beer fermentation  
9912 (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.  
9913

9914 Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel lined copper  
9915 equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer  
9916 following the hot brewing steps in the beer making process. Some also use pitch coated oak vats or glass-  
9917 lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is  
9918 common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for  
9919 successful fermentation.  
9920

9921 The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage  
9922 from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in  
9923 order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as  
9924 low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to 2½ hours or more. After  
9925 boiling, the wort is cooled, inoculated with brewer's yeast, and fermented. The use of copper equipment  
9926 during the prefermentation and fermentation steps typically result in some leaching of copper.  
9927

### 9928 **Galvanized Containers**

9929  
9930 Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized  
9931 containers into foods that are high in water content. The risk of leaching increases with increased acidity  
9932 of foods contacting the galvanized container.  
9933  
9934

9935

**9936 Pewter**

9937

9938 Pewter refers to a number of silver gray alloys of tin containing various amounts of antimony, copper,  
9939 and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized  
9940 metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of  
9941 acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

9942

**9943 Wood**

9944

9945 The limited acceptance of the use of wood as a food contact surface is determined by the nature of the  
9946 food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface  
9947 may become difficult to clean. In addition, wood that is treated with preservatives may result in illness  
9948 due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are  
9949 allowed.

9950

**9951 Nonstick Surfaces**

9952

9953 Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware  
9954 a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of  
9955 this material as safe for food contact surfaces. The Agency has determined that neither the particles that  
9956 may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this  
9957 nonstick finish may be scratched by sharp or rough edged kitchen tools, the manufacturer's  
9958 recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or  
9959 cleaners avoided.

9960

**9961 Linens**

9962

9963 Because of their absorbency, linens and napkins used as liners that contact food must be replaced  
9964 whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to  
9965 become fomites.

9966

**9967 4-203—Nonfood-Contact Surfaces**

9968

9969 Nonfood contact surfaces of equipment routinely exposed to splash or food debris are required to be  
9970 constructed of nonabsorbent materials to facilitate cleaning. Equipment that is easily cleaned minimizes  
9971 the presence of pathogenic organisms, moisture, and debris and deters the attraction of rodents and  
9972 insects.

9973

9974 Hard to clean areas could result in the attraction and harborage of insects and rodents and allow the  
9975 growth of foodborne pathogenic microorganisms. Well designed equipment enhances the ability to keep  
9976 nonfood contact surfaces clean.

9977

**9978 4-204—Clean In Place (CIP) Equipment**

9979

9980 Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to  
9981 disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be  
9982 monitored via access points to ensure that cleaning has been effective throughout the system.

9983



9984 The CIP design must ensure that all food contact surfaces of the equipment are contacted by the  
9985 circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas that are not contacted by  
9986 the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic  
9987 microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the  
9988 system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-  
9989 draining.

9990

#### 9991 **4-205 —“V” Threads, Use Limitation**

9992

9993 V-type threads present a surface, which is difficult to clean routinely; therefore, they are not allowed on  
9994 food contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on  
9995 the high temperatures that are used in this equipment. The high temperature in effect sterilizes the  
9996 equipment, including debris in the "V" threads.

9997

#### 9998 **4-206 —Hot Oil Filtering Equipment**

9999

10000 The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible  
10001 for replacement. Filtering the oil reduces the likelihood that off odors, tastes, and possibly toxic  
10002 compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is  
10003 necessary for the filter to be accessible for replacement.

10004

#### 10005 **4-207 —Bearings and Gear Boxes, Leakproof**

10006

10007 It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation  
10008 of these types of equipment could contaminate food or food contact surfaces if the equipment is not  
10009 properly designed and constructed.

10010

10011 Food contact surfaces must be lubricated in a manner that does not introduce contaminants to those  
10012 surfaces. Equipment must be reassembled in a way that food contact surfaces are not contaminated.

10013

10014 Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants  
10015 used must be approved as food additives or generally recognized as safe. Lubricants that are not safe  
10016 present the possibility of foodborne illness if they find their way into the food.

10017

#### 10018 **4-208 —Beverage Tubing, Separation**

10019

10020 Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct  
10021 contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and  
10022 drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

10023

10024 The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may  
10025 be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment,  
10026 mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

10027

#### 10028 **4-209 —Ice Units, Separation of Drains**

10029

10030 Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination  
10031 due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice  
10032 through condensate migrating along the exterior of the lines.

10033

10034 Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that  
10035 are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for  
10036 mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae  
10037 that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in  
10038 the bin.

#### 10039 **4-210—Condenser Unit, Separation**

10040 A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-  
10041 contact areas from contamination by dust that is accumulated and blown about as a result of the  
10042 condenser's operation.

#### 10043 **4-211—Molluscan Shellfish Tanks**

10044 Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in  
10045 the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow  
10046 concentration of pathogenic viruses and bacteria.

10047 Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of  
10048 pathogenic microorganisms in shellfish held in display tanks is of concern. If shellfish stored in  
10049 molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in  
10050 a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination  
10051 must be controlled or eliminated. Procedures must emphasize strict monitoring of the water quality of the  
10052 tank including the filtering and disinfection system.

#### 10053 **4-212—Ventilation and Ventilation Hood Systems**

10054 If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings  
10055 of the food establishment, causing an unsanitary condition and possible deterioration of the surfaces of  
10056 walls and ceilings. The accumulation of grease and condensate may contaminate food and food contact  
10057 surfaces as well as present a possible fire hazard.

10058 The dripping of grease or condensation onto food constitutes adulteration and may involve contamination  
10059 of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use  
10060 articles that are subjected to such drizzle are no longer clean.

10061 When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls,  
10062 ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and  
10063 no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

10064 Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

#### 10065 **4-3—Location and Installation**

##### 10066 **4-301—Equipment, and Storage Cabinets, Contamination Prevention**

10067 Food equipment and the food that contacts the equipment must be protected from sources of overhead  
10068 contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects.  
10069 When equipment is installed, it must be situated with consideration of the potential for contamination  
10070 from such overhead sources.

10071

10085 ~~Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and~~  
10086 ~~single service and single use articles can become contaminated before their intended use in a variety of~~  
10087 ~~ways such as through water leakage, pest infestation, or other unsanitary condition.~~

10088  
10089 ~~The improper storage of clean and sanitized equipment, utensils, laundered linens, and single service and~~  
10090 ~~single use articles may allow contamination before their intended use. Contamination can be caused by~~  
10091 ~~moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic~~  
10092 ~~materials, litter, dust, and other materials. The contamination is often related to unhygienic employee~~  
10093 ~~practices, unacceptable high risk storage locations, or improper construction of storage facilities.~~

10094  
10095 **4-302—Fixed Equipment, Spacing or Sealing**

10096  
10097 This section is designed to ensure that fixed equipment is installed in a way that:

- 10098  
10099 1. ~~Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes~~  
10100 ~~the need for cleaning due to closely abutted surfaces;~~  
10101 2. ~~Ensures that equipment that is subject to moisture is sealed;~~  
10102 3. ~~Prevents the harborage of insects and rodents; and~~  
10103 4. ~~Provides accessibility for the monitoring of pests.~~

10104  
10105 ~~The inability to adequately or effectively clean areas under equipment could create a situation that may~~  
10106 ~~attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through~~  
10107 ~~food.~~

10108  
10109 ~~The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed~~  
10110 ~~equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or~~  
10111 ~~prohibitively expensive, sealing to prevent contamination is required.~~

10112  
10113 ~~The economic impact of the requirement to elevate display units in retail food stores, coupled with the~~  
10114 ~~fact that the design, weight, and size of such units are not conducive to casters or legs, led to the~~  
10115 ~~exception for certain units located in consumer shopping areas, provided the floor under the units is kept~~  
10116 ~~clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer~~  
10117 ~~units in the consumer shopping areas requires a rigorous cleaning schedule.~~

10118  
10119 ~~This requirement is intended to protect both the machine dispensed, unpackaged, liquid foods and the~~  
10120 ~~machine components from contamination. Barriers need to be provided so that the only liquid entering the~~  
10121 ~~food container is the liquid intended to be dispensed when the machine's mechanism is activated.~~

10122 ~~Recessing of the machine's components and self closing doors prevent contamination of machine ports by~~  
10123 ~~people, dust, insects, or rodents. If the equipment components become contaminated, the product itself~~  
10124 ~~will be exposed to possible contamination.~~

10125 ~~A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the~~  
10126 ~~food.~~

10127  
10128 ~~The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation~~  
10129 ~~does not meet Regulation requirements, debris could accumulate and create a situation that may attract~~  
10130 ~~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  $3^{\circ}\text{F}$  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  $3^{\circ}\text{F}$  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  $20^{\circ}\text{C}$  ( $68^{\circ}\text{F}$ ). 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

10184 ~~monitoring system that uses probe-like sensors that are placed in material resembling the density of food~~  
10185 ~~is an acceptable alternative. Thus, the direct temperature of the substitute product is measured by use of~~  
10186 ~~this product mimicking method.~~

10187  
10188 ~~A permanent temperature measuring device is required in any unit storing potentially hazardous food~~  
10189 ~~because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed~~  
10190 ~~Regulation requirements. In order to facilitate routine monitoring of the unit, the device must be clearly~~  
10191 ~~visible.~~

10192  
10193 ~~The exception to requiring a temperature measuring device for the types of equipment listed is primarily~~  
10194 ~~due to equipment design and function. It would be difficult and impractical to permanently mount a~~  
10195 ~~temperature measuring device on the equipment listed. The futility of attempting to measure the~~  
10196 ~~temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the~~  
10197 ~~equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point.~~  
10198 ~~In such cases, it would be more practical and accurate to measure the internal temperature of the food.~~

10199  
10200 ~~The importance of maintaining potentially hazardous foods at the specified temperatures requires that~~  
10201 ~~temperature measuring devices be easily readable. The inability to accurately read a thermometer could~~  
10202 ~~result in food being held at unsafe temperatures.~~

10203  
10204 ~~The required incremental gradations are more precise for food measuring devices than for those used to~~  
10205 ~~measure ambient temperature because of the significance at a given point in time, i.e., the potential for~~  
10206 ~~pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the~~  
10207 ~~ambient temperature of the storage unit; it will depend on many variables including the temperature of the~~  
10208 ~~food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time~~  
10209 ~~the food is stored in the unit.~~

10210  
10211 ~~A utensil or food temperature measuring device can act as a source of contamination to the food it~~  
10212 ~~contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not~~  
10213 ~~maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature~~  
10214 ~~problem may not be detected, or conversely, a corrective action may be needlessly taken.~~

#### 10215 10216 **4-402—Testing Devices**

10217  
10218 ~~Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:~~

- 10219  
10220 ~~1.—The use of chemical sanitizers requires minimum concentrations of the sanitizer~~  
10221 ~~during the final rinse step to ensure sanitization; and~~  
10222 ~~2.—Too much sanitizer in the final rinse water could be toxic.~~

10223  
10224 ~~The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the~~  
10225 ~~sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the~~  
10226 ~~chemical sanitizer solution.~~

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

##### **Manual**

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

The 3-compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used. Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

- 1.—Application of cleaners and the removal of soil;
- 2.—Removal of any abrasive and removal or dilution of cleaning chemicals; and
- 3.—Sanitization.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

Hot water sanitization is accomplished in water of not less than 77°C (170°F) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

The draining requirement in equipment components is needed to prevent the pooling of water. Pooled water whether from drainage, condensate, drippage, or melting ice could contain or provide a favorable environment for pathogens and other contaminants.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization. If the temperature during the hot water sanitizing step is less than 77°C (171°F), sanitization will not be achieved. As a result, pathogenic organisms may survive and be subsequently transferred from utensils to food.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 21 CFR 178.1010 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Regulation.

10279 ~~With respect to chemical sanitization, the Rules and Regulations addresses the proper make up of the~~  
10280 ~~sanitizing solution, i.e., chemical concentration, pH, and temperature at the required MINIMUM levels~~  
10281 ~~specified when considered together (and, with respect to quaternary ammonia sanitizers, the MAXIMUM~~  
10282 ~~hardness level). If these minimums (maximum hardness) are not as specified, then this provision is~~  
10283 ~~violated.~~  
10284  
10285 ~~If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing~~  
10286 ~~and thawing foods, contamination of equipment and utensils could occur.~~  
10287  
10288 ~~Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create~~  
10289 ~~safety concerns for the employee and consumer. For example, employees could suffer chemical burns,~~  
10290 ~~and chemical residues could find their way into food if detergents or cleaners are used carelessly.~~  
10291  
10292 ~~Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or~~  
10293 ~~detergents are used.~~  
10294  
10295 ~~Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing~~  
10296 ~~operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.~~  
10297  
10298 ~~The wash solution temperature required in the Regulation is essential for removing organic matter. If the~~  
10299 ~~temperature is below 43°C (110°F), the performance of the detergent may be adversely affected, e.g.,~~  
10300 ~~animal fats that may be present on the dirty dishes would not be dissolved.~~  
10301  
10302 ~~Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-~~  
10303 ~~contact surfaces are sanitized before coming in contact with food and before use.~~  
10304  
10305 ~~Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used.~~  
10306 ~~When using a sanitizer that is different from the detergent sanitizer of the wash compartment, the~~  
10307 ~~sanitizer may be inhibited by carry over, resulting in inadequate sanitization.~~  
10308  
10309 ~~It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or~~  
10310 ~~inactivating the sanitizer.~~  
10311  
10312 ~~Some pieces of equipment are too large (or fixed) to be cleaned in a sink. Nonetheless, cleaning of such~~  
10313 ~~equipment requires the application of cleaners for the removal of soil and rinsing for the removal of~~  
10314 ~~abrasive and cleaning chemicals, followed by sanitization.~~  
10315  
10316 ~~Effective sanitization procedures destroy organisms of public health importance that may be present on~~  
10317 ~~wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse~~  
10318 ~~solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its~~  
10319 ~~maximum benefit.~~  
10320  
10321 ~~Efficacious sanitization is dependent upon warewashing being conducted within certain parameters. Time~~  
10322 ~~is a parameter applicable to both chemical and hot water sanitization. The time that hot water or~~  
10323 ~~chemicals contact utensils or food contact surfaces must be sufficient to destroy pathogens that may~~  
10324 ~~remain on surfaces after cleaning. Other parameters, such as temperature or chemical concentration, are~~  
10325 ~~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



10379 sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-  
10380 pressure. A pressure below the design pressure results in inadequate spray patterns and incomplete  
10381 coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water  
10382 droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

10383  
10384 The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The  
10385 chemicals used may not adequately perform their function if the temperature is too low. Therefore, the  
10386 manufacturer's instructions must be followed. The temperatures vary according to the specific equipment  
10387 being used.

10388  
10389 The temperature of the hot water delivered to the warewashing machine manifold must be maintained  
10390 according to the equipment manufacturer's specification to ensure that the surfaces of utensils or  
10391 tableware accumulate and build up enough heat to destroy pathogens that may be present on such  
10392 surfaces. The surface temperature should reach at least 71°C (160°F) as measured by an irreversible  
10393 registering temperature indicator to affect sanitization.

10394  
10395 If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing  
10396 solution may be inadequate to reach all surfaces of equipment or utensils.

10397  
10398 Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure  
10399 adequate cleaning. Items, which are stacked, or trays, which are heavily loaded with silverware, cannot  
10400 receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

10401  
10402 Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to  
10403 facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned,  
10404 detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be  
10405 presoaked or scrubbed with an abrasive.

10406  
10407 Items must be allowed to drain and to air dry before being stacked or stored. Stacking wet items such as  
10408 pans prevents them from drying and may allow an environment where microorganisms can begin to grow.  
10409 Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to  
10410 equipment or utensils.

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10412 **4-405—Drainboard and Dishtable Requirements**

10413  
10414 **4-406—Drying**

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10416 **4-407—Food-Contact Surfaces of Equipment and Utensils**

10417  
10418 The purpose of the requirements for multiuse food contact surfaces is to ensure that such surfaces are  
10419 capable of being easily cleaned and accessible for cleaning. Food contact surfaces that do not meet these  
10420 requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces, which have  
10421 imperfections such as cracks, chips, or pits, allow microorganisms to attach and form biofilms. Once  
10422 established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and  
10423 sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to  
10424 disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

10425  
10426 The objective of cleaning focuses on the need to remove organic matter from food contact surfaces so that  
10427 sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic  
10428 microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

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10430 Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers,  
10431 or other food contact surfaces. Food contact surfaces and equipment used for potentially hazardous foods  
10432 should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent  
10433 the growth of microorganisms on those surfaces.

10434  
10435 Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary  
10436 to clean every four hours. However, the time period between cleaning equipment and utensils may not  
10437 exceed 24 hours. A time-temperature chart is provided in Section 4-405 to accommodate operations that  
10438 use equipment and utensils in a refrigerated room or area that maintains a temperature between 5°C  
10439 (41°F) or less and 13°C (55°F).

10440  
10441 Surfaces of utensils and equipment contacting food that is not potentially hazardous such as iced tea  
10442 dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending  
10443 equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent  
10444 the development of slime, mold, or soil residues that may contribute to an accumulation of  
10445 microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry,  
10446 develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide  
10447 cleaning specifications for food contact surfaces of equipment that are not readily visible, the person in  
10448 charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular  
10449 items of equipment.

10450  
10451 Regarding the possible adulteration from one species of meat to another between cleaning of food contact  
10452 surfaces, USDA/FSIS does not automatically consider species adulteration as a health hazard. FSIS stated  
10453 in an Advance Notice of Proposed Rulemaking that species adulteration falls into a gray area between  
10454 safety and economic adulteration (65 FR 14486, March 17, 2000). FSIS will review public comments  
10455 received on the species adulteration issue and further review the scientific literature and risk assessment  
10456 mechanisms before declaring species adulteration a health hazard. Meanwhile, species adulteration is  
10457 generally considered by FSIS as an economic issue. However, investigations by FSIS of species  
10458 adulteration incidents may include a determination regarding the impact of species adulteration as a health  
10459 hazard on a case-by-case basis.

10460  
10461 Food contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede  
10462 heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect  
10463 attractant when not in use.

#### 10464 10465 **4-408—Nonfood-Contact Surfaces**

10466  
10467 The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for  
10468 the growth of microorganisms, which employees may inadvertently transfer to food. If these areas are not  
10469 kept clean, they may also provide harborage for insects, rodents, and other pests.

#### 10470 10471 **4-409—Dry Equipment Cleaning Methods**

10472  
10473 Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not  
10474 potentially hazardous. Under some circumstances, attempts at wet cleaning may create microbiological  
10475 concerns.

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~~4-5 — Laundry Facilities~~

~~4-501 — Laundry Facilities~~

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~~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.~~

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~~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.~~

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~~Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.~~

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~~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.~~

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~~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.~~

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~~Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.~~

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~~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.~~

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~~4-6 — Equipment and Utensil Handling and Storage~~

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

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~~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.~~

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~~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.~~

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**4-602—Single-Service and Single-Use Articles**

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In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-

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service and single-use articles must be used to ensure safety.

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.

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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.

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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.

**4-603—Preset Tableware**

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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.

**Chapter 5—Water, Plumbing, and Waste**

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**5-1—Water Supply****5-101—General**

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.

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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.

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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

10572 to ensure the safety of drinking water used in the establishment. The most recent water sampling report  
10573 must be kept on file to document a safe water supply.

10574  
10575 Availability of sufficient water is a basic requirement for proper sanitation within a food establishment.  
10576 An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and  
10577 utensils and of food employees' hands.

10578  
10579 Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This  
10580 requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be  
10581 safe, through a distribution system, which is protected.

#### 10582 **5-102—System Flushing and Disinfection**

10584  
10585 During construction, repair, or modification, water systems may become contaminated with microbes  
10586 from soil because pipes are installed underground or by chemicals resulting from soldering and welding.  
10587 Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as  
10588 oils may also be present on or in the components of the system. To render the water safe, the system must  
10589 be properly flushed and disinfected before being placed into service.

10590  
10591 Contaminants of various types may be introduced into a water system during construction or repair or  
10592 other incidents. The system must be flushed and sanitized after maintenance and before it is placed into  
10593 service to prevent contamination of the water introduced into the tank.

#### 10594 **5-103—Bottled Drinking Water**

10596  
10597 Bottled water is obtained from a public water system or from a private source such as a spring or well.  
10598 Either means of production must be controlled by public health law to protect the consumer from  
10599 contaminated water.

#### 10600 **5-104—Transportation**

10602  
10603 Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed  
10604 and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport  
10605 vehicles and containers, may result in contamination of safe water and render it hazardous to human  
10606 health.

#### 10607 **5-105—Emergency Alternative Water Supply**

10608  
10609 Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed  
10610 and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport  
10611 vehicles and containers, may result in contamination of safe water and render it hazardous to human  
10612 health.

#### 10613 **5-106—Non-Drinking Water**

10614  
10615 Food establishments may use non-drinking water for purposes such as air conditioning or fire protection.  
10616 Non-drinking water is not monitored for bacteriological or chemical quality or safety as is drinking water.  
10617 Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking  
10618 water, or food-contact surfaces. Identifying the piping designated as non-drinking waterlines and  
10619 inspection for cross connections are examples of safety precautions.

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### **5-107—Pressure and Temperature**

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

10725 inspection and maintenance schedules for these devices, must be strictly followed to prevent failure  
10726 during operation.

10727  
10728 Improper plumbing installation or maintenance may result in potential health hazards such as cross  
10729 connections, back siphonage or backflow. These conditions may result in the contamination of food,  
10730 utensils, equipment, or other food contact surfaces. It may also adversely affect the operation of  
10731 equipment such as warewashing machines.

### 10732 10733 **5-203—Conditioning Device, Design**

10734  
10735 Water conditioning devices must be designed for easy disassembly for servicing so that they can be  
10736 maintained in a condition that allows them to perform the function for which they were designed.

10737  
10738 When not located for easy maintenance, conditioning devices will be inconvenient to access and devices  
10739 such as filters, screens, and water softeners will become clogged because they are not properly serviced.

### 10740 10741 **5-204—Grease Trap / Grease Interceptor**

10742  
10743 Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the  
10744 harborage of vermin and/or the failure of the sewage system.

### 10745 10746 **5-205—Food Waste Grinders/Garbage Disposals**

### 10747 10748 **5-206—Drainage of Equipment**

### 10749 10750 **5-207—Drainage System Installation**

10751  
10752 The drainage system must be designed and installed properly to prevent the backup of sewage and the  
10753 possible contamination of foods or food contact surfaces in the establishment.

### 10754 10755 **5-208—Handwashing, Lavatory, Water Temperature, and Flow**

10756  
10757 Because handwashing is such an important factor in the prevention of foodborne illness, sufficient  
10758 facilities must be available to make handwashing not only possible, but likely.

10759  
10760 Hands are probably the most common vehicle for the transmission of pathogens to foods in an  
10761 establishment. Hands can become soiled with a variety of contaminants during routine operations. Some  
10762 employees are unlikely to wash their hands unless properly equipped handwashing facilities are  
10763 accessible in the immediate work area. Facilities, which are improperly located, may be blocked by  
10764 portable equipment or stacked full of soiled utensils and other items, rendering the facility unavailable for  
10765 regular employee use. Nothing must block the approach to a handwashing facility thereby discouraging  
10766 its use, and the facility must be kept clean and well stocked with soap and sanitary towels to encourage  
10767 frequent use.

10768  
10769 Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An  
10770 adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands.  
10771 ASTM Standards for testing the efficacy of handwashing formulations specify a water temperature of  
10772  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$  (100 to 107°F).

10773  
10774 An inadequate flow or temperature of water may lead to poor handwashing practices by food employees.  
10775 A mixing valve or combination faucet is needed to provide properly tempered water for handwashing.



10776 ~~Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding~~  
10777 ~~is a possible hazard.~~

10778  
10779 ~~Facilities must be maintained in a condition that promotes handwashing and restricted for that use.~~

10780 ~~Convenient accessibility of a handwashing facility encourages timely handwashing, which provides a~~  
10781 ~~break in the chain of contamination from the hands of food employees to food or food contact surfaces.~~

10782 ~~Sinks used for food preparation and warewashing can become sources of contamination if used as~~  
10783 ~~handwashing facilities by employees returning from the toilet or from duties, which have contaminated~~  
10784 ~~their hands.~~

10785  
10786 ~~Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on~~  
10787 ~~hands.~~

10788  
10789 ~~Provisions must be provided for hand drying so that employees will not dry their hands on their clothing~~  
10790 ~~or other unclean materials.~~

10791  
10792 ~~Waste receptacles at handwashing lavatories are required for the collection of disposable towels so that~~  
10793 ~~the paper waste will be contained, will not contact food directly or indirectly, and will not become an~~  
10794 ~~attractant for insects or rodents.~~

10795  
10796 ~~Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of~~  
10797 ~~the food employee for proper and routine handwashing to prevent contamination of the food and food-~~  
10798 ~~contact surfaces.~~

10799  
10800 ~~Handwashing facilities must be maintained in operating order at all times so they will be used.~~

#### 10801 ~~5-209 Toilets and Urinals~~

10802  
10803  
10804 ~~Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries~~  
10805 ~~pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.~~

10806 ~~Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food~~  
10807 ~~contamination and to motivate employees to use sanitary practices in the establishment.~~

10808  
10809 ~~Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of~~  
10810 ~~flies and other insects between the toilet facility and food preparation areas.~~

10811  
10812 ~~To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use~~  
10813 ~~of toilet facilities. Toilet tissue must be supplied to meet the demand.~~

10814  
10815 ~~Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use~~  
10816 ~~of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.~~

#### 10817 ~~5-210 Utility Facility~~

10818  
10819  
10820 ~~Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Liquid wastes~~  
10821 ~~generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and~~  
10822 ~~food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks~~  
10823 ~~such as food preparation and handwashing sinks.~~

#### 10824 ~~5-211 Sewage~~

10825  
10826

10827 Many diseases can be transmitted from one person to another through fecal contamination of food and  
10828 water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal  
10829 contamination. This Regulation provision is intended to ensure that wastes will not contaminate ground  
10830 surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or  
10831 insects to serve as vectors of disease from this source.

10832  
10833 Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations  
10834 of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

#### 10835 10836 **5-212 — Water Reservoir of Fogging Devices, Cleaning**

10837  
10838 Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol  
10839 or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with  
10840 respiratory pathogens such as *Legionella pneumophila*. This organism is extremely infectious and can be  
10841 transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's  
10842 cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by  
10843 this bacterium.

#### 10844 10845 **5-3 — Refuse, Recyclables, and Returnables**

##### 10846 10847 **5-301 — Containers**

10848  
10849 Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors,  
10850 prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents,  
10851 and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates  
10852 nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of  
10853 food, equipment, and utensils.

10854  
10855 Outside receptacles must be constructed with tight fitting lids or covers to prevent the scattering of the  
10856 garbage or refuse by birds, the breeding of flies, or the entry of rodents.

10857  
10858 Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of  
10859 garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

##### 10860 10861 **5-302 — Storage**

10862  
10863 Garbage containers should be available wherever garbage is generated to aid in the proper disposal of  
10864 refuse.

10865  
10866 Storage areas for garbage, refuse, compost and recyclables containers must be constructed so that they  
10867 can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In  
10868 addition, such storage areas must be large enough to accommodate all the containers necessitated by the  
10869 operation in order to prevent scattering of the garbage and refuse.

10870  
10871 All containers must be maintained in good repair and cleaned as necessary in order to store garbage and  
10872 refuse under sanitary conditions as well as to prevent the breeding of flies. If refuse areas are not graded  
10873 properly, wastewater will pool and attract insects and rodents.

10874  
10875 Waste materials and empty product containers are unclean and can be an attractant to insects and rodents.  
10876 Food, equipment, utensils, linens, and single service and single use articles must be protected from  
10877 exposure to filth and unclean conditions and other contaminants. This Regulation provision addresses

10878 these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas,  
10879 and to preclude creation of a nuisance.

10880

### 10881 **5-303—Disposal**

10882

10883 Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of  
10884 the original contents. Spillage from these containers soils receptacles and storage areas and becomes an  
10885 attractant for insects, rodents, and other pests. The handling of these materials entails some of the same  
10886 problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these  
10887 materials are removed from the premises at a reasonable frequency.

10888

### 10889 **5-304—Storage Areas, Redeeming Machines, Equipment, and Receptacles, Location**

10890

10891 Alternative means of solid waste disposal must be conducted properly to prevent environmental  
10892 consequences and the attraction of insects, rodents, and other pests.

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## Chapter 6—Physical Facilities

10895

### 10896 **6-1—Floors**

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#### 10898 **6-101—Floor Construction**

10899

10900 Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Floor  
10901 surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of  
10902 foods from dust and organisms from pooled moisture. Grading of the floor to drain allows liquid wastes  
10903 to be quickly carried away, thereby preventing pooling which could attract pests such as insects and  
10904 rodents or contribute to problems with certain pathogens such as *Listeria monocytogenes*.

10905

10906 Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is  
10907 intended to ensure that the physical facilities are properly maintained in order to serve their intended  
10908 purpose.

10909

#### 10910 **6-102—Floor Carpeting**

10911

10912 The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture  
10913 are intended to ensure that the cleanability of these surfaces is retained.

10914

10915 Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective  
10916 cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for  
10917 carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or  
10918 waste is likely.

10919

#### 10920 **6-103—Utility Line Installation**

10921

10922 Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are  
10923 intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is  
10924 minimized.

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#### **6-104—Floor Junctures**

~~Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.~~

~~When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing.~~

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

~~Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.~~

~~Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.~~

#### **6-106—Mats and Duckboards**

~~Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.~~

### **6-2—Walls and Ceilings**

#### **6-201—Construction**

~~Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned.~~

~~Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.~~

~~Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.~~

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

~~Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.~~

~~Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or 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.

11025

11026 ~~6-5 — Premises~~

11027

11028 ~~6-501 — General~~

11029

11030 ~~The requirements concerning surface characteristics of outdoor areas are intended to facilitate~~  
11031 ~~maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide~~  
11032 ~~durable exterior building surfaces, and prevent the attracting, harboring, or breeding of insects, rodents,~~  
11033 ~~and other pests where refuse, recyclables, or returnables are stored.~~

11034

11035 ~~If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the~~  
11036 ~~establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and~~  
11037 ~~driving surfaces may also attract rodents and breed insects.~~

11038

11039 ~~The presence of unnecessary articles, including equipment, which is no longer used, makes regular and~~  
11040 ~~effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.~~  
11041 ~~Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary~~  
11042 ~~manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and~~  
11043 ~~insects.~~

11044

11045 ~~6-502 — Living Areas~~

11046

11047 ~~Areas or facilities that are not compatible with sanitary food establishment operations must be located~~  
11048 ~~and/or separated from other areas of the establishment to preclude potential contamination of food and~~  
11049 ~~food contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly~~  
11050 ~~designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.~~

11051

11052 ~~Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure~~  
11053 ~~in their homes against unreasonable search and seizure. This provision could hinder the regulatory~~  
11054 ~~authority's access to conduct routine inspections of a food establishment operated in the living area of a~~  
11055 ~~private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be~~  
11056 ~~difficult to obtain and might not authorize the necessary inspectional activities.~~

11057

11058 ~~6-503 — Dressing Rooms and Locker Areas~~

11059

11060 ~~Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because~~  
11061 ~~street clothing and personal belongings carry contaminants, areas designated to accommodate employees'~~  
11062 ~~personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-~~  
11063 ~~service and single-use articles must not be in jeopardy of contamination from these areas.~~

11064

11065

**Chapter 7 – Poisonous or Toxic Materials**

11066

**7-1 Labeling and Identification**

11068

**7-101 – Identifying Information, Prominence**

11070

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.

11074

**7-102 – Working Containers**

11076

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.

11082

**7-103 – Separation**

11084

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.

11089

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.

11093

**7-104 – Restriction**

11095

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.

11099

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.

11107

**7-105 – Use of Materials**

11109

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.

11112

11113  
11114 Particular precautions must be taken during the application of poisonous or toxic materials to prevent the  
11115 contamination of food and other food contact surfaces. Residues of certain materials are not discernible to  
11116 the naked eye and present an additional risk to the employee and consumer.

11117  
11118 Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used  
11119 in accordance with requirements listed in the Regulation of Federal Regulations (CFR). Large  
11120 concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the  
11121 materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered  
11122 safe.

11123  
11124 Whether or not the chemical agent being applied as a sanitizer is approved and listed for that use under 40  
11125 CFR 180.940, Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations  
11126 (food contact sanitizing solutions) or 40 CFR 180.2020, Non food determinations. Because there is no  
11127 EPA registration of solutions generated and used on site, the user of the equipment should look to the  
11128 equipment manufacturer for data to validate the efficacy of the solution that is generated by the device as  
11129 well as the conditions for use of the solution.

11130

#### 11131 **7-106—Food Containers**

11132

11133 Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of  
11134 the potential for contamination of the food. The risk of serious medical consequences to anyone  
11135 consuming food stored in these containers coupled with the lack of confidence that all of the material  
11136 could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

11137

#### 11138 **7-107—Chemicals for Washing Fruits and Vegetables, Criteria**

11139

11140 21 CFR Section 173.315 specifically identifies chemicals that may be used in washing fruits and  
11141 vegetables, regardless of whether the chemicals are commercially produced or generated on site. Sodium  
11142 hypochlorite is listed in 21 CFR 173.315 for use in washing fruits and vegetables at levels not exceeding  
11143 the minimum amount required to accomplish the intended technical effect. FDA has no objection to the  
11144 use of calcium hypochlorite in the place of sodium hypochlorite under 21 CFR 173.315.

#### 11145 **7-108—Boiler Water Additives, Criteria**

11146

11147 Boiler water additives that may be safely used in the preparation of steam that may contact food, and their  
11148 condition of use, are identified in 21 CFR 173.310 Boiler Water Additives.

#### 11149 **7-109—Drying Agents, Criteria**

11150

11151 If the sanitizer, chemical wash, boiler water additive, or drying agent used is not made up of components  
11152 that are approved as food additives or generally recognized as safe, illness may result. This could be due  
11153 to residues that may remain from the use of compounds such as unrecognized drying agents. This is why  
11154 only those chemicals that are listed in the CFR can be used.

11155

11156 Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive  
11157 Petition. Sanitizers, wash chemicals, and drying agents are classified as food additives because of the  
11158 possibility that they may end up in food. Therefore, they are subject to review before being used or listed  
11159 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.

11210

**8-103—Insect Control Devices, Design and Installation**

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11212  
11213 Insect electrocution devices are considered supplemental to good sanitation practices in meeting the  
11214 Regulation requirement for controlling the presence of flies and other insects in a food establishment.

11215

11216 Improper design of the device and dead insect collection tray could allow dead insect parts and injured  
11217 insects to escape, rendering the device itself a source of contamination.

11218

11219 Exposed food and food contact surfaces must be protected from contamination by insects or insect parts.

11220 Installation of the device over food preparation areas or in close proximity to exposed food and/or food-

11221 contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or

11222 be blown from the device onto food or food contact surfaces.

11223

**8-104—Pesticide Application**

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11225  
11226 Because of the toxicity of restricted use pesticides, they can only be applied by certified operators. A  
11227 certified operator would be aware of the dangers involved in the contamination of food and food contact  
11228 surfaces during the application of these materials. Improperly applied pesticides present health risks to  
11229 employees as well as consumers and special precautions must be taken when restricted use pesticides are  
11230 applied.

11231

11232 Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to  
11233 transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on  
11234 food contact surfaces and ultimately in the food being prepared or served.

11235

11236 The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the  
11237 establishment. Consequently, the powder could directly or indirectly contaminate food being prepared.

11238 This contamination could adversely affect both the safety and quality of the food and, therefore, tracking

11239 powder pesticides are not allowed.

11240

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

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11242  
11243 Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary  
11244 facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

11245

**8-106—Prohibiting of Animals**

11246

11247  
11248 Animals carry disease causing organisms and can transmit pathogens to humans through direct and/or

11249 indirect contamination of food and food contact surfaces. The restrictions apply to live animals with

11250 limited access allowed only in specific situations and under controlled conditions and to the storage of

11251 live and dead fish bait. Employees with service animals are required to wash their hands after each

11252 contact with animals to remove bacteria and soil.

11253

11254 Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and  
11255 more frequent and rigorous cleaning efforts.

11256

11257 The definition for "service animal" is adapted from 28 CFR 36.104 adopted pursuant to the Americans

11258 with Disabilities Act (ADA) of 2010 (42 U.S.C. 12101 et seq.). A service animal is dog or miniature

11259 horse that performs some of the functions that persons with a disability cannot perform for themselves,

11260 such as those provided by "seeing eye dogs"; alerting persons with hearing impairments to sounds;

11261 ~~pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and~~  
11262 ~~assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.~~

11263  
11264 ~~Under Title III of the ADA, privately owned businesses that serve the public are prohibited from~~  
11265 ~~discriminating against individuals with disabilities. The ADA requires these businesses to allow people~~  
11266 ~~with disabilities to bring their service animals onto business premises in whatever areas customers are~~  
11267 ~~generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all,~~  
11268 ~~are licensed or certified and have identification papers.~~

11269  
11270 ~~Decisions regarding a food employee or applicant with a disability who needs to use a service animal~~  
11271 ~~should be made on a case by case basis. An employer must comply with health and safety requirements,~~  
11272 ~~but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is~~  
11273 ~~available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S.~~  
11274 ~~Equal Employment Opportunity Commission, the federal agency which has the lead in these matters, in~~  
11275 ~~documents such as, "National Network Information, Guidance and Training on the Americans with~~  
11276 ~~Disabilities Act—Service Animals" and "Service Animals Welcome—Service Animals & the ADA". The~~  
11277 ~~ADA Information Line is 800-949-4232 (voice/TTY) and the Internet Home Page address is~~  
11278 ~~[www.adata.org](http://www.adata.org).~~

11279  
11280 ~~Dogs and other animals, like humans, may harbor pathogens that are transmissible through food.~~  
11281 ~~Handling or caring for animals that may be legally present is prohibited because of the risk of~~  
11282 ~~contamination of food employee hands and clothing.~~

11283