

# Regulatory Analysis Form

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REVIEW COMMISSION

(1) Agency

Department of Agriculture

(2) I.D. Number (Governor's Office Use)

2-137

IRRC Number: 2255

(3) Short Title

The Food Code

(4) PA Code Cite

7 Pa. Code Chapter 46

(5) Agency Contacts & Telephone Numbers

Primary Contact: Sheri Dove: (717) 772-8353

Secondary Contact: Lenchen Radle: (717) 772-3234

(6) Type of Rulemaking (check one)

Proposed Rulemaking

Final Order Adopting Regulation XXXXX

Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

No XXXXX

Yes: By the Attorney General

Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

This regulation draws authority from several food safety statutes to establish a comprehensive "Food Code" for the Commonwealth. The primary purpose of this regulation is to achieve the public health goal of reducing foodborne illness to the fullest extent possible.

The regulation will bring the Commonwealth's food safety standards into step with the current national standards for food safety set forth in the 2001 edition of the United States Public Health Service Food Code ("Model Food Code").

Food safety science is an evolving body of knowledge. It is the Department's intention to adopt regulatory food safety standards that reflect current recommended national standards, and to revise these standards in the future as necessary to track with relevant revisions to these national standards.

Food safety considerations and procedures are essentially the same, whether the entity being regulated is a "food establishment" as described in the Food Act or a "public eating and drinking place" as described in the Public Eating and Drinking Places Law. For this reason, the regulation will merge the definitions of these two terms into a single new term - "food facility" - and establish sanitation and food safety standards and procedures for these facilities.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Food Act (31 P.S. §§ 20.1-20.18), the Public Eating and Drinking Places Law (35 P.S. §§ 655.1-655.13) and Section 1705(d) of the Administrative Code of 1929 (71 P.S. § 445(d) provide the legal authority for this regulation.

The Food Act charges the Department with the responsibility to: (1) regulate, register and inspect "food establishments" in the Commonwealth (31 P.S. § 20.14(a)); (2) promulgate regulations and food safety standards necessary to the proper enforcement of the food safety requirements set forth in that statute (31 P.S. § 20.13(a)); and (3) construe the statute and its attendant regulations in a manner that is as consistent with Federal statutory and regulatory authority as practicable (31 P.S. § 20.16).

The Public Eating and Drinking Places Law charges the Department with responsibility to regulate, license and inspect "public eating and drinking places" in the Commonwealth (35 P.S. §§ 655.2 and 655.6(a)), and to regulate the cleanliness and sanitation of these public eating and drinking places (35 P.S. § 655.9). This responsibility had originally been assigned the former Department of Environmental Resources, but was transferred to the Department by the act of December 12, 1994 (P.L. 903, No. 131).

Section 1705(d) of the Administrative Code of 1929 requires the Department to establish regulatory standards necessary to enforce food safety laws.

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(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Yes. The Food Law (at 31 P.S. §§ 20.13(a) and 20.14(a)) and the Public Eating and Drinking Places Law (at 35 P.S. § 655.6(a)) require the Department to promulgate regulations necessary to the implementation and enforcement of each of these statutes.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The regulation will help to protect public health and safety by decreasing the number of incidents of foodborne illness originating from food facilities.

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

If the regulation is not promulgated, incidents of foodborne illness might occur that would not have occurred had the regulation been in effect. This risk cannot be readily quantified.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Persons who consume food originating from restaurants, grocery stores and other food facilities should benefit from the regulation, in that the number of cases of foodborne illness originating from these food facilities should decrease. This benefit - the absence of foodborne illness - cannot be readily quantified.

Owners and operators of food facilities should benefit from the regulation in that the expected decrease in the number of cases of foodborne illness should translate into a proportional decrease in the number of claims and lawsuits related to foodborne illness. This benefit - the absence of claims and lawsuits - cannot be readily quantified.

### **Regulatory Analysis Form**

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

The Department of Agriculture does not anticipate the regulation will adversely affect any person.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Owners, operators and employees of "food facilities" will be required to comply with the regulation. "Food facilities" include both establishments possessing licenses to operate "public eating or drinking places" under the Public Eating or Drinking Places Law and establishments registered as "food establishments" under the Food Act.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The regulation is modeled after the Model Food Code. The Model Food Code is the product of a collaborative effort among the Department, the Food and Drug Administration, the Food Safety Inspection Service, the Centers for Disease Control, various state and local public health and food control agencies, food industry representatives, academia and consumers. It represents the state-of-the-science with respect to food handling and food safety.

The Commonwealth's food industry is familiar with the standards set forth in the regulation. These standards are also consistent with the content of many of the food safety training courses offered to food industry employees over the years.

The Department also circulated drafts of the proposed rulemaking among groups representing a cross-section of affected food facilities, and solicited their comments and suggestions.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

As stated above in response to Question No. 13, compliance with the regulation is expected to result in fewer instances of foodborne illness originating from food facilities in the Commonwealth, with resultant benefits to public health and safety and a decrease in claims and lawsuits related to foodborne illnesses. These benefits cannot be readily quantified.

It is not expected the regulated community - food facilities - would incur appreciable costs in complying with the regulation. The regulation has the Model Food Code (see the response to Question No. 16) as its basis, and adopts standards that are already well-known in the food industry. These standards are typically incorporated into in-house training programs conducted by food facilities or in

training provided to food employees by the Department and industry groups. In addition, the Food Employee Certification Act (3 Pa.C.S.A. §§ 6501-6510) requires (as of July 1, 2003) food safety training for at least one supervisory employee of each food establishment (with some exceptions). This training uses the Model Food Code as a basis for much of its food-safety content. Given the fact that the Commonwealth's food industries are quite familiar with the Model Food Code and frequently incorporate it into food safety training programs, the Department does not foresee the regulation will impose appreciable additional cost or confusion upon the regulated industry.

### **Regulatory Analysis Form**

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

The regulation is not expected to result in appreciable costs or savings to local governments.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

The regulation is not expected to result in appreciable costs or savings to State government.



## Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
<b>Regulated</b>	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
<b>Local Government</b>	0	0	0	0	0	0
<b>State Government</b>	0	0	0	0	0	0
<b>Total Savings</b>	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
<b>COSTS:</b>						
<b>Regulated</b>	0	0	0	0	0	0
<b>Local Government</b>	0	0	0	0	0	0
<b>State Government</b>	0	0	0	0	0	0
<b>Total Costs</b>	0	0	0	0	0	0
<b>REVENUE LOSSES:</b>						
<b>Regulated</b>	0	0	0	0	0	0
<b>Local Government</b>	0	0	0	0	0	0
<b>State Government</b>	0	0	0	0	0	0
<b>Total Revenue Losses</b>	0	0	0	0	0	0

(20a) Explain how the cost estimates listed above were derived.

As stated response to Question Nos. 13 and 17, above, the regulation is expected to result in a reduction in cases of foodborne illness originating from food facilities, with a related reduction in claims and lawsuits relating to such foodborne illness. As stated in response to Question Nos. 17, 18 and 19, above, the Department does not expect appreciable costs or revenue losses to industry or government in connection with the implementation of the regulation.

### Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Food Safety	\$4,225,916	\$4,312,160	\$4,400,164	\$4,500,000 (approx.)

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

There are not expected to be appreciable costs associated with the implementation of the regulation. The food safety standards and procedures described in the regulation are part of a Model Food Code that is widely-known in the food industry and that is integrated into most food safety training programs.

As stated, the regulation should serve to benefit public health and safety, in that it is expected to result in fewer incidents of foodborne illness originating from food facilities. It is also expected to reduce the number of claims or lawsuits related to such incidents. Although the Department cannot put a specific dollar value on these savings, it expects they will outweigh the costs of implementing the regulation.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Nonregulatory alternatives were not considered. The food safety standards set forth in the regulation are authorized under statute (See the response to Question No. 9, above).

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered. An objective of the regulation is to repeat, to the extent practicable, the well-known standards set forth in the national Model Food Code. Given this objective, there were no alternative regulatory schemes to consider.

### Regulatory Analysis Form

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

The regulation is not more stringent than Federal standards. Although the Model Food Code is not a Federal statute or regulation, it is the product of a collaborative effort involving Federal and State government authorities, local food control agencies, food industry representatives, academia and consumers, and is recommended as a set of workable food safety standards to be adopted nationwide. Since the regulation will adopt the substance of the Model Food Code, the regulation will not establish standards that are stronger or more strict than Federal standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The regulation will not put Pennsylvania at a competitive disadvantage with other states. Most other states are moving toward adopting regulatory food safety standards that emulate the Model Food Code.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No, the regulation will not affect the regulations of the Department or other State agencies.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

The Department does not plan any public hearings or informational meetings. The Model Food Code standards are well-known in the affected industry - whether they are known to affected persons as the formal Model Food Code or as the food safety standards that are taught to food industry employees throughout the Commonwealth.

### **Regulatory Analysis Form**

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

The regulation will not appreciably increase or change paperwork requirements.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

The regulation includes special precautions to be followed with respect to certain foods prepared and served to "highly susceptible populations." These populations might include the very old, the very young, ill persons and others who are immunocompromised. The term "highly susceptible populations" is defined in § 46.3 (relating to definitions), and is used in the regulation.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will take effect at the earliest date consistent with the requirements of the Regulatory Review Act. The registration and license requirements referenced in the regulation are already required under the Food Act or the Public Eating and Drinking Places Law, so the regulation will not impose any new registration/license requirements on the regulated community.

(31) Provide the schedule for continual review of the regulation.

The efficacy of the regulation will be reviewed on an ongoing basis. The Department will also review and consider any changes made to the Model Food Code, and evaluate whether similar changes should be made to the regulation.

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Copy below is hereby approved as to form and legality.  
Attorney General

By: \_\_\_\_\_  
(Deputy Attorney General)

DATE OF APPROVAL \_\_\_\_\_

☒ Check if applicable  
Copy not approved. Objections attached.

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(AGENCY)

DOCUMENT/FISCAL NOTE NO. 2-137

DATE OF ADOPTION 7/30/03

BY \_\_\_\_\_

Dennis C Wolff

TITLE Secretary, Pennsylvania Department of  
Agriculture

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality  
Executive or Independent Agencies

BY \_\_\_\_\_

*Tanya C. Lento*

9/15/03  
DATE OF APPROVAL

*Asst*  
(Deputy General Counsel)  
(~~Chief Counsel - Independent Agency~~)  
(Strike inapplicable title)

☒ Check if applicable. No Attorney General Approval  
or objection within 30 days after submission.

**Notice of Final Rulemaking**

**Title 7 – AGRICULTURE**

**7 Pa. Code Chapters 31, 35, 41, 43, 45, 46,  
47, 53, 55, 61, 63 and 78-81**

**Food Code**

# **FINAL RULEMAKING**

## **DEPARTMENT OF AGRICULTURE**

**[7 PA CODE CHS. 31, 35, 41, 43, 45, 46, 47, 53, 55, 61, 63 AND 78-81]**

### **Food Code**

The Department of Agriculture (Department) hereby revises Title 7 of the Pa. Code by establishing the Food Code at Chapter 46 (relating to food code) and rescinding the following chapters: 31 (relating to bakeries and bakery products), 35 (relating to condiments, spices, pickles and related products), 41 (relating to fruit and fruit products, butters, jellies and preserves), 43 (relating to flavoring materials), 45 (relating to general foods), 47 (relating to oleaginous materials: animal and vegetable fats and oils), 53 (relating to cider and vinegar standards), 55 (relating to coffee and tea standards), 61 (relating to packaged nonalcoholic drinks), 63 (relating to salad dressing and related products), 78 (relating to food establishments), 79 (relating to food service), 80 (relating to food vending machines) and 81 (relating to public places). The revisions read as set forth in Annex "A."

#### ***Statutory Authority***

The Food Act (act) (31 P.S. §§ 20.1-20.18), the Public Eating and Drinking Places Law (law) (35 P.S. §§ 655.1-655.13) and Section 1705(d) of the Administrative Code of 1929 (71 P.S. § 445(d)) provide the legal authority for this regulation.

The act charges the Department with the responsibility to: (1) regulate, register and inspect "food establishments" in the Commonwealth, under section 14(a) of the act (31 P.S. § 20.14(a)); (2) promulgate regulations and food safety standards necessary to the proper enforcement of the food safety requirements, under section 13(a) of the act (31 P.S. § 20.13(a)); and (3) construe the statute and its attendant regulations in a manner that is as consistent with Federal statutory and regulatory authority as practicable, under section 16 of the act (31 P.S. § 20.16).

The law charges the Department with responsibility to regulate, license and inspect "public eating and drinking places" in this Commonwealth, under sections 2 and 6(a) of the law (35 P.S. §§ 655.2 and 655.6(a)), and to regulate the cleanliness and sanitation of these public eating and drinking places, under section 9 of the law (35 P.S. § 655.9). This responsibility had originally been assigned the former Department of Environmental Resources, but was transferred to the Department by the act of December 12, 1994 (P.L. 903, No. 131).

Section 1705(d) of the Administrative Code of 1929 requires the Department to establish regulatory standards necessary to enforce food safety laws.

#### ***Purpose***

This regulation draws authority from several food safety statutes to establish a comprehensive Food Code for this Commonwealth. The primary purpose of this regulation is to achieve the public health goal of reducing foodborne illness to the fullest extent possible.

The regulation will bring the Commonwealth's food safety standards into step with the current national standards for food safety set forth in the 2001 edition of the United States Public Health Service Food Code (2001 FDA Model Food Code). Although the proposed regulation was based upon the 1999 version of that same Model Food Code, that model code was revised during the regulatory promulgation process and supplanted by the 2001 FDA Model Food Code. The 2001 FDA Model Food Code is the product of a collaborative effort among the Department, the Food and Drug Administration, the Food Safety Inspection Service, the Centers for Disease Control, various state and local public health and food control agencies, food industry representatives, academia and consumers. It represents the state-of-the-science with respect to food handling and food safety.

The standards set forth in the regulation are also consistent with the content of many of the food safety training courses offered to food industry employees over the years. For this reason, the regulation presents a set of standards with which a large segment of the Commonwealth's food industry is already familiar.

Food safety science is an evolving body of knowledge. It is the Department's intention to adopt regulatory food safety standards that reflect current recommended national standards, and to revise these standards in the future as necessary to track with relevant revisions to these national standards.

Food safety considerations and procedures are essentially the same, whether the entity being regulated is a "food establishment" as described in the act or a "public eating and drinking place" as described in the law. For this reason, the regulation merges the definitions of these two terms into a single new term - "food facility" - and establishes sanitation and food safety standards and procedures for these facilities.

### ***Need for the Regulation***

The regulation is needed to reduce foodborne illness to the fullest extent possible. This public health and safety objective is the primary reason for the regulation.

The food safety standards set forth in the regulation will serve the regulated community by helping to lower the number of claims and lawsuits related to foodborne illness.

The Department is satisfied there are no reasonable alternatives to proceeding with the regulation. The Department is also satisfied the proposed regulation meets the requirements of Executive Order No. 1996-1, "Regulatory Review and Promulgation."

### ***Comments***

Notice of Proposed Rulemaking was published at 32 *Pennsylvania Bulletin* 1046 (February 23, 2002), and provided for a 30-day public comment period. Comments were received from the Pennsylvania Food Merchants Association (PFMA), the Philadelphia County Health Department (PCHD), the Pennsylvania School Boards Association, Inc. (PSBA), the Chester County Health Department (CCHD), the Pennsylvania Catholic Conference (PCC), the Bucks County Health Department (BCHD) and the Independent Regulatory Review Commission (IRRC).

*Comment:* IRRC, PSBA and PCC requested clarification regarding the jurisdiction of the Department to apply this chapter to schools. PCC also noted that school cafeterias and private clubs (such

as lodges) are not public eating and drinking places. PCC cited the Food Employee Certification Act (at 3 Pa.C.S.A. § 6510(d)) as an example of legislative intent to limit the regulatory reach of the Department to commercial or for-profit food establishments.

*Response:* The Department agrees that the definitions of “food facility” and “food facility premises” in proposed § 46.3 (relating to definitions) were too broad, and has revised these definitions to clarify that school cafeterias (and other specific food facilities and food processing plants) are not included within the term, and are not subject to the provisions of the regulation. The Department has not, historically, regulated food service facilities at schools. The act of December 29, 2002 (P.L. 1421, No. 179) amended the law (at 35 P.S. §§ 655.1, 655.6(c) and 655.12a) to clarify that school cafeterias are not public eating and drinking places subject to regulation and licensure under that statute. Although the Department must provide inspections of school cafeterias and training for school cafeteria personnel in accordance with the standards applied to public eating and drinking places, school cafeterias are not otherwise subject to the provisions of that statute or this regulation.

*Comment:* IRRC noted that the proposed regulation would repeal existing regulations that are referenced in regulations of other Commonwealth agencies, and asked what steps the Department has taken to notify these agencies of the need to update their regulations. As an example, IRRC cited the Department of Environmental Protection regulation at 25 Pa. Code § 76.6 (relating to food service), which requires food services in schools to meet the regulatory standards of the Department’s regulation at 7 Pa. Code Chapter 78 – a chapter repealed by this regulation.

*Response:* The Department has had open communication with the Pennsylvania Departments of Education, Health, Corrections, Environmental Protection and Public Welfare with respect to the regulation, and has encouraged these agencies to update their regulations, as necessary.

*Comment:* IRRC and the PCC noted that the primary responsibility for issuing licenses to food facilities that are public eating and drinking places lies with county or local health authorities, rather than the Department, and expressed concern that the proposed regulation did not make this clear. IRRC recommended the Department consider making use of the term “licensor,” which appears in the Public Eating and Drinking Places Law and accurately describes entities that have authority to issue licenses.

*Response:* The Department has added a definition of “licensor” to § 46.3 (relating to definitions). The definition identifies those non-Department entities authorized to issue public eating and drinking place licenses under the Public Eating and Drinking Places Act. In addition, references to the “licensor” have been added throughout the regulation where the subject of the issuance of licenses is addressed.

*Comment:* IRRC noted repeated references to the Pennsylvania Construction Code Act throughout the regulation, and recommended each reference be revised to identify the specific applicable sections of that statute.

*Response:* The Department has revised proposed paragraph 46.821(a) (relating to approved materials to be used in plumbing systems), subsection 46.825(e) (relating to operation and maintenance of plumbing facilities), subsections 46.862(b) and (d) (relating to retention, drainage and delivery of sewage, other liquid waste and rainwater), section 46.863 (relating to disposal of sewage and nonsewage), and subsection 46.902(b) (relating to outdoor areas of food facilities: surface characteristics) by inserting a reference to Chapter 3 of the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304).



*Comment:* IRRC suggested that the definition of “adulterated” in proposed § 46.3 (relating to definitions) be edited into shorter sentences. IRRC also suggested the references to “the Federal acts” in paragraphs (iii), (iv), (viii), (ix) and (xiv) of this definition be more specific.

*Response:* The Department is reluctant to edit and redraft this definition, since it is a restatement of § 8 of the act (31 P.S. § 20.8). It has added the same definition of “Federal acts” as is contained in § 2 of the act (31 P.S. § 20.2), in § 46.3.

*Comment:* IRRC expressed several concerns with respect to the definition of “approved” in proposed § 46.3. The commentator was concerned that the regulation does not specify the process for making the determination of conformity. It also offered that the phrase “principles, practices and generally recognized standards” is unclear, and suggested the definition include examples, cross-references or citations to these practices or standards.

*Response:* The Department has added new language at § 46.1102 (relating to obtaining department or licensor approval), describing a process by which any of the “approvals” referenced in the regulation can be obtained. The definition of the term “approved” was derived directly from the 2001 FDA Model Food Code. There are literally thousands of types of foods and food manufacturing processes, and the scientific knowledge surrounding food safety is constantly evolving. For this reason, the principles, practices and generally recognized standards are a “moving target” that will vary with the food, time and knowledge. The Department believes it has gone as far as it can reasonably go in defining the term “approved.” The Department also believes the regulated community is quite familiar with the fact that food safety science is an ever-evolving body of knowledge, and takes the absence of comments from the regulated community on this subject as some indication of familiarity/comfort with the defined term.

*Comment:* PFMA noted that the term “critical items” is not defined within the regulation, and requested there be “process or guidance” to clearly define this term.

*Response:* The term “critical items” is not used in the regulation, so it is not defined. The Department has, historically, used the inspection process and inspection report to indicate to food facilities the critical nature of specific violations encountered in the course of the inspection. The Department intends to continue this into the future.

*Comment:* CCHD commented on the use of the definition of “Department” in proposed § 46.3, and requested it be broadened in scope to include local health departments acting under authority of the act or the law.

*Response:* The Department has implemented this request by defining a new term – “Licensor” – in § 46.3 and making appropriate references to “the Department or Licensor” throughout the regulation.

*Comment:* PFMA commented on the inconsistency of the proposed definition for “foodborne disease outbreak” in § 46.3 with that found in the 2001 FDA Model Food Code.

*Response:* The proposed definition has been supplanted by the 2001 FDA Model Food Code definition.

*Comment:* IRRC requested a typographical correction to the definition of “food employee” in proposed § 46.3.

*Response:* The Department has made the correction.

*Comment:* IRRC suggests that the definition of “hazard” in proposed § 46.3 include examples of what might constitute an “unacceptable consumer health risk.”

*Response:* The Department has modified the definition to include examples such as pathogens, pesticides, natural toxins, rodent contamination, or foreign materials.

*Comment:* IRRC noted the use of the term “honestly presented” in several sections of the proposed regulation, and suggested that the term be defined. IRRC recommended the Department consider language from proposed paragraph 46.421(b)(1) (relating to accurate representation).

*Response:* The Department has implemented the suggestion by defining the term in § 46.3.

*Comment:* IRRC noted that the term “package” is defined in § 2 of the act (31 P.S. § 20.2), and that § 46.3 of the proposed regulation does not contain that definition but, instead, a definition of the term “packaged.” IRRC further noted that the definition of “packaged” in the proposed regulation is not similar to the definition of “package” in section 2 of the act. IRRC suggested the Department review the regulation and determine the most appropriate term.

*Response:* The Department has reviewed the use of the term “packaged” in the proposed regulation and intends to continue to use that term, rather than “package.” The definition of “packaged” is consistent with the 2001 FDA Model Food Code.

*Comment:* PFMA commented on the inconsistency of the proposed definition for “potentially hazardous food” with that found in the 2001 FDA Model Food Code.

*Response:* The Department agrees the definitions are not identical, but the term is defined in § 2 of the act (31 P.S. § 20.2), and the Department must use that statutory definition for the term.

*Comment:* IRRC and CCHD noted that although the proposed regulation defined the term “private water system” in section 46.3, the remainder of that document made reference to a “non-public water supply.” The commentators requested that this be resolved by using one term or the other exclusively.

*Response:* The Department has implemented this request by deleting the term “private water system” and adding the term “nonpublic water supply.”

*Comment:* PCHD and IRRC commented on the misspelling of the word “ingredient” in the definition of “potentially hazardous food” in proposed § 46.3

*Response:* The Department has corrected this error.

*Comment:* CCHD noted the defined term “bed and breakfast homestead or inn” in proposed § 46.3, and did not believe the term was used anywhere else in the body of the regulation.

*Response:* The term “bed and breakfast homestead or inn” is used in the definition of a “public eating and drinking place” in § 46.3, where it is identified as an exception with respect to which the regulation is not applicable. The definition itself is from section 1 of the law (35 P.S. § 65.1).

*Comment:* Both IRRC and PCHD noted an error in the definition of “public eating and drinking place” in proposed § 46.3, which included dining cars and bed and breakfast homestead inns within that term.

*Response:* The Department has corrected this error.

*Comment:* IRRC commented that the definition of the term “substance” in proposed § 46.3 contained the word “substance,” and noted this was inconsistent with the Pennsylvania Code and Bulletin Style Manual.

*Response:* The Department changed the word “substance” in the referenced definition to “material.”

*Comment:* IRRC reviewed proposed § 46.112 (relating to diseases or medical conditions that must be reported) and suggested that paragraphs (5) through (8) be rewritten to identify the person(s) to whom the provision applies and to “... more closely reflect the 1999 Federal Recommended Food Code at Section 2-201.11.”

*Response:* The Department has implemented this suggestion. The phrase “food employee or food employee applicant” was added to the referenced section, making it more consistent with the 2001 FDA Model Food Code (the successor to the 1999 version of that model code).

*Comment:* IRRC and CCHD both suggested that proposed § 46.112 (relating to diseases or medical conditions that must be reported) and proposed subparagraph 46.113(a)(2)(ii) (relating to duty to impose exclusions and restrictions) be amended to replace the phrase “Escherichia coli O157:H7” with “Shiga toxin-producing E. coli.”

*Response:* The term “Escherichia coli O157:H7” was replaced by “Shiga toxin-producing E. coli” in §§ 46.112 and 46.113, as well as when used in other sections throughout the chapter. The replacement is consistent with the 2001 FDA Model Food Code.

*Comment:* IRRC and CCHD suggested that proposed § 46.132 (relating to duty of food employees to wash) be revised to include a requirement that employees wash their hands before donning gloves, as stated in the 2001 FDA Model Food Code.

*Response:* The suggestion has been implemented in the regulation.

*Comment:* IRRC and PCHD reviewed proposed § 46.133 (relating to required washing locations) and commented on the need to define the term “utility sink” and to provide clarification regarding the allowance for utilizing the utility sink as a handwash location in small food establishments with limited space. PCHD also suggested the section be renamed “approved hand washing locations.”

*Response:* A definition of “utility sink” has been added to § 46.3 (relating to definitions). As a general food safety practice, a utility sink used for disposal of mop water or other liquid waste should not

be used as a handwash sink. However, § 46.1103 (relating to variances) permits variances to allow this practice (when justifiable).

*Comment:* IRRC suggested that the Department provide a definition of the acronym "OTC," used in proposed § 46.134 (relating to hand sanitizers).

*Response:* The suggested definition has been added.

*Comment:* IRRC noted numerous references to other authority in proposed § 46.213 (relating to packaged food), and suggested these references be replaced by a single reference to § 46.422 (relating to labeling), which contains the same references and greater detail regarding labeling requirements. IRRC also suggested the term "Food Act" be changed to "Act" throughout the regulation.

*Response:* The referenced section has been revised as recommended by IRRC. With respect to the use of the term "Act" or "Food Act," the Department has deleted the definition of "Act" from § 46.3 and defined "Food Act" and "Public Eating and Drinking Places Law" to clearly distinguish between the two statutes upon which the regulation is premised.

*Comment:* IRRC noted references to the Food Act in proposed §§ 46.213, 46.421 (relating to accurate representation) and 46.422 (relating to labeling), and suggested these references be to the specific applicable sections of the Food Act.

*Response:* The reference to the Food Act in § 46.213 has been deleted. The references to the Food Act in §§ 46.421 and 46.422 have been made more specific.

*Comment:* IRRC requested that the references to the Milk Sanitation Law in proposed §§ 46.217 (relating to milk and milk products) and 46.244 (relating to receiving eggs and milk products) be revised to provide references to specific sections of that statute.

*Response:* The recommended revision has been made in § 46.217. The Department believes it appropriate to leave the reference to the Milk Sanitation Law in § 46.244 general, though.

*Comment:* IRRC commented that the reference to "the act and this chapter" in proposed subsection 46.219(a) (relating to molluscan shellfish) should be made more specific.

*Response:* The references have been clarified to reflect the applicable section of the act (31 P.S. § 20.14) and the applicable subchapter of the regulation (Subchapter C). In addition, a reference to Chapter 49 (relating to shellfish) has also been added. The proposed regulation reflected the Department's intention to rescind Chapter 49, but during the comment review process, the Department decided to leave Chapter 49 intact and pursue revisions of that chapter as a separate regulatory promulgation effort.

*Comment:* Both PFMA and IRRC noted the use of the term "mushroom identification expert" in proposed § 46.220 (relating to wild mushrooms), and recommended the regulation establish required qualifications and training for mushroom identification experts. PFMA acknowledged an ongoing debate between "state public health agencies and the food industry" as to appropriate qualifications and training, and that the 2001 FDA Model Food Code does not address this subject.

*Response:* The Department declines to implement this recommendation. It has revised the section to show it will not “approve” mushroom identification experts. The mushroom production industry and individuals will remain responsible for mushroom identification safety. The Department will continue to monitor this area, and will consider any subsequent Food and Drug Administration opinions on what is relevant to qualifications of a wild mushroom expert in its determination as to whether it is necessary to regulate in this area.

*Comment:* IRRC reviewed proposed §§ 46.220 and 46.221 (relating to game animals), and requested that the Department explain what other regulatory agencies would have jurisdiction over food and food establishments.

*Response:* A definition of “other food regulatory authority” has been added to § 46.3. A food sold or used in food preparation within the Commonwealth is not always processed, manufactured, or commercially prepared under the statutory authority of this Department.

*Comment:* IRRC noted that proposed subparagraph 46.221(b)(2)(i) (relating to game animals) contains broad references to laws governing meat and poultry and other unspecified regulatory agencies. The commentator requested the regulation identify these laws more specifically.

*Response:* The Department has defined “other food regulatory agency” in § 46.3, and has used that term in the referenced subparagraph, and at other appropriate places in the regulation. It is difficult to specifically identify each agency that might have authority with respect to food within this Commonwealth. Federal agencies and the food safety authorities of other states and nations might have a role, depending upon the point of origin of the food or its ingredients.

*Comment:* PFMA recommended that proposed §§ 46.241 (relating to receiving temperature of food) and 46.385 (relating to potentially hazardous food: hot and cold holding) be revised by changing the minimum holding temperature for hot potentially hazardous foods from “60°C (140°F)” to “54°C (130°F).”

*Response:* The Department has implemented this recommendation. In consideration of this comment, the Department reviewed the recommendations resulting from the 2002 Conference for Food Protection to be forwarded to FDA for inclusion in the next Model Food Code publication. The conference forwarded a resolution to FDA to modify the hot holding temperature from 60°C (140°F) to 58°C (135°F), and the Department has modified all references in this chapter to reflect this change.

*Comment:* PCHD and IRRC requested proposed subsection 46.241(d) be revised to include examples of visible evidence of previous temperature abuse.

*Response:* The Department has added examples to the referenced subsection. These include “dehydration, ice crystals, discoloration or damaged packaging.”

*Comment:* PCHD reviewed proposed § 46.242 (relating to additives), and offered that sulfiting agents may be used as an additive in a number of commercial foods. When such foods are offered to the consumer for immediate consumption there is no direct notice to the consumer of the presence of sulfites. The commentator requested that a new subparagraph be added to require that consumers be notified of the presence of sulfiting agents in food.

*Response:* The Department considered this comment carefully, and declines to add the requested language. The Department does not have the scientific expertise to evaluate the extent of the food safety risk of sulfite in relation to any other known food allergen, such as MSG or red food coloring. The Department will continue to follow the federal requirements as written with respect to food additives and labeling. The specific federal regulatory references in this section will reflect any changes in the federal standards which may occur in the future.

*Comment:* IRRC noted that proposed § 46.242 contained two citations to the Code of Federal Regulations (9 CFR 318.7 and 40 CFR 185) that appeared to be inaccurate.

*Response:* The Department has corrected these citations, and checked citations elsewhere in the regulation to ensure they are accurate.

*Comment:* IRRC requested that proposed § 46.243 (relating to receiving shell eggs) be revised to identify the specific applicable sections of the Egg Refrigeration Law and Chapter 87.

*Response:* The Department has revised the referenced section by inserting the requested reference. The reference to "Chapter 87" in subsection (a) has been changed to "§ 87.41 (relating to standards)" and the same reference in subsection (c) was revised to refer to "§§ 87.51 (relating to receptacles) and 87.52 (relating to marketing)." The reference to the Egg Refrigeration Law in subsection (b) has also been made more specific.

*Comment:* CCHD commented on the provision for detention of shellfish in section 46.246 (relating to receiving shucked shellfish: packaging and identification) and suggested that detention provisions provided for in the act should be delineated in this chapter.

*Response:* The Department declines to implement this suggestion, as it believes that § 6 of the Act (31 P.S. § 20.6) is sufficiently clear.

*Comment:* PFMA, IRRC and CCHD suggested the Department revise proposed § 46.261 (relating to preventing contamination from food employees' hands) to more clearly describe the circumstances under which food employees may contact food with their bare hands. PFMA offered language for this revision.

*Response:* The Department has implemented this suggestion in the regulation, and has used language from the 2001 FDA Model Food Code that is quite similar to the language proposed by PFMA. The additional language is an adaptation of that found in the annex section of the 2001 FDA Model Food Code.

*Comment:* PCHD and IRRC offered comment with respect to proposed § 46.303 (relating to linens and napkins: use limitations). The commentators noted the section did not allow for use of clean linens in retail displays of dry non-potentially hazardous foods, such as rolls in a bakery. The commentators recommend adding the term "approved retail display" to this section to provide for the use of linens in contact with food on display.

*Response:* The Department has revised the referenced section to allow for linens to be in contact with non-potentially hazardous food for the purposes of retail display, but requires that the linens and napkins be replaced upon restocking of the retail display.

*Comment:* IRRC suggested that the Department should clarify the safe distance between food and a source of contamination in proposed § 46.321 (relating to food storage).

*Response:* The Department cannot adequately define the safe distance between food and a source of contamination. The safe distance can vary widely – depending upon the circumstances. A professional evaluation with consideration of the type of contamination (such as airborne or wet), the environmental conditions (such as air currents or amount of usage) and other conditions would be necessary.

*Comment:* IRRC reviewed proposed § 46.345 (relating to miscellaneous sources of contamination), and expressed concern that the Department would be unable to measure or observe compliance with this provision and the regulated community would not be able to know whether it was in compliance. The commentator suggested that the Department outline procedures staff or public health officials will follow when notifying regulated facilities of a previously-unidentified source of contamination.

*Response:* The Department deleted the referenced section.

*Comment:* IRRC noted a typographical omission in the first sentence of proposed § 46.362 (relating to microwave cooking).

*Response:* The Department corrected the error.

*Comment:* PCHD and IRRC noted that proposed § 46.385 (relating to potentially hazardous food: hot and cold holding) contains no provisions relating to date marking, tracking, or use of foods within a specified time frame. PCHD requested that PDA consider adding language on this subject consistent with the 2001 FDA Model Food Code.

*Response:* The Department added date marking language in subsection (b) of the referenced section. The language is not directly from the 2001 FDA Model Food Code but, instead, is a compromise found acceptable by both the Department and PFMA – the entity representing the retail food industry.

*Comment:* PFMA suggested proposed § 46.422 (relating to labeling) be revised to clarify alternative options with respect to “unpackaged foods portioned to consumer specifications.”

*Response:* The Department believes proposed subsection 46.422(c) was sufficiently specific, but has added an example.

*Comment:* IRRC suggested that proposed paragraph 46.422(e)(1) be revised to include citations to the law referenced in that provision.

*Response:* The referenced paragraph has been deleted.

*Comment:* PFMA suggested the addition of a “pizza peel” to the examples provided in subparagraph 46.521(i)(1)(i) (relating to materials in multiuse utensils and food-contact surfaces).

*Response:* The suggestion has been implemented.

*Comment:* PFMA asked the Department to clarify subsection 46.591(d) (relating to warewashing machines) with respect to audible or visual alarms that indicate when the sanitizer reservoir of a warewashing machine is empty.

*Response:* The Department modified the subsection to use the specific language on this subject contained in the 2001 FDA Model Food Code. The section now requires "... a visual means to verify that detergents and sanitizers are delivered or a visual or audible alarm to signal if the detergents and sanitizer are not delivered to the respective washing and sanitizing cycles."

*Comment:* IRRC suggested the Department either delete the word "equipment" or add a clarifying term such as "equipment that requires cleaning by immersion" to proposed subsection 46.612(b) (relating to manual warewashing: sink compartment requirements).

*Response:* The Department has revised the referenced subsection to describe equipment and utensils that require cleaning by immersion.

*Comment:* IRRC suggested that the Department add examples to the "other task-specific cleaning equipment" described in proposed paragraphs 46.612(c)(3) and (4).

*Response:* The Department has implemented this suggestion.

*Comment:* PFMA offered the opinion that proposed § 46.633 (relating to temperature measuring devices for manual warewashing) is intended for *mechanical* warewashing machines, rather than *manual* warewashing.

*Response:* The section is intended to address temperature measuring devices for manual warewashing. Subsection 46.591(c) (relating to warewashing machines) addresses temperature measuring devices for mechanical warewashing machines.

*Comment:* PCHD reviewed proposed subsection 46.676(b) (relating to manual warewashing equipment), permitting the use of a warewashing sink for food washing, food thawing, and for washing of soiled wiping cloths, and suggested that separate equipment should be provided to limit cross-contamination of foods.

*Response:* Subsection 46.676(a) was amended to prohibit the use of a warewashing sink for food preparation. The Department could ascertain no food safety hazard, however, in the washing of linens in a warewashing sink. Soiled linens would create no further food safety hazard than dirty dishes, if properly washed, rinsed and sanitized.

*Comment:* PFMA suggested proposed subparagraph 46.712(d)(2)(ii) (relating to frequency of cleaning equipment food-contact surfaces and utensils) be revised to require cleaning frequency to be "monitored," rather than "documented."

*Response:* The Department declines to implement this suggestion. The required frequency for food equipment cleaning is set forth in subsection (c) of that section. Since paragraph (d)(2) describes an exception to the general cleaning frequency requirement, the Department believes it reasonable to require an entity cleaning in accordance with the requirements of that paragraph to be able to prove compliance through documentation.



*Comment:* BCHD noted that proposed § 46.801 (relating to sources of drinking water) does not prohibit cross-connections between a public and non-public water supply, and that the section makes no mention of disinfection facilities (such as ultraviolet light treatment) or whether such facilities are required.

*Response:* The referenced section states that water must comply with the regulation of the Department of Environmental Protection at 25 PA Code Chapter 109 (relating to safe drinking water). That chapter requires back-flow prevention to protect the public water system. In the event of a cross-connection between a public and non-public water supply, adherence to this requirement protects the public water system. The regulation at 25 Pa. Code Chapter 109 does not require disinfection facilities in all cases, but requires them when necessary for safe drinking water, and requires that these disinfection facilities be maintained and operated appropriately.

*Comment:* BCHD and IRRC noted that proposed § 46.802 (relating to drinking water system flushing and disinfection) does not mention the requirement for obtaining "... check samples on a water supply prior to placing back in service after an emergency situation."

*Response:* The Department has revised the section by adding language requiring that the water meet the quality standards for public drinking water set forth in the regulations of the Pennsylvania Department of Environmental Protection, at 25 Pa. Code Chapter 109 (relating to safe drinking water) before a drinking water system is placed back into service after construction, repair, modification or emergency.

*Comment:* IRRC reviewed proposed § 46.804 (relating to quality of water) and recommended the section include a procedure (or a cross-reference or citation) for obtaining the Department's approval for a "non-drinking water supply."

*Response:* The Department has added § 46.1102 (relating to obtaining department or licenser approval), clarifying the procedure for obtaining approval of the Department.

*Comment:* IRRC recommended proposed subsection 46.805(b) (relating to quantity and availability of water: capacity and pressure) be rewritten for clarity.

*Response:* The Department has implemented this recommendation.

*Comment:* BCHD noted that proposed § 46.806 (relating to distribution, delivery and retention of water) does not have a provision for having a chlorine residual for emergency or alternative water supplies for food facilities.

*Response:* All emergency or alternative water supplies must meet the requirements as stated in § 46.802 (relating to drinking water system flushing and disinfection). This section was revised to require such water supplies to comply with the safe drinking water regulations at 25 PA Code Chapter 109.

*Comment:* IRRC noted a typographical error in proposed paragraph 46.822(a)(2) (relating to design, construction and installation of plumbing systems).

*Response:* The error has been corrected in the regulation.

*Comment:* BCHD and CCHD opined that proposed paragraph 46.823(a)(1) (relating to numbers and capacities of plumbing facilities) does not provide for any type of handwashing facilities for the general public. The commentators recommended that in public eating and drinking places or where self-service foods are available for the consumer (such as at salad bars), public health concerns should dictate that facilities should be provided for patron handwashing prior to food handling or consumption.

*Response:* The Department accepts the recommendation, and has implemented it by adding paragraph (a)(4) to the referenced section.

*Comment:* IRRC asked for clarification of the process by which the Departmental approvals referenced in proposed paragraphs 46.823(a)(2) and (a)(3) (relating to numbers and capacities of plumbing facilities) can be obtained.

*Response:* The Department has added § 46.1102 (relating to obtaining department or licenser approval), clarifying the procedure for obtaining approval of the Department.

*Comment:* IRRC reviewed subsection 46.823(b) and asked whether the Department planned to impose toilet requirements that differed from those established by the Department of Labor and Industry. If not, IRRC recommended the phrase "the Department or" be deleted from that subsection.

*Response:* The referenced phrase has been deleted. The Department's intention is to require a *minimum* of one toilet, and the subsection accomplishes this objective.

*Comment:* IRRC reviewed proposed subsection 46.841(1) (relating to materials used in construction of water tanks and mobile food facility water tanks) and proposed paragraph 46.842(f)(1) (relating to design and construction of water tanks and mobile food facility water tanks), and recommended the Department use the defined term "safe materials" instead of the term "safe" in those provisions.

*Response:* The recommendation has been implemented.

*Comment:* IRRC commented on the provision in proposed paragraph 46.843(c)(2) requiring a hose connection that cannot possibly be used for another purpose.

*Response:* The fresh water supply of a mobile food unit must be protected from cross-contamination. Although the hose connection may be of a type commonly found, the intent is that the hose connection must be unique on each mobile unit so that it is not vulnerable to environmental contaminants, such as a sewage hose connected to the fresh water tank.

*Comment:* BCHD reviewed proposed subsection 46.922(d) (relating to functionality of various physical facilities of a food facility) and opined that toilet room doors in shopping malls should not be mentioned in that subsection, as "Most of the large malls across the State have bathroom facilities with self-closing doors."

*Response:* The Department feels that although most malls may have self-closing doors, the situation does not require self-closing doors to protect food safety where the toilet room does not open directly into the food facility.

*Comment:* BCHD reviewed proposed subsection 46.922(e) and noted it makes no mention of the use of air-curtain doorways into food facilities.

*Response:* The provision allows for air curtains, at 46.922(e)(4)(ii).

*Comment:* IRRC offered several comments with respect to proposed § 46.922. It opined that proposed subparagraphs 46.922(e)(3)(ii) and (iii) appear to be different ways of saying the same thing and one should be deleted. IRRC also offered that proposed subparagraph 46.922(e)(4)(iii) should give examples of "other effective means." IRRC also suggested that proposed paragraphs 46.922 (e)(4) and (e)(5) should use consistent language concerning insects, rodents, flying insects, and other pests.

*Response:* The Department has revised the referenced section by combining subparagraphs 46.922(e)(3)(ii) and (iii). The Department cannot provide examples of "other effective means" in subparagraph 46.922(e)(4)(iii). That subparagraph was inserted to allow for the use of devices developed in the future that perform satisfactorily to be used, although the Department is not aware of any currently-existing devices it can cite as examples. Paragraph 46.922 (e)(5) has been revised to make it consistent with paragraph 46.922(e)(4).

*Comment:* PCHD requested that proposed paragraph 46.982(b)(1) (relating to limitations on animals) be revised to more-clearly state that animals that do not meet the exceptions set forth in that section may not be brought onto the premises of a food facility.

*Response:* The Department agrees the recommended change will add clarity, and has implemented it.

*Comment:* IRRC recommended that proposed paragraph 46.1022(b)(3) (relating to poisonous or toxic substances: limitations on presence and use) either be deleted or revised to establish the parameters within which the Department would establish the "additional conditions" referenced in that section.

*Response:* The Department reworded the section to read "approved by the Department," and requirements for obtaining approval are outlined in section 46.1102.

*Comment:* IRRC noted that proposed paragraph 46.1026(a)(1) (relating to pesticides) contains an inaccurate citation to the United States Code Annotated.

*Response:* This error has been corrected.

*Comment:* IRRC recommended that proposed § 46.1101 (relating to application for intended purpose: public health protection) be deleted, since it repeats the substance of proposed § 46.1 (relating to purpose).

*Response:* The Department accepts the recommendation and has made the deletion.

*Comment:* IRRC reviewed proposed § 46.1102 (relating to access to food facilities), and suggested the word “credentials” be replaced by “identification” and that the Department provide examples of “other reasonable times” when an inspection might occur. IRRC also suggested the phrase “any other relevant statutory or regulatory authority” be deleted.

*Response:* The substance of proposed § 46.1102 has been moved to § 46.1101 in the regulation, and the Department has implemented IRRC’s recommendations.

*Comment:* PFMA offered that proposed subsection 46.1121(b) (relating to facility and operating plans) seems to imply that HACCP plans would be required for facility plan reviews.

*Response:* The referenced section has been revised, and clarifies that a HACCP plan is not required of *all* food facilities – just those specified under subsection 46.1122(a) (relating to HACCP plans).

*Comment:* IRRC raised several concerns with respect to proposed § 46.1121 (relating to facility and operating plans). IRRC recommended that proposed paragraph 46.1121(b)(5) be revised to require any Department-issued request for “other information” to be in writing. IRRC also recommended the referenced section describe how plans and specifications are to be communicated to the Department.

*Response:* The Department accepts the commentator’s recommendation that Department-issued requests for additional information be in writing. Paragraph 46.1121(b)(7) now requires the referenced requests for “other information” to be in writing. The Department also added a cross-reference to § 46.1142 (relating to application procedure for appropriate license or registration) at paragraph 46.1121(a). Section 46.1142 requires an applicant (operator of a food facility) to obtain appropriate application forms from the Department or licenser. The location to which these forms are to be submitted may vary. Different licensors have different addresses, and different applications received by the Department might be processed at different regional offices of the Department. The application materials will contain specific instructions regarding the application process.

*Comment:* PFMA noted that the reference in proposed subparagraph 46.1122(a)(1)(ii) to “§ 46.345(d)(3)” is incorrect.

*Response:* The Department agrees, and has made the correction.

*Comment:* PCC reviewed proposed § 46.1142 (relating to application procedure for appropriate license or registration), and expressed concern that the regulation does not: “... adequately explain the distinctions among permits, licenses or registrations.” The commentator expressed concern that food facilities would be subjected to arbitrary standards.

*Response:* The Department has added language to the referenced section to clarify that a food facility that is a public eating and drinking place must have a license, while a food facility that is a food establishment must have a registration. These requirements are not new, but are imposed by the Food Act and the Public Eating and Drinking Places Law. The regulation has deleted the reference to a “permit” that appeared throughout the proposed regulation.

*Comment:* PFMA requested clarification that the use of the term "variance" in proposed subsection 46.1144(9) (relating to conditions or retention: responsibilities of the food facility operator) "is not intended to mean a HACCP plan would be required."

*Response:* The Department believes the referenced provision does not impose a HACCP plan requirement. The term "variance" is defined in § 46.3, and does not require a HACCP plan. The Department believes § 46.1122 (relating to HACCP plans) clearly described the circumstances under which a HACCP plan is required.

### ***Fiscal Impact***

*Commonwealth.* The final-form regulation does not impose costs and has no fiscal impact on the Commonwealth. The Department currently registers and inspects food establishments under the Food Act and issues licenses allowing the operation of public eating and drinking places under the Public Eating and Drinking Places Law. The proposed regulation would merge the Department's regulatory functions into a single set of standards applicable to all "food facilities" in the Commonwealth.

*Political Subdivisions:* The final-form regulation does not impose costs and has no fiscal impact upon political subdivisions.

*Private Sector:* The final-form regulation might impose some initial cost on the private sector, although this cannot be readily quantified. Since the food safety standards prescribed by the final-form regulation reflect rather widely-known food safety concerns, the Department expects most food facilities in operation within the Commonwealth are currently meeting these standards or would have relatively little difficulty meeting them. In addition, the final-form regulation is likely to result in a decrease in the number of lawsuits relating to foodborne illness originating from food facilities, with a resultant savings in costs attributable to litigation and awards of damages. These savings are not readily quantifiable.

*General Public:* The final-form regulation will enhance public health and safety. It is expected to reduce the number of cases of foodborne illness attributable to food originating from food facilities in the Commonwealth. This should result in some indeterminate cost savings to the general public.

### ***Paperwork Requirements***

The final-form regulation is not likely to appreciably impact upon the paperwork generated by the Department or food facilities.

### ***Sunset Date***

There is no sunset date for the final-form regulation. The Department will review the efficacy of this regulation on an ongoing basis.

### ***Contact Person***

Further information is available by contacting the Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: Sheri Dove. Telephone: (717) 787-4315.

## ***Regulatory Review***

Under § 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Department submitted a copy of the Notice of Proposed Rulemaking published at 32 *Pennsylvania Bulletin* 1046 (February 23, 2002) on February 8, 2002 to the Independent Regulatory Review Commission and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs for review and comment. In compliance with § 5(b.1), the Department also provided the Commission and the Committees with copies of all comments received, as well as other documentation.

In preparing this final-form regulation, the Department has considered all comments received from the Commission, the Committees and the public.

This final-form regulation was \_\_\_\_\_ (approved or deemed approved) by the House Agricultural and Rural Affairs Committee on \_\_\_\_\_, 2003, was \_\_\_\_\_ (approved or deemed approved) by the Senate Agriculture and Rural Affairs Committee on \_\_\_\_\_, 2003, and was approved by the Commission on \_\_\_\_\_, 2003.

## ***Findings***

The Department of Agriculture finds the following:

1. Public notice of its intention to adopt the regulation encompassed by this Order has been given under §§ 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240)(45 P.S. §§ 1201 and 1202) and their attendant regulations at 1 Pa. Code §§ 7.1 and 7.2.
2. A public comment period was provided as required by law and all comments received were considered.
3. The modifications that were made to this regulation in response to comments received do not enlarge the purpose of the proposed regulation published at 32 *Pennsylvania Bulletin* 1046 (February 23, 2002).
4. The adoption of the regulation in the manner provided in this Order is necessary and appropriate for the administration of the authorizing statute.

## ***Order***

The Department of Agriculture, acting under authority of the authorizing statute, orders the following:

1. The regulations of the Department of Agriculture at 7 Pa. Code Chapter 46 (relating to food code) are adopted as set forth at Annex A hereto.
2. The regulations of the Department of Agriculture at the following chapters of Title 7 of the Pa. Code are hereby rescinded in their entirety: Chapter 31 (relating to bakeries and bakery products), Chapter 35 (relating to condiments, spices, pickles and related products), Chapter 41 (relating to fruit and fruit products, butters, jellies and preserves), Chapter 43 (relating to flavoring materials), Chapter 45 (relating to general foods), Chapter 47 (relating to oleaginous materials: animal and vegetable fats and oils),

Chapter 53 (relating to cider and vinegar standards), Chapter 55 (relating to coffee and tea standards), Chapter 61 (relating to packaged nonalcoholic drinks), Chapter 63 (relating to salad dressing and related products), Chapter 78 (relating to food establishments), Chapter 79 (relating to food service), Chapter 80 (relating to food vending machines) and Chapter 81 (relating to public places).

3. The Secretary of Agriculture shall submit this Order, 32 *Pennsylvania Bulletin* 1046 (February 23, 2002) and Annex "A" hereto to the Office of General Counsel and to the Office of Attorney General for approval as required by law.

4. The Secretary of Agriculture shall certify this Order, 32 *Pennsylvania Bulletin* 1046 (February 23, 2002) and Annex "A" hereto and deposit them with the Legislative Reference Bureau as required by law.

5. This Order shall take effect upon publication in the *Pennsylvania Bulletin*.

DENNIS C WOLFF,  
*Secretary*

**Annex A**

**DEPARTMENT OF AGRICULTURE**

**[7 PA. CODE CHS. 31, 35, 41, 43, 45--47,  
53, 55, 61, 63 AND 78-81]**

**Food Code**

**TITLE 7. AGRICULTURE.**

**PART III. BUREAU OF FOOD SAFETY AND  
LABORATORY SERVICES**

**CHAPTER 31. (Reserved)**

**§ 31.1. (Reserved).**

**§§ 31.11--31.23. (Reserved).**

**§§ 31.31--31.39. (Reserved).**

**CHAPTER 35. (Reserved)**

**§§ 35.1--35.11. (Reserved).**

**CHAPTER 41. (Reserved)**

**§§ 41.1--41.4. (Reserved).**

**§§ 41.11--41.14. (Reserved).**

**§§ 41.21--41.24. (Reserved).**

**CHAPTER 43. (Reserved)**

**§§ 43.1--43.8. (Reserved).**

**§§ 45.1--45.7. (Reserved).**

**§§ 45.21--45.24. (Reserved).**

**§§ 45.31--45.33. (Reserved).**

**§§ 45.41--45.44. (Reserved).**

**§§ 45.51--45.54. (Reserved).**

**§§ 45.61--45.64. (Reserved).**

**§ 45.71. (Reserved).**



§ 45.72. (Reserved).

§§ 45.81--45.87. (Reserved).

§§ 45.91--45.93. (Reserved).

## CHAPTER 46. FOOD CODE

Subch.

- A. PURPOSE AND DEFINITIONS
- B. MANAGEMENT AND PERSONNEL
- C. FOOD
- D. EQUIPMENT, UTENSILS AND LINENS
- E. WATER, PLUMBING AND WASTE
- F. PHYSICAL FACILITIES
- G. POISONOUS OR TOXIC MATERIALS
- H. ADMINISTRATIVE PROCEDURES

### Subchapter A. PURPOSE AND DEFINITIONS

Sec.

- 46.1. Purpose.
- 46.2. Scope.
- 46.3. Definitions.

#### § 46.1. Purpose.

The purpose of this chapter is to safeguard public health and ensure that consumers are provided food that is safe, unadulterated and honestly presented.

#### § 46.2. Scope.

This chapter establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities; and provides for food facility plan review, ~~permitting~~, licensing, registration, inspection and employee restriction.

#### § 46.3. Definitions.

The following terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

~~Act--The Food Act (31 P. S. §§ 20.1--20.18).~~

*Additive*--A food additive or a color additive.

*Adulterated*--Food with respect to which one or more of the following is accurate:

(i) The food bears or contains any poisonous or deleterious substance, which may render it injurious to health. However, if the substance is not an added substance, the food will not be considered adulterated if the quantity of the substance in the food does not ordinarily render it injurious to health.

(ii) The food bears or contains any added poisonous or added deleterious substance, which is unsafe within the meaning of section 11 of the ~~aet~~ FOOD ACT (31 P. S. §

20.11). This subparagraph does not apply to a pesticide chemical in or on a raw agricultural commodity, a food additive or a color additive.

(iii) The food is a raw agricultural commodity and bears or contains a pesticide chemical which is unsafe within the meaning of section 11 of the ~~aet~~ FOOD ACT, except that, when a pesticide chemical has been used in or on a raw agricultural commodity with an exception granted or tolerance prescribed under section 11 of the ~~aet~~ FOOD ACT or under any of the Federal acts and the raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating or milling, the residue of the pesticide remaining in or on the processed food will, notwithstanding section 11 of the ~~aet~~ FOOD ACT and this subparagraph, not be deemed unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity.

(iv) The food bears or contains any food additive, which is unsafe within the meaning of section 11 of the ~~aet~~ FOOD ACT or any of the Federal acts.

(v) The food consists in whole or in part of any diseased, contaminated, filthy, putrid or decomposed substance or is otherwise unfit for food.

(vi) The food has been produced, prepared, packed or held under unsanitary conditions so that it may have become contaminated with filth or may have been rendered diseased, unwholesome or injurious to health.

(vii) The food is, in whole or part, the product of a diseased animal or of an animal which has died otherwise than by slaughter.

(viii) The food is in a container composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health, unless the container is fabricated or manufactured with good manufacturing practices as that standard is defined and delineated by any of the Federal acts and their regulations.

(ix) The food has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption under section 11 of the ~~aet~~ FOOD ACT or under one of the Federal acts.

(x) The food has had any valuable constituent, in whole or part, omitted or abstracted therefrom.

(xi) The food has had any substance substituted wholly or in part.

(xii) Damage or inferiority of the food is concealed in any manner.

(xiii) A substance has been added to the food and it is mixed or packed so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is.

(xiv) The food bears or contains any color additive which is unsafe within the meaning of section 11 of the ~~aet~~ FOOD ACT or under one of the Federal acts.

(xv) The food bears or contains eggs processed by or egg products derived from a manufacturing, processing or preparing method wherein whole eggs are broken using a

centrifuge-type egg breaking machine that separates the egg's liquid interior from the shell.

*Approved*--Acceptable to the Department based on a determination of conformity with principles, practices and generally recognized standards PROVEN TO BE SCIENTIFICALLY SOUND that protect public health.

*Bed and breakfast homestead or inn*--A private residence which contains 10 or fewer bedrooms used for providing overnight accommodations to the public, and in which breakfast is the only meal served and is included in the charge for the room.

*Beverage*--A liquid for drinking, including water.

*Bottled drinking water*--Water that is sealed in bottles, packages or other containers and offered for sale for human consumption. The term includes bottled mineral water.

*CFR*— THE MOST-RECENTLY PUBLISHED EDITION OR REVISION OF THE CODE OF FEDERAL REGULATIONS, A COMPILATION OF THE GENERAL AND PERMANENT RULES PUBLISHED IN THE FEDERAL REGISTER BY THE EXECUTIVE DEPARTMENTS AND AGENCIES OF THE FEDERAL GOVERNMENT.

*CIP*--cleaned in place--

(i) Cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine.

(ii) The term does not include the cleaning of equipment such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

*CASING*—A TUBULAR CONTAINER FOR SAUSAGE PRODUCTS MADE OF EITHER NATURAL OR ARTIFICIAL (SYNTHETIC) MATERIAL.

*Certification number*--A unique combination of letters and numbers assigned by the Department or other shellfish control authority having jurisdiction to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

*Color additive*--A material which is a dye, pigment or other substance made by a process of synthesis or similar artifice or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source and when added or applied to a food is capable, alone or through reaction with other substances, of imparting color thereto.

(i) The term includes black, white and intermediate grays.

(ii) The term does not include materials, which the Secretary, by regulation, determines are used, or are intended to be used, solely for a purpose other than coloring.

(iii) The term does not include any pesticide chemical, soil or plant nutrient or other agricultural chemical solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly, the growth or otherwise natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

**COMMINGLE**--TO COMBINE SHELLSTOCK HARVESTED ON DIFFERENT DAYS OR FROM DIFFERENT GROWING AREAS AS IDENTIFIED ON THE TAG OR LABEL OR TO COMBINE SHUCKED SHELLFISH FROM CONTAINERS WITH DIFFERENT CONTAINER CODES OR DIFFERENT SHUCKING DATES.

**Comminuted**--A food that is reduced in size by methods including chopping, flaking, grinding or mincing. The term includes fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef and sausage; and a mixture of two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.

**Confirmed disease outbreak**--A foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness.

**Controlled atmosphere packaging**--A type of reduced oxygen packaging in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food and impermeable packaging material.

**Consumer**--A person, who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food facility OR FOOD PROCESSING PLANT, and does not offer the food for resale.

**Corrosion-resistant material**--A material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

**Critical control point**--A point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

**Critical limit**--The maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

**Department**--The Department of Agriculture of the Commonwealth.

**Drinking water, potable water or water**--Safe drinking water as defined in the Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1--721.17). The term does not include water such as boiler water, mop water, rainwater, wastewater and "nondrinking" water.

**Dry storage area**--A room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous and dry goods such as single service items.

**EPA**--The United States Environmental Protection Agency.

**Easily cleanable**--

(i) A characteristic of a surface that:

(A) Allows effective removal of soil by normal cleaning methods.

(B) Is dependent on the material, design, construction and installation of the surface.

(C) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose and use.

(ii) The term includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in subparagraph (i) to different situations in which varying degrees of cleanability are required, such as one of the following:

(A) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining.

(B) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

*Easily movable*--A unit of equipment that is both of the following:

(i) Portable; mounted on casters, gliders or rollers; or provided with a mechanical means to safely tilt the unit of equipment for cleaning.

(ii) Has no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

**EGG**—THE SHELL EGG OF THE DOMESTICATED CHICKEN, TURKEY, DUCK, GOOSE OR GUINEA.

**Employee**—The ~~permit~~, license or registration holder, person in charge, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food facility.

*Equipment*--

(i) An article that is used in the operation of a food facility such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine or warewashing machine.

(ii) The term does not include items used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks and skids.

**EXCLUDE**—TO PREVENT A PERSON FROM WORKING AS A FOOD EMPLOYEE OR ENTERING A FOOD FACILITY EXCEPT FOR THOSE AREAS OPEN TO THE GENERAL PUBLIC.

**FDA**--The United States Food and Drug Administration.

**FEDERAL ACTS**—THE WHOLESALE MEAT ACT (PUBLIC LAW 90-201, 21 U.S.C. § 601 ET SEQ.), THE FEDERAL FOOD, DRUG AND COSMETIC ACT (52 STAT. 1040, 21 U.S.C. § 301 ET SEQ.), THE POULTRY PRODUCTS INSPECTION ACT (PUBLIC LAW 85-172, 21 U.S.C. § 451 ET SEQ.), THE FAIR PACKAGING AND LABELING ACT (PUBLIC LAW 89-755, 15 U.S.C. § 1451 ET SEQ.), THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (61 STAT. 163, 7 U.S.C. § 136 ET SEQ.) AND THE NATIONAL LABELING AND EDUCATION ACT OF 1990 (PUBLIC LAW 101-535, 104 STAT. 2353).

**Fish**--The term includes:

(i) Fresh or saltwater finfish, crustaceans, all mollusks and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of those animals), other than birds or mammals, if the animal life is intended for human consumption.

(ii) The term includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.

**Food**--An article used for food or drink by humans, including chewing gum and articles used for components of any article. The term does not include medicines and drugs.

**Foodborne disease outbreak**--~~One of the following:~~

~~(i) An incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiological analysis implicates the food as the source of the illness.~~

~~(ii) An incident in which one or more persons experience illness from botulism or chemical poisoning~~ THE OCCURRENCE OF TWO OR MORE CASES OF A SIMILAR ILLNESS AFTER INGESTION OF A COMMON FOOD.

**Food-contact surface**--One of the following:

(i) A surface of equipment or a utensil with which food normally comes into contact.

(ii) A surface of equipment or a utensil from which food may drain, drip or splash into a food, or onto a surface normally in contact with food.

**FOOD ACT**—THE FOOD ACT (31 P. S. §§ 20.1--20.18).

**Food additive**--

(i) A substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, with respect to which one or more of the following is correct:

(A) The substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.

(B) The substance has been used in food prior to January 1, 1958, and is not generally recognized, among experts qualified by scientific training and experience to

evaluate its safety, as having been adequately shown through scientific procedures or experience based on common use in food, to be safe under the conditions of its intended use.

(ii) The term does not include the following:

(A) A pesticide chemical in or on a raw agricultural commodity.

(B) A pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity.

(C) A color additive.

(D) A substance used in accordance with a sanction or approval granted prior to the enactment of this subparagraph under a statute repealed by the act FOOD ACT, under the Poultry Products Inspection Act (21 U.S.C.A. §§ 451--471) or under the Wholesome Meat Inspection Act (21 U.S.C.A. §§ 476a--467f and 470).

(E) A new animal drug.

*Food employee*--An individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

*Food establishment*--

(i) A retail food store and a room, building or place or portion thereof or vehicle maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, baking, canning, freezing, packing or otherwise preparing or transporting or handling food.

(ii) The term includes those portions of public eating and drinking licensees which offer food for sale for off-premises consumption, except those portions of establishments operating exclusively under milk or milk products permits.

*Food facility*--A public eating or drinking place or a RETAIL food establishment. The term ~~includes food service facilities provided by an organized camp or campground~~ DOES NOT INCLUDE THE FOLLOWING:

(i) A FOOD SERVICE FACILITY PROVIDED BY OR AT AN ORGANIZED CAMP OR CAMPGROUND.

(ii) A FOOD SERVICE FACILITY PROVIDED BY OR AT A SCHOOL.

(iii) A FOOD SERVICE FACILITY AT AN INSTITUTION SUCH AS A NURSING HOME OR HOSPITAL.

(iv) ANY OTHER FOOD SERVICE FACILITY THAT IS NOT A PUBLIC EATING OR DRINKING PLACE.

(v) FOOD PROCESSING PLANTS, WAREHOUSING ESTABLISHMENTS AND OTHER FOOD ESTABLISHMENTS THAT:

(A) ARE NOT RETAIL FOOD ESTABLISHMENTS;

(B) DO NOT PROVIDE FOOD TO THE CONSUMER EITHER DIRECTLY OR INDIRECTLY (SUCH AS THROUGH THE HOME DELIVERY OF GROCERIES); AND

(C) COMPLY WITH APPLICABLE FEDERAL REGULATIONS.

*Food facility operator*--The entity that is legally responsible for the operation of the food facility, such as the owner, owner's agent or other person.

*Food facility premises*--The food facility, its contents and the contiguous land or property under the control of the food facility operator. If a food facility is a component of a larger operation, such as a hotel, motel, ~~school~~, shopping mall or ~~recreation camp~~ PUBLIC CAMPGROUND, and that larger operation is also under the control of the food facility operator, that larger operation is part of the food facility premises to the extent it may impact the food facility, its personnel or its operations.

*FOOD PROCESSING PLANT*-- A COMMERCIAL OPERATION THAT MANUFACTURERS, PACKAGES, LABELS, OR STORES FOOD FOR HUMAN CONSUMPTION AND DOES NOT PROVIDE FOOD DIRECTLY TO A CONSUMER. THE TERM DOES NOT INCLUDE A FOOD FACILITY.

*Game animal*--

(i) An animal, the products of which are food, that is not classified as any of the following:

(A) Fish, as that term is defined in this chapter.

(B) Cattle, sheep, swine, goat, horse, mule or other equine, as those terms are used in 9 CFR Chapter III, Subchapter A (relating to agency organization and terminology; mandatory meat and poultry products inspection and voluntary inspection and certification), ~~or any subsequent revision or restatement thereof.~~

(C) Poultry, as that term is used in 9 CFR Chapter III, Subchapter A (relating to ~~mandatory poultry products inspection) or any subsequent revision or restatement thereof~~ AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POULTRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION).

(D) Ratites, such as ostriches, emus or rheas.

(ii) The term includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

*General use pesticide*--A pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175 (relating to pesticides classified for restricted use), ~~or any subsequent revision or restatement thereof.~~

*HACCP--Hazard Analysis Critical Control Point*--A system developed by the National Advisory Committee on Microbiological Criteria for Foods that identifies and



monitors specific foodborne hazards that can adversely affect the safety of the food products.

*HACCP plan*--A written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

*Hazard*--A biological, chemical or physical property (SUCH AS THE PRESENCE OF PATHOGENS, PESTICIDES, NATURAL TOXINS, RODENT CONTAMINATION OR FOREIGN MATERIALS) that may cause an unacceptable consumer health risk.

*Hermetically sealed container*--A container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

*High humidity cooking*--Cooking in an oven that attains relative humidity of greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven, or cooking in a moisture-impermeable bag that provides 100% humidity.

*Highly susceptible population*--A group of persons who are more likely than other populations PEOPLE IN THE GENERAL POPULATION to experience foodborne disease because BOTH OF THE FOLLOWING CONDITIONS EXIST:

(i) ~~they are~~ THE GROUP IS COMPRISED OF immunocompromised PERSONS, PRESCHOOL-AGE CHILDREN OR OLDER ADULTS; AND

(ii) THE GROUP OBTAINS FOOD AT A FACILITY THAT PROVIDES SERVICES SUCH AS CUSTODIAL CARE, HEALTH CARE, ASSISTED LIVING SERVICES, NUTRITIONAL SERVICES OR SOCIALIZATION SERVICES. EXAMPLES OF FACILITIES PROVIDING SUCH SERVICES INCLUDE CHILD OR ADULT DAY CARE CENTERS, HEALTH CARE CENTERS, ASSISTED LIVING FACILITIES, HOSPITALS, NURSING HOMES, KIDNEY DIALYSIS CENTERS AND SENIOR CENTERS.

*HONESTLY PRESENTED*—FOOD OFFERED FOR HUMAN CONSUMPTION IN A WAY THAT DOES NOT MISLEAD OR MISINFORM THE CONSUMER, AND WITHOUT MISREPRESENTING THE TRUE APPEARANCE, COLOR OR QUALITY OF THE FOOD THROUGH THE USE OF FOOD OR COLOR ADDITIVES, COLORED OVERWRAPS, LIGHTING OR OTHER MEANS.

*Imminent health hazard*--A significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on one or more of the following:

(i) The number of potential injuries.

(ii) The nature, severity and duration of the anticipated injury.

*Injected*--Manipulating a meat so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the meat such as with juices which may be referred to as "injecting," "pinning" or "stitch pumping."

*Juice*--When used in the context of food safety, the term refers to the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate of the liquid or purée. THE TERM INCLUDES JUICE AS A WHOLE BEVERAGE, AN INGREDIENT OF A BEVERAGE, AND A PUREE AS AN INGREDIENT OF A BEVERAGE. This definition does not apply to standards of identity established by the FDA or USDA.

*Kitchenware*--Food preparation and storage utensils.

*LICENSE* --A GRANT TO A LICENSEE TO OPERATE A PUBLIC EATING OR DRINKING PLACE, AS DEFINED IN THE PUBLIC EATING AND DRINKING PLACES LAW.

*LICENSOR*-THE COUNTY DEPARTMENT OF HEALTH OR JOINT-COUNTY DEPARTMENT OF HEALTH, WHENEVER SUCH PUBLIC EATING OR DRINKING PLACE IS LOCATED IN A POLITICAL SUBDIVISION WHICH IS UNDER THE JURISDICTION OF A COUNTY DEPARTMENT OF HEALTH OR JOINT-COUNTY DEPARTMENT OF HEALTH, OR THE HEALTH AUTHORITIES OF CITIES, BOROUGH, INCORPORATED TOWNS AND FIRST-CLASS TOWNSHIPS, WHENEVER SUCH PUBLIC EATING OR DRINKING PLACE IS LOCATED IN A CITY, BOROUGH, INCORPORATED TOWN OR FIRST-CLASS TOWNSHIP NOT UNDER THE JURISDICTION OF A COUNTY DEPARTMENT OF HEALTH OR JOINT-COUNTY DEPARTMENT OF HEALTH, OR THE HEALTH AUTHORITIES OF SECOND CLASS TOWNSHIPS AND SECOND CLASS TOWNSHIPS WHICH HAVE ADOPTED A HOME RULE CHARTER WHICH ELECT TO ISSUE SUCH LICENSES UNDER THE PROVISIONS OF THE PUBLIC EATING AND DRINKING PLACES LAW WHENEVER SUCH PUBLIC EATING AND DRINKING PLACE IS LOCATED IN SUCH SECOND CLASS TOWNSHIP OR SECOND CLASS TOWNSHIP WHICH HAS ADOPTED A HOME RULE CHARTER NOT UNDER THE JURISDICTION OF A COUNTY DEPARTMENT OF HEALTH OR JOINT-COUNTY DEPARTMENT OF HEALTH, OR THE DEPARTMENT, WHENEVER SUCH PUBLIC EATING AND DRINKING PLACE IS LOCATED IN ANY OTHER AREA OF THE COMMONWEALTH.

*Linens*--Fabric items such as cloth hampers, cloth napkins, tablecloths, wiping cloths and work garments, including cloth gloves.

*mg/L*--Milligrams per liter, which is the metric equivalent of parts per million (ppm).

*Meat*--The flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals. The term does not include fish, poultry and wild game animals as specified under § 46.221(b) and (c) (relating to game animals).

*Milk Sanitation Law*--The act of July 2, 1935 (P. L. 589, No. 210) (31 P. S. §§ 645--660e).

**MOBILE FOOD FACILITY**—ANY STATIONARY, MOVABLE, OR TEMPORARY FOOD FACILITY – SUCH AS A STAND, VEHICLE, CART, BASKET, BOX OR SIMILAR STRUCTURE FROM WHICH FOOD IS STORED, PREPARED, PROCESSED, DISTRIBUTED, OR SOLD – WHICH PHYSICALLY LOCATES AT ONE SITE OR LOCATION FOR NO MORE THAN 14 CONSECUTIVE DAYS, WHETHER OPERATING CONTINUOUSLY OR NOT DURING THIS TIME. A FOOD FACILITY THAT IS PHYSICALLY LOCATED AT ANY ONE SITE FOR MORE THAN 14 CONSECUTIVE DAYS SHALL NOT BE CONSIDERED A MOBILE FOOD FACILITY.

*Modified atmosphere packaging--*

(i) A type of reduced oxygen packaging in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food.

(ii) The term includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen.

*Molluscan shellfish*--An edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

**NONPUBLIC WATER SUPPLY**-A SYSTEM FOR THE PROVISION OF PIPED WATER FOR HUMAN CONSUMPTION THAT IS NOT A PUBLIC WATER SYSTEM.

**OTHER FOOD REGULATORY AGENCY**-LOCAL BODIES, STATE BODIES OTHER THAN THE COMMONWEALTH, OR FEDERAL ENFORCEMENT BODIES HAVING JURISDICTION OVER A FOOD ESTABLISHMENT OR FOOD PROCESSING PLANT. EXAMPLES INCLUDE USDA WITH RESPECT TO MOST MEAT PROCESSING PLANTS WITHIN THE COMMONWEALTH AND FDA HAVING JURISDICTION OVER FOOD PRODUCTS IMPORTED FROM OTHER COUNTRIES.

*pH*--The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

*Packaged--*

(i) Bottled, canned, cartoned, securely bagged or securely wrapped in a food facility OR A FOOD PROCESSING PLANT.

(ii) The term does not include a wrapper, carryout box or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer.

*Pennsylvania Construction Code Act*--35 P. S. §§ 7210.101--7210.1103.

*PENNSYLVANIA SEWAGE FACILITIES ACT*- 35 P.S. §§ 750.1-750.20a.

**PERMANENT FOOD FACILITY**--A FOOD FACILITY -- WHETHER STATIONARY OR MOBILE -- THAT IS NOT A TEMPORARY FOOD FACILITY OPERATING MORE THAN FOURTEEN DAYS IN A SINGLE CALENDAR YEAR -- WHETHER THESE DAYS ARE CONSECUTIVE OR NOT.

**Person**--A corporation, partnership, limited liability company, business trust, other association, government entity (other than the Commonwealth), estate, trust, foundation or natural person.

**Person in charge**--The individual present at a food facility responsible for the operation at the time of inspection.

**Personal care items**--

- (i) Items or substances that may be poisonous, toxic or a source of contamination and are used to maintain or enhance a person's health, hygiene or appearance.
- (ii) The term includes items such as medicines, first aid supplies, cosmetics, toiletries (such as toothpaste and mouthwash) and similar items.

**Physical facilities**--The structure and interior surfaces of a food facility, including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

**Plumbing fixture**--A receptacle or device that is one or more of the following:

- (i) Permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system.
- (ii) Discharges used water, waste materials or sewage directly or indirectly to the drainage system of the premises.

**Plumbing system**--The water supply and distribution pipes; plumbing fixtures and traps; soil, waste and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices and appurtenances within the premises; and water-treating equipment.

**Poisonous or toxic material**--A substance that is not intended for ingestion and that fits within one or more of the following categories:

- (i) Cleaners and sanitizers, including cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes and other chemicals.
- (ii) Pesticides.
- (iii) Substances necessary for the operation and maintenance of the establishment, such as nonfood grade lubricants, solvents and personal care items that may be deleterious to health.
- (iv) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

**Potentially hazardous food**--

(i) A food which consists in whole or part of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustacea or other ingredients, including synthetic ingredients INGREDIENTS, which is in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms.

(ii) The term does not include foods that have a pH level of 4.6 or below or a water activity of 0.85 or less under standard conditions or food products in hermetically sealed containers processed to maintain commercial sterility.

*Poultry*--One or more of the following:

(i) A domesticated bird (chickens, turkeys, ducks, geese or guineas), whether live or dead, as defined in 9 CFR Chapter III, Subchapter A, Part 381 (RELATING TO POULTRY PRODUCTS INSPECTION REGULATIONS) ~~or any subsequent revision or restatement thereof.~~

(ii) A migratory waterfowl; OR game bird, ~~or squab~~ such as pheasant, partridge, quail, grouse ~~or~~, guineas, PIGEON OR SQUAB, whether live or dead, as defined in the USDA regulations in 9 CFR Chapter III, Subchapter A, Part 362 (relating to voluntary poultry inspection program) ~~or any subsequent revision or restatement thereof~~ REGULATIONS).

(iii) The term does not include ratites.

*Primal cut*--A basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank or veal breast.

~~*Private water system*--A system for the provision of piped water for human consumption that is not a public water system.~~

*Public Eating and Drinking Place PLACES Law*- The act of May 23, 1945 (P. L. 926, No. 369) (35 P. S. §§ 655.1--655.13).

~~*Public eating and drinking places license*--A grant to a licensee to conduct a public eating and drinking place as defined in the Public Eating and Drinking Place Law.~~

*Public eating or drinking place*--

(i) A place within this Commonwealth where food or drink is served to or provided for the public, with or without charge.

(ii) This ~~provisions~~ PROVISION does NOT apply to dining cars operated by a railroad company in interstate commerce or a bed and breakfast homestead or inn.

*Public water system*--A system which provides water to the public for human consumption, and which has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year, OR AS OTHERWISE SPECIFIED IN THE REGULATION AT 25 PA. CODE CHAPTER 109 (RELATING TO SAFE DRINKING WATER).

(i) The term includes collection, treatment, storage and distribution facilities under control of the operator of the system and used in connection with the system.

(ii) The term also includes a system which provides water for bottling or bulk hauling for human consumption.

*Ratite*--An animal belonging to the same family as ostriches, emus and rheas.

*Ready-to-eat food*—ANY OF THE FOLLOWING TYPES OF FOOD:

(i) Food in a form that is ~~edible without [washing, cooking or ]~~ EDIBLE WITHOUT additional preparation ~~by the food facility or the consumer, and that is reasonably expected to be consumed in that form,~~ TO ACHIEVE FOOD SAFETY, SUCH AS RAW ANIMAL-DERIVED FOODS THAT HAVE BEEN COOKED IN ACCORDANCE WITH § 46.361 (RELATING TO COOKING RAW ANIMAL-DERIVED FOODS) OR § 46.362 (RELATING TO MICROWAVE COOKING), OR FISH THAT HAVE BEEN FROZEN IN ACCORDANCE WITH § 46.364 (RELATING TO PARASITE DESTRUCTION IN FISH OTHER THAN MOLLUSCAN SHELLFISH BY FREEZING), ALTHOUGH ADDITIONAL PREPARATION MAY OCCUR FOR PALATABILITY OR AESTHETIC, EPICUREAN, GASTRONOMIC OR CULINARY PURPOSES.

(ii) ~~The term includes: (A) Unpackaged potentially hazardous food that is cooked to the temperature and time required for the specific food under § 46.361 (relating to cooking raw animal foods):~~ FOOD THAT IS RAW OR PARTIALLY-UNDERCOOKED ANIMAL-DERIVED FOOD, WHERE THE FOOD FACILITY OFFERING THE FOOD HAS COMPLIED WITH THE PROVISIONS OF PARAGRAPH 46.361(D)(1) (RELATING TO COOKING RAW ANIMAL-DERIVED FOODS) AND THE CONSUMER NOTIFICATION REQUIREMENTS OF § 46.423 (RELATING TO CONSUMER ADVISORY REQUIRED WITH RESPECT TO ANIMAL-DERIVED FOODS THAT ARE RAW, UNDERCOOKED OR NOT OTHERWISE PROCESSED TO ELIMINATE PATHOGENS), ALTHOUGH ADDITIONAL PREPARATION MAY OCCUR FOR PALATABILITY OR AESTHETIC, EPICUREAN, GASTRONOMIC OR CULINARY PURPOSES.

(III) FOOD THAT IS PREPARED IN ACCORDANCE WITH A VARIANCE ISSUED BY THE DEPARTMENT UNDER §§ 46.361(d)(2) AND 46.1103 (RELATING TO VARIANCES), ALTHOUGH ADDITIONAL PREPARATION MAY OCCUR FOR PALATABILITY OR AESTHETIC, EPICUREAN, GASTRONOMIC OR CULINARY PURPOSES.

~~(B)~~ (IV) Raw, ~~washed, cut~~ fruits and vegetables THAT ARE WASHED IN ACCORDANCE WITH §46.285 (RELATING TO WASHING RAW FRUITS AND VEGETABLES).

~~(C) Whole, raw fruits and vegetables that are presented for consumption without the need for further washing, such as at a buffet.~~

(V) FRUITS AND VEGETABLES THAT ARE COOKED FOR HOT HOLDING IN ACCORDANCE WITH § 46.363 (RELATING TO PLANT FOOD COOKING FOR HOT HOLDING).

(VI) POTENTIALLY HAZARDOUS FOOD THAT IS COOKED IN ACCORDANCE WITH THE TIME AND TEMPERATURE REQUIREMENTS FOR THAT SPECIFIC FOOD IN §§ 46.361 - 46.363, AND THAT IS COOLED AS SPECIFIED IN § 46.384.

~~(D)~~ (VII) ~~Other food presented for consumption for~~ PLANT FOOD WITH RESPECT TO which further washing, ~~or~~ cooking OR OTHER PROCESSING is not required FOR

FOOD SAFETY, and from which rinds, peels, husks or shells (IF NATURALLY PRESENT) are removed.

*Reduced oxygen packaging--*

(i) The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding 21% oxygen atmosphere.

(ii) A process as specified in subparagraph (i) that involves a food for which *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form.

(iii) The term includes vacuum packaging, modified atmosphere packaging and controlled atmosphere packaging.

*Refuse--*Solid waste not carried by water through the sewage system.

**REGISTRATION**—A GRANT TO A PERSON TO OPERATE A FOOD ESTABLISHMENT WITHIN THE COMMONWEALTH AS REQUIRED BY SECTION 14 OF THE FOOD ACT (31 P.S. §20.14).

*Reg. Penna. Dept. Agr.--*An abbreviation connoting that a food bearing that abbreviation on its package label has been processed by a food facility ESTABLISHMENT that is "registered with the Pennsylvania Department of Agriculture" in accordance with section 14(a) of the act FOOD ACT (31 P. S. § 20.14(a)).

**RESTRICT**—TO LIMIT THE ACTIVITIES OF A FOOD EMPLOYEE SO THAT THERE IS NO RISK OF TRANSMITTING A DISEASE THAT IS TRANSMISSIBLE THROUGH FOOD AND THE FOOD EMPLOYEE DOES NOT WORK WITH EXPOSED FOOD, CLEAN EQUIPMENT, UTENSILS, LINENS, AND UNWRAPPED SINGLE-SERVICE OR SINGLE-USE ARTICLES.

**RESTRICTED EGG**—ANY CHECK, DIRTY EGG, INCUBATOR REJECT, INEDIBLE, LEAKER, OR LOSS AS DEFINED IN CHAPTER 87 (RELATING TO STANDARDS FOR GRADING AND MARKETING EGGS).

*Restricted use pesticide--*A pesticide classified for restricted use under section 3(d) of the Federal Insecticide, Fungicide and Rodenticide Act of 1947 (7 U.S.C.A. § 136(d)), or a pesticide designated by the Secretary for restricted use under section 7(b)(6) of the Pennsylvania Pesticide Control Act of 1973 (3 P. S. § 111.27(b)(6)).

**RETAIL FOOD ESTABLISHMENT**—A FOOD ESTABLISHMENT WHICH STORES, PREPARES, PACKAGES, VENDS, OFFERS FOR SALE, OR OTHERWISE PROVIDES FOOD FOR HUMAN CONSUMPTION AND WHICH RELINQUISHES POSSESSION OF FOOD TO A CONSUMER DIRECTLY, OR INDIRECTLY THROUGH A DELIVERY SERVICE SUCH AS HOME DELIVERY OF GROCERY ORDERS OR DELIVERY SERVICE PROVIDED BY COMMON CARRIERS.

**RISK**—THE LIKELIHOOD THAT AN ADVERSE HEALTH EFFECT WILL OCCUR WITHIN A POPULATION AS A RESULT OF A HAZARD IN A FOOD.

*Safe material*--One or more of the following:

(i) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food.

(ii) An additive that is used as specified in section 409 or section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301 and 376).

(iii) A material that is not an additive and that is used in conformity with applicable regulations of the FDA.

*Sanitization*--The application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

*Sealed*--Free of cracks or other openings that allow the entry or passage of moisture.

*Service animal*--An animal such as a guide dog, signal dog or other animal individually trained to provide assistance to an individual with a disability.

*Secretary*--The Secretary of the Department or an authorized representative, employee or agent of the Department.

*Servicing area*--An operating base location to which a mobile food facility or transportation vehicle returns regularly for things such as discharging liquid or solid wastes, refilling water tanks and ice bins and boarding food.

*Sewage*--A substance, which contains waste products or excrements or other discharges from the bodies of human beings or animals and any noxious or deleterious substance being harmful or inimical to the public health, or to animal or aquatic life, or to the use of water for domestic water supply or for recreation.

*Shellfish control authority*--A State, Federal, foreign, tribal or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.

*Shellfish permit*--A permit issued by the Department in accordance with ~~this chapter~~ CHAPTER 49 (RELATING TO SHELLFISH) and the National Shellfish Sanitation Program, that authorizes a person to operate a food establishment for shellfish.

*Shellfish permit holder*--The entity that meets the following conditions:

(i) Is legally responsible for the operation of the food ~~facility~~ ESTABLISHMENT such as the owner, owner's agent or other person.

(ii) Possesses a valid shellfish permit to operate a shellfish food ~~facility~~ ESTABLISHMENT.

*Shellstock*--Raw, in-shell molluscan shellfish.

**SHIGA TOXIN-PRODUCING ESCHERICHIA COLI**--ANY *E. COLI* CAPABLE OF PRODUCING SHIGA TOXINS, ALSO CALLED VEROCYTOTOXINS OR SHIGA-LIKE TOXINS. THIS INCLUDES, BUT IS NOT LIMITED TO, *E. COLI* SEROTYPES O157:H7, O157:NM, AND O157:H.



*Shucked shellfish*--Molluscan shellfish that have one or both shells removed.

*Single-service articles*--Tableware, carry-out utensils and other items such as bags, containers, place mats, stirrers, straws, toothpicks and wrappers that are designed and constructed for one time, one person consumer use after which they are intended for discard.

*Single-use articles*--

(i) Utensils and bulk food containers designed and constructed to be used once and discarded.

(ii) The term includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles and number 10 cans which do not meet the materials, durability, strength and cleanability specifications in §§ 46.521(a), 46.541(a) and 46.542(a) and (b) (relating to materials in multiuse utensils and food-contact surfaces; durability and strength; and cleanability of multiuse food-contact surfaces and CIP equipment) for multiuse utensils.

(iii) The term does not include formed aluminum containers, used in conjunction with pan liners that may be reused to cook nonpotentially hazardous baked goods.

*Slacking*--The process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -23°C (-10°F) to -4° C (25°F) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach.

*Smooth*--One or more of the following:

(i) A food-contact surface having a surface free of pits and inclusions with cleanability equal to or exceeding that of (100 grit) number-3 stainless steel.

(ii) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale.

(iii) A floor, wall or ceiling having an even or level surface with no roughness or projections that renders it difficult to clean.

*Substance*--A substance MATERIAL intended for use in producing, manufacturing, packaging, processing, preparing, treating, transporting or holding food and any source of radiation intended for any use.

*Sulfiting agent*--A substance which imparts a residual of sulfur dioxide.

*Table-mounted equipment*--Equipment that is not portable and is designed to be mounted off the floor on a table, counter or shelf.

*Tableware*--Eating, drinking and serving utensils for table use such as plates, flatware (including forks, knives, and spoons) and hollowware (including bowls, cups, serving dishes and tumblers).

*Temperature measuring device*--A thermometer, thermocouple, thermistor or other device that indicates the temperature of food, air or water.

*Temporary food facility*--A food facility that operates for a period of no more than 14 CONSECUTIVE days IN A FIXED LOCATION AND ~~a year utilizing a permanent~~

facility or in conjunction with a single event or celebration (SUCH AS A FAIR, FESTIVAL, CARNIVAL OR OTHER TRANSITORY GATHERING).

*TEMPORARY LICENSE*—EITHER OF THE FOLLOWING:

(I) A LICENSE THAT IS:

- (A) ISSUED TO THE OPERATOR OF A TEMPORARY FOOD FACILITY;
- (B) VALID FOR THE DURATION OF A PARTICULAR EVENT OR CELEBRATION (SUCH AS A FAIR OR CARNIVAL) OF NO MORE THAN 14 DAYS' DURATION (WHETHER THESE DAYS ARE CONSECUTIVE OR NON-CONSECUTIVE); AND
- (C) ISSUED TO THE OPERATOR WITH RESPECT TO NO MORE THAN THREE SUCH EVENTS OR CELEBRATIONS IN A PARTICULAR CALENDAR YEAR.

(II) A LICENSE THAT IS:

- (A) ISSUED TO A FOOD FACILITY OPERATOR OPERATING A FOOD FACILITY, WHETHER STATIONARY OR MOBILE;
- (B) THAT IS IN OPERATION FOR A TOTAL OF NO MORE THAN 14 DAYS WITHIN A PARTICULAR CALENDAR YEAR; AND
- (C) THAT IS NOT IN CONJUNCTION WITH AN EVENT OR CELEBRATION.

*USDA*--The United States Department of Agriculture.

*Utensil*--A food-contact implement or container used in the storage, preparation, transportation, dispensing, sale or service of food. The term includes the following:

- (i) Kitchenware or tableware that is multiuse, single-service or single-use.
- (ii) Gloves used in contact with food.
- (iii) ~~Food~~ THE TEMPERATURE SENSING PROBES OF FOOD temperature measuring devices.
- (iv) Probe-type price or identification tags used in contact with food.

*UTILITY SINK*--A SINK USED FOR THE DISPOSAL OF MOP WATER OR OTHER SIMILAR LIQUID WASTE.

*Vacuum packaging*--A type of reduced oxygen packaging in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package, such as sous vide.

*Variance*--A written document issued by the Department that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the Department, a health hazard or nuisance will not result from the modification or waiver.

*Vending machine*--A self-service device that, upon insertion of a coin, paper currency, token, card or key, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

*Vending machine location*--The room, enclosure, space or area where one or more vending machines are installed and operated. The term includes the storage areas and areas on the premises that are used to service and maintain the vending machines.

*Warewashing*--The cleaning and sanitizing of food-contact surfaces of equipment and utensils.

*Water activity or  $a_w$* --A measure of the free moisture in a food, obtained by dividing the water vapor pressure of the substance by the vapor pressure of pure water at the same temperature. Water activity is typically indicated by the symbol  $a_w$ .

*Water for human consumption*--The term includes water that is used for drinking, bathing and showering, cooking, dishwashing or maintaining oral hygiene.

*Whole-muscle, intact beef*--Whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

## **Subchapter B. MANAGEMENT AND PERSONNEL**

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### **PERSONAL CLEANLINESS**

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## **SUPERVISION**

### **§ 46.101. Designation of person in charge.**

The food facility 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 food facility during all hours of operation.

### **§ 46.102. Duties of the person in charge.**

The person in charge shall perform the following duties:

(1) Ensure that food facility operations are not conducted in a private home where the food facility has not been approved by the Department, or in a room used as living or sleeping quarters as specified in § 46.922(k) (relating to functionality of various physical facilities of a food facility).

(2) Ensure that persons unnecessary to the food facility operation are not allowed in the food preparation, food storage or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, linens and unwrapped single-service and single-use articles are protected from contamination.

(3) Ensure that employees and other persons (such as delivery and maintenance persons and pesticide applicators) entering the food preparation, food storage and warewashing areas comply with this chapter.

(4) Routinely monitor employee handwashing to ensure that employees effectively clean their hands.

(5) Routinely monitor employee observations and periodically evaluate foods upon receipt to ensure that employees visibly observe foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated and accurately presented.

(6) Conduct daily oversight of the employees' routine monitoring of cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated in accordance with §§ 46.561 and 46.691(b) (relating to accuracy of temperature measuring devices for food; and to utensils and temperature and pressure measuring devices: repair and calibration), to ensure the employees are properly cooking potentially hazardous food, and are being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats.

(7) Conduct daily oversight of the employees' routine monitoring of food temperatures during cooling, to ensure that employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours.

(8) Ensure that consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed, in accordance with § 46.423 (relating to consumer advisory required with respect to ~~animal~~ ANIMAL-DERIVED foods that are raw, undercooked or

not otherwise processed to eliminate pathogens), that the food is not cooked sufficiently to ensure its safety.

(9) Routinely monitor solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing, to ensure that employees properly sanitize cleaned multiuse equipment and utensils before they are reused.

(10) Ensure that consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets, in accordance with § 46.306 (relating to using clean tableware for second portions and refills).

(11) Ensure that employees prevent cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils. ~~These utensils may include,~~ SUCH AS deli tissue, spatulas, tongs, single-use gloves or dispensing equipment, OR BY FOLLOWING A PROCEDURE APPROVED UNDER § 46.261(D) (RELATING TO PREVENTING CONTAMINATION FROM FOOD EMPLOYEES' HANDS).

(12) Ensure that employees are properly trained in food safety as it relates to their assigned duties.

## **EMPLOYEE HEALTH**

### **§ 46.111. Duty to report disease or medical condition.**

(a) *Responsibility of a food facility operator to require reporting.* A food facility operator shall require a food employee and a food employee applicant to whom a conditional offer of employment is made to report to the person in charge, information about their health and activities as they relate to diseases described in § 46.112 (relating to diseases or medical conditions that must be reported) or diseases that are transmissible through food.

(b) *Responsibility of a person in charge to report information to Department.* The person in charge shall notify the Department that a food employee is diagnosed with an illness due to *Salmonella typhi*, *Shigella* spp., SHIGA TOXIN-PRODUCING *Escherichia coli*, O157:H7 or hepatitis A virus.

(c) *Responsibilities of a food employee or food employee applicant.* A food employee or a person who applies for a job as a food employee shall report to the person in charge the information specified in this section in a manner that allows the person in charge to prevent the likelihood of foodborne disease transmission. This information includes the date of onset of jaundice or the date of onset of any illness or condition specified in § 46.112.

### **§ 46.112. Diseases or medical conditions that must be reported.**

A food employee or food employee applicant shall report the following diseases, or medical conditions OR SPECIAL CIRCUMSTANCES to the person in charge:

(1) A diagnosis of an illness due to any of the following:

(i) *Salmonella typhi*.

(ii) *Shigella* spp.

(iii) SHIGA TOXIN-PRODUCING *Escherichia coli* O157:H7.

(iv) Hepatitis A virus.

(2) A past illness from any of the ~~infectious agents listed in paragraph (1)~~  
FOLLOWING:

(I) SALMONELLA TYPHI WITHIN THE PAST THREE MONTHS.

(II) SHIGELLA SPP. WITHIN THE PAST MONTH.

(III) SHIGA TOXIN-PRODUCING ESCHERICHIA COLI WITHIN THE LAST MONTH.

(IV) HEPATITIS A VIRUS.

(3) A symptom caused by illness, infection or other source, where that symptom is associated with an acute gastrointestinal illness such as any of the following:

(i) Diarrhea.

(ii) Fever.

(iii) Vomiting.

(iv) Jaundice.

(v) Sore throat with fever.

(4) A lesion containing pus such as a boil or infected wound that is open or draining and is any of the following:

(i) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover.

(ii) On exposed portions of the arms, unless the lesion is protected by an impermeable cover.

(iii) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage.

(5) ~~Is~~ THE FOOD EMPLOYEE OR FOOD EMPLOYEE APPLICANT IS suspected of causing a confirmed disease outbreak caused by *S. typhi*, *Shigella* spp., ~~*E. coli*~~ O157:H7 SHIGA TOXIN-PRODUCING ESCHERICHIA COLI or hepatitis A virus, including an outbreak at an event such as a family meal, church supper or festival because the food employee or applicant prepared food implicated in the outbreak.

(6) ~~Is~~ THE FOOD EMPLOYEE OR FOOD EMPLOYEE APPLICANT IS suspected of being exposed to a confirmed disease outbreak caused by *S. typhi*, *Shigella* spp., ~~*E. coli*~~ O157:H7 SHIGA TOXIN-PRODUCING ESCHERICHIA COLI, or hepatitis A virus, including an outbreak at an event such as a family meal, church supper or festival because the food employee or applicant did either of the following:

(i) Consumed food implicated in the outbreak.

(ii) Consumed food at the event prepared by a person who is infected or ill with the infectious agent that caused the outbreak or who is suspected of being a shedder of the infectious agent.

(7) ~~Lives~~ THE FOOD EMPLOYEE OR FOOD EMPLOYEE APPLICANT LIVES in the same household as a person who is diagnosed with a disease caused by *S. typhi*, *Shigella* spp., ~~*E. coli* 0157:H7~~ SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* or hepatitis A virus, AND KNOWS OF THAT DIAGNOSIS.

(8) ~~Lives~~ THE FOOD EMPLOYEE OR FOOD EMPLOYEE APPLICANT LIVES in the same household as a person who attends or works in a setting where there is a confirmed disease outbreak caused by *S. typhi*, *Shigella* spp., ~~*E. coli* 0157:H7~~ SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* or hepatitis A virus, AND KNOWS OF THAT OUTBREAK.

**§ 46.113. Duty to impose exclusions and restrictions.**

(a) *General exclusions and restrictions.* A person in charge shall impose the following exclusions and restrictions:

(1) Exclude a food employee from a food facility if the food employee is diagnosed with an infectious agent specified in § 46.112(1) (relating to diseases or medical conditions that must be reported).

(2) Restrict a food employee from working with exposed food; clean equipment, utensils, linens and unwrapped single-service and single-use articles, in a food facility if the food employee is either of the following:

(i) Experiencing a symptom specified in § 46.112(3) or (4).

(ii) Not experiencing a symptom of acute gastroenteritis specified in § 46.112(3), but has a stool that yields a specimen culture that is positive for *Salmonella typhi*, *Shigella* spp. or SHIGA TOXIN-PRODUCING *Escherichia coli* ~~0157:H7~~.

(b) *Special exclusions with respect to a food employee who is jaundiced.* If a food employee is jaundiced, the person in charge shall exclude the food employee as a food handler until 7 days after the onset of jaundice. If a food employee is jaundiced more than 7 days after onset, the person in charge shall restrict the food employee from working with exposed food and clean equipment, utensils, linens and unwrapped single service and single use articles in a food facility.

(c) *Special exclusions with respect to a food facility serving a highly susceptible population.* If the population served by the food facility is a highly susceptible population, a person in charge shall impose any exclusions or restrictions required under subsection (a) and also exclude a food employee from the food facility if the food employee is any of the following:

(1) Experiencing a symptom of acute gastrointestinal illness specified in § 46.112(3) and meets any of the high-risk conditions specified in § 46.112(5), (6), (7) or (8).

(2) Is not experiencing a symptom of acute gastroenteritis specified in § 46.112(3), but has a stool that yields a specimen culture that is positive for *S. typhi*, *Shigella* spp. or SHIGA TOXIN-PRODUCING *Escherichia coli* ~~0157:H7~~.

(3) Had a past illness from *S. typhi* within the last 3 months.

(4) Had a past illness from *Shigella* spp. or ~~*E. coli* 0157:H7~~ SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* within the last month.

(5) Jaundiced, regardless of the time of onset.

**§ 46.114. Duty to comply with exclusions and restrictions.**

A food employee or a person who applies for a job as a food employee shall comply with exclusions and restrictions that are imposed by the person in charge under authority of § 46.113 (relating to duty to impose exclusions and restrictions).

**§ 46.115. Removing exclusions and restrictions.**

(a) *Disease or medical condition described in § 46.112(1).* A person in charge ~~may~~ SHALL NOT remove an exclusion imposed as a result of a disease or medical condition described in § 46.112(1) (relating to diseases or medical conditions that must be reported) ~~if~~ UNLESS the excluded person provides the person in charge written medical documentation specifying that the excluded person may work in an unrestricted capacity in a food facility, including a facility that serves a highly susceptible population, because the person is free of the infectious agent of concern. This documentation shall be from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician assistant.

(b) *Disease or medical condition with respect to which restrictions are imposed under § 46.113(a)(2)(i).* A person in charge ~~may~~ SHALL NOT remove a restriction imposed under authority of § 46.113(a)(2)(i) (relating to duty to impose exclusions and restrictions) as a result of a disease or medical condition ~~if any~~ UNLESS AT LEAST ONE of the following are accurate:

(1) The person is free of the symptoms specified in § 46.112(3) and (4), and no foodborne illness occurs that may have been caused by the restricted person.

(2) The person is suspected of causing foodborne illness, but both of the following are true:

(i) The person is free of the symptoms specified in § 46.112(3) and (4).

(ii) The person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician assistant, stating that the restricted person is free of the infectious agent that is suspected of causing the person's symptoms or causing foodborne illness.

(3) The restricted person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician assistant stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome or ulcerative colitis.

(c) *Disease or medical condition with respect to which restrictions are imposed under authority of § 46.113(a)(2)(ii).* A person in charge ~~may~~ SHALL NOT remove a restriction imposed as a result of a disease or medical condition imposed under authority of § 46.113(a)(2)(ii) ~~if~~ UNLESS the restricted person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician assistant that indicates the restricted person's stools are free from Salmonella typhi, Shigella spp. or SHIGA TOXIN-PRODUCING Escherichia coli O157:H7--whichever is the infectious agent of concern.



(d) *Disease or medical condition with respect to which exclusions or restrictions are imposed under authority of § 46.113(b).* A person in charge ~~may~~ SHALL NOT remove an exclusion or restriction imposed as a result of a disease or medical condition described in § 46.113(b) if UNLESS the excluded or restricted person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician's assistant that specifies that the person is free of hepatitis A virus.

(e) *Disease or medical condition with respect to which exclusions are imposed under authority of § 46.113(c).* A person in charge ~~may~~ SHALL NOT remove an exclusion imposed with respect to a food facility serving a highly susceptible population as a result of a disease or medical condition described in § 46.113(c) if UNLESS the restricted person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician's assistant that states, as applicable, that the person is:

- (1) Free of the infectious agent of concern.
- (2) Free of jaundice, if hepatitis A virus is the infectious agent of concern.
- (3) Experiencing symptoms resulting from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome or ulcerative colitis.

## **PERSONAL CLEANLINESS**

### **§ 46.131. Cleanliness of hands and exposed portions of arms.**

(a) *Responsibility of food employees.* Food employees shall keep their hands and exposed portions of their arms clean.

(b) *Cleaning procedure.*

(1) *General procedure.* Except as specified in paragraph (2), food employees shall clean their hands and exposed portions of their arms ~~with (OR SURROGATE PROSTHETIC DEVICES FOR HANDS OR ARMS) FOR AT LEAST 20 SECONDS USING a cleaning compound in a lavatory HANDWASHING SINK that is equipped as specified in § 46.822(b) (relating to design, construction and installation of plumbing systems) by vigorously rubbing together the surfaces of their lathered hands and arms for at least 20 seconds and thoroughly rinsing with clean water~~ BY USING THE FOLLOWING CLEANING PROCEDURE:

(I) CREATE VIGOROUS FRICTION ON THE SURFACES OF THE LATHERED FINGERS, FINGER TIPS, AREAS BETWEEN THE FINGERS, HANDS AND ARMS (OR BY VIGOROUSLY RUBBING THE SURROGATE PROSTHETIC DEVICES FOR HANDS AND ARMS) FOR AT LEAST 10 – 15 SECONDS.

(II) THOROUGHLY RINSE UNDER CLEAN RUNNING, WARM WATER.

(III) IMMEDIATELY FOLLOW THE RINSE WITH THOROUGH DRYING OF CLEANED HANDS AND ARMS (OR SURROGATE PROSTHETIC DEVICES) USING A METHOD SPECIFIED IN §46.941(C) (RELATING TO HANDWASHING FACILITIES:NUMBERS AND CAPACITIES).

(IV) Employees shall pay particular attention to the areas underneath the fingernails and between the fingers DURING THIS CLEANING PROCEDURE.

(2) *Alternative procedure.* An automatic handwashing facility may be used by food employees to clean their hands if the facility is approved and capable of removing the types of soils encountered in the food operations involved.

#### **§ 46.132. Duty of food employees to wash.**

Food employees shall clean their hands and exposed portions of their arms as specified in § 46.131 (relating to cleanliness of hands and exposed portions of arms) as follows:

- (1) Immediately before engaging in food preparation activities such as working with exposed food, working with clean equipment and utensils, and working with unwrapped single-service and single-use articles.
- (2) After touching bare human body parts other than clean hands and clean, exposed portions of arms.
- (3) After using the toilet room.
- (4) After caring for or handling service animals or aquatic animals as specified in § 46.153(b) (relating to animals).
- (5) Except as specified in § 46.151(a)(2) (relating to food contamination prevention), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking.
- (6) After handling soiled equipment or utensils.
- (7) During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks.
- (8) When switching between working with raw food and working with ready-to-eat food.
- (9) ~~After engaging in other activities that contaminate the hands.~~ BEFORE DONNING GLOVES FOR WORKING WITH FOOD.
- (10) AFTER ENGAGING IN OTHER ACTIVITIES THAT CONTAMINATE THE HANDS.

#### **§ 46.133. Required washing locations.**

Food employees shall clean their hands in a handwashing lavatory SINK or approved automatic handwashing facility. Food employees ~~may~~ SHALL not clean their hands in a sink used for food preparation OR WAREWASHING, OR IN a utility sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste.

#### **§ 46.134. Hand sanitizers.**

(a) *Requirements.* A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall:

- (1) Comply with one or more of the following:

(i) Be an approved drug that is listed in the most current FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* as an approved drug based on safety and effectiveness.

(ii) Have active antimicrobial ingredients that are listed in ~~one or more of the following:~~

~~(A) The~~ THE most current FDA monograph for OTC (OVER-THE-COUNTER) Health-Care Antiseptic Drug Products as an antiseptic handwash.

~~(B) The most current USDA List of Proprietary Substances and Nonfood Compounds, Miscellaneous Publication No. 1419 or its successor.~~

(2) Comply with one or more of the following:

(i) Have components that are exempted from the requirement of being listed in Federal food additive regulations as specified in 21 CFR 170.39 (relating to threshold of regulation for substances used in food-contact articles) ~~or its successor.~~

(ii) Comply with, and be listed in, one or more of the following:

(A) 21 CFR 178 (relating to indirect food additives: adjuvants, production aids, and sanitizers) as regulated for use as a food additive with conditions of safe use).

(B) 21 CFR 182 (relating to substances generally recognized as safe), 21 CFR 184 (relating to direct food substances affirmed as generally recognized as safe) or 21 CFR 186 (relating to indirect food substances affirmed as generally recognized as safe).

(iii) Be limited to situations when use is followed by a thorough hand rinsing in clean water before hand contact with food, or when hand contact with food is avoided by the use of gloves, or where there is no direct contact with food by bare hands.

(3) Be applied only to hands that are cleaned as specified in § 46.131(b) (relating to cleanliness of hands and exposed portions of arms).

(b) *Chemical hand sanitizing solution.* A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L (ppm) chlorine.

#### **§ 46.135. Cleanliness of fingernails.**

(a) *General.* Food employees shall keep their fingernails trimmed, filed and maintained so the edges and surfaces are cleanable and not rough.

(b) *Fingernail polish and artificial fingernails.* Unless wearing intact gloves in good repair, a food employee ~~may~~ SHALL not wear fingernail polish or artificial fingernails when working with exposed food.

#### **§ 46.136. Jewelry.**

Food employees ~~may~~ SHALL not wear jewelry (INCLUDING MEDICAL INFORMATION JEWELRY) on their arms and hands while preparing food. This prohibition does not apply to a plain ring such as a wedding band.

### **§ 46.137. Cleanliness of outer clothing.**

Food employees shall wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, single-service articles and single-use articles.

## **HYGIENIC PRACTICES**

### **§ 46.151. Food contamination prevention.**

(a) *Eating, drinking or using tobacco.*

(1) *General prohibition.* An employee ~~may~~ SHALL not eat, drink or use any form of tobacco unless the use occurs in designated areas where the contamination of exposed food; clean equipment, utensils and linens; unwrapped single-service and single-use articles; or other items needing protection ~~can not~~ CANNOT result. The sole exception to this prohibition is in paragraph (2).

(2) *Exception for closed beverage containers.* A food employee may drink from a closed beverage container if the container is handled to prevent contamination of the following:

(i) The employee's hands.

(ii) The container.

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

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

### **§ 46.152. Hair restraints.**

(a) *General requirement.* Employees shall wear hair restraints such as hats, hair coverings or nets, beard restraints and clothing that covers body hair, that are effectively designed and worn to keep their hair from contacting exposed food; clean equipment, utensils and linens; and unwrapped single-service and single-use articles.

(b) *Exception.* This section does not apply to food employees who present a minimal risk of contaminating exposed food, clean equipment, utensils, linens and unwrapped single-service and single-use articles. These food employees may include employees such as counter staff who only serve beverages and wrapped or packaged foods, hostesses and wait staff.

### **§ 46.153. Animals.**

(a) *Circumstances under which handling of animals is prohibited.* Food employees ~~may~~ SHALL not care for or handle animals that may be present such as patrol dogs, service animals or pets that are allowed as specified in § 46.982 (relating to limitations on animals).

(b) *Circumstances under which handling of animals is permissible.* Employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified in §§ 46.131(b) and 46.132 (relating to cleanliness of hands and exposed portions of arms; and duty of food employees to wash).

## **Subchapter C. FOOD CHARACTERISTICS**

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### **CHARACTERISTICS**

#### **§ 46.201. Food shall be safe, unadulterated and honestly presented.**

Food shall be safe, unadulterated and--in accordance with § 46.421(b) (relating to accurate representation)--honestly presented.

### **FOOD SOURCES**

#### **§ 46.211. Food sources.**

Food shall be obtained from sources that comply with the ~~aet~~ FOOD ACT, the Public Eating and Drinking ~~Plaee~~ PLACES Law and this chapter. RECORDS OF FOOD SOURCES SHALL BE MAINTAINED AND MADE AVAILABLE FOR REVIEW UPON REQUEST BY THE DEPARTMENT.

#### **§ 46.212. Food prepared in a private home.**

Food prepared in a private home, not approved by the Department, ~~may~~ SHALL not be used or offered for human consumption in a food facility.

#### **§ 46.213. Packaged food.**

Packaged food shall be labeled as specified in ~~the Food Act, this chapter, 21 CFR 101 (relating to food labeling), 9 CFR 317 (relating to labeling, marking devices, and containers) and 9 CFR 381, Subpart N (relating to labeling and containers)~~ § 46.422 (RELATING TO LABELING).

#### **§ 46.214. Whole-muscle, intact beef.**

Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in § 46.361(c) (relating to cooking raw ~~animal~~ ANIMAL-DERIVED foods) shall be one of the following:

(1) Obtained from a food establishment that EITHER packages the steaks and labels them to indicate that they meet the definition of whole-muscle, intact beef OR

PROVIDES AN INVOICE OR OTHER DOCUMENTATION INDICATING THAT THE STEAKS MEET THAT DEFINITION.

(2) Individually cut in a food facility, and all of the following:

(i) Cut from whole-muscle intact beef that is labeled OR DOCUMENTED by a food establishment to indicate that the beef meets the definition of "whole-muscle intact beef" AS SPECIFIED IN PARAGRAPH (1).

(ii) Prepared so they remain intact.

(iii) If packaged for undercooking in a food facility, labeled OR DOCUMENTED to indicate that they meet the definition of "whole-muscle, intact beef" AS SPECIFIED IN PARAGRAPH 1.

**§ 46.215. Packaged meat and poultry that is not a ready-to-eat food.**

Meat and poultry that is not a ready-to-eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in the act FOOD ACT, including 9 CFR 317.2(I) (relating to labels: definitions; required features) and 9 CFR 381.125(b) (relating to special handling label requirements).

**§ 46.216. Food in a hermetically sealed container.**

Food in a hermetically sealed container shall be obtained from a food establishment that is regulated by the Department or other food regulatory agency that has jurisdiction over the FOOD PROCESSING plant.

**§ 46.217. Milk and milk products.**

Milk and milk products shall be obtained from sources that comply with SECTION 2 OF the Milk Sanitation Law (31 P.S. § 646).

**§ 46.218. Fish.**

(a) *Sources.* Fish that are received for sale or service shall be one of the following:

(1) Commercially and legally caught or harvested.

(2) Approved for sale or service.

(b) *Nonmolluscan fish for raw consumption.* Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified in § 46.361(d)(1) (relating to cooking of raw ~~animal~~ ANIMAL-DERIVED foods) ~~may~~ SHALL NOT be offered for sale or service ~~if~~ UNLESS they are obtained from a supplier that freezes the fish as specified in § 46.364(a) and (b) (relating to parasite destruction in fish other than molluscan shellfish by freezing); or frozen on the premises as specified in § 46.364(a) and (b) and records are retained as specified in § 46.364(c).

**§ 46.219. Molluscan shellfish.**

(a) *Sources.* Molluscan shellfish shall be obtained from sources ~~according to the act~~ THAT ARE IN COMPLIANCE WITH § 14 OF THE FOOD ACT (31 P.S. § 20.14), CHAPTER 49 (RELATING TO SHELLFISH) and this ~~chapter~~ SUBCHAPTER, and the



requirements specified in the United States Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(b) *Molluscan shellfish received or intended for sale in interstate commerce.*

Molluscan shellfish received or intended for sale in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

(c) *Molluscan shellfish that are recreationally caught.* Molluscan shellfish that are recreationally caught ~~may~~ SHALL not be received for sale or service.

#### **§ 46.220. Wild mushrooms.**

(a) *General source requirement.* Mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by ~~an approved~~ A mushroom identification expert. The exceptions to this requirement are in subsection (b).

(b) *Exceptions.* Subsection (a) does not apply to the following:

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

(2) Wild mushroom species if they are in packaged form and are the product of a food ~~establishment~~ PROCESSING PLANT that is regulated by the Department or other food regulatory agency that has jurisdiction over the food ~~establishment~~ PROCESSING PLANT.

#### **§ 46.221. Game animals.**

(a) *Game animals commercially raised for food.* If game animals commercially raised for food are received for sale or service they shall be at least one of the following:

(1) Raised, slaughtered and processed under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo or bison) that are "inspected and approved" in accordance with the Voluntary Exotic Animal Program established in 9 CFR 352 (relating to exotic animals; voluntary inspection) or rabbits that are "inspected and certified" in accordance with the Rabbit Inspection Program established in 9 CFR 354 (relating to voluntary inspection of rabbits and edible products thereof).

(2) Under a routine inspection program conducted by the Department or other FOOD regulatory agency that has animal health jurisdiction, and raised, slaughtered and processed according to both of the following:

(i) Laws governing meat and poultry, as determined by the Department or other FOOD regulatory agency that has animal health jurisdiction.

(ii) Requirements which are developed by the Department or other FOOD regulatory agency that has animal health jurisdiction, with consideration of factors such as the need for antemortem and postmortem examination by a licensed veterinarian or veterinarian's designee.

(b) *Wild game animals that are live-caught.* Wild game animals that are live-caught ~~may~~ SHALL NOT be received for sale or service if UNLESS ALL OF the following apply:

(1) The animal is under a routine inspection program conducted by the Department or other regulatory agency that has animal health jurisdiction.

(2) The animal is slaughtered and processed according to the following:

(i) Laws governing meat and poultry, as determined by the Department or other FOOD regulatory agency that has animal health jurisdiction.

(ii) Requirements which are developed by the Department or other FOOD regulatory agency that has animal health jurisdiction, with consideration of factors such as the need for antemortem and postmortem examination by a licensed veterinarian or veterinarian's designee.

(c) *Field-dressed wild game animals.* Field-dressed wild game animals ~~may~~ SHALL NOT be received for sale or service UNLESS under a routine inspection program that ensures that the following occur:

(1) The animals receive a postmortem examination by a licensed veterinarian or veterinarian's designee.

(2) The animals are field-dressed and transported according to requirements specified by the Department or other regulatory agency that has animal health jurisdiction.

(3) The animals are processed according to laws governing meat and poultry as determined by the Department or other regulatory agency that has animal health jurisdiction.

(d) *Endangered or threatened wildlife.* A game animal ~~may~~ SHALL not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 (relating to endangered and threatened wildlife and plants).

#### **§ 46.222. Ice.**

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

### **SPECIFICATIONS FOR RECEIVING, ORIGINAL CONTAINERS AND RECORDS**

#### **§ 46.241. Receiving temperature of food.**

(a) *Refrigerated potentially hazardous food.* Except as specified in §§ 46.243(b) and 46.244(b) (relating to receiving shell eggs; and receiving eggs and milk products), refrigerated potentially hazardous food shall be at an internal temperature of 5°C (41°F) or below when received.

(b) *Cooked potentially hazardous food.* Potentially hazardous food that is cooked to a temperature and for a time specified in §§ 46.361--46.363 (relating to cooking raw animal ANIMAL-DERIVED foods; microwave cooking; and plant food cooking for hot

holding) and received hot shall be at an internal temperature of 60°C 58°C (140°F) (135°F) or above.

(c) *Frozen food.* A food that is labeled frozen and shipped frozen by a food establishment shall be received frozen.

(d) *Visible evidence of improper temperature.* Upon receipt, potentially hazardous food shall be free of evidence of previous temperature abuse. THIS EVIDENCE MIGHT INCLUDE DEHYDRATION, ICE CRYSTALS, DISCOLORATION OR DAMAGED PACKAGING.

#### **§ 46.242. Additives.**

Food ~~may~~ SHALL not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170—180 (relating to food additives) THROUGH 180 (RELATING TO FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY), generally recognized as safe or prior-sanctioned substances that exceed amounts specified in 21 CFR 181—186 (RELATING TO PRIOR-SANCTIONED INGREDIENTS) THROUGH 186 (relating to INDIRECT food substances AFFIRMED AS generally recognized as safe), substances that exceed amounts specified in 9 CFR 318.7 (~~Reserved~~) 424.21 (RELATING TO USE OF FOOD INGREDIENTS AND SOURCES OF RADIATION), or pesticide residues that exceed provisions specified in 40 CFR 185 (~~Reserved~~) 180 (RELATING TO TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS).

#### **§ 46.243. Receiving shell eggs.**

(a) *General.* Shell eggs shall be received clean and sound and ~~may~~ SHALL not exceed the restricted egg tolerances for PA Consumer Grade B as specified in ~~Chapter 87~~ (relating to standards for grading and marketing eggs) § 87.41 (RELATING TO STANDARDS).

(b) *Temperature.* Shell eggs shall be received by a food facility in refrigerated equipment that maintains an ambient temperature of 7°C (45°F) or less, or as otherwise specified in § 3 OF the Egg Refrigeration Law (~~31 P.S. §§ 300.1—300.9~~) (31 P.S. § 300.3).

(c) *Labeling.* Shell eggs received by a food facility shall be labeled as specified in ~~Chapter 87~~ §§ 87.51 (RELATING TO RECEPTACLES) AND 87.52 (RELATING TO MARKETING) and include safe handling instructions as specified in 21 CFR 101.17(h) (relating to food labeling WARNING, NOTICE, AND SAFE HANDLING STATEMENTS).

(D) *REPACKAGING.* CARTONS OF SHELL EGGS NOT IN SOUND CONDITION, SUCH AS THOSE CONTAINING CRACKED EGGS, LEAKING EGGS, OR FROZEN EGGS, SHALL BE REMOVED FROM RETAIL SALE. THE FOOD FACILITY SHALL NOT REWORK, REPACK, OR TRANSFER SHELL EGGS FROM THEIR ORIGINAL CARTONS OR CONTAINERS. HOWEVER, SHELL EGGS MAY BE SOLD AS AN INCOMPLETE DOZEN OR CONTAINER PROVIDED THAT THE QUANTITY

LABELING ON THE CARTON OR CONTAINER IS CHANGED TO REFLECT THE ACTUAL NUMBER OF SHELL EGGS WITHIN.

**§ 46.244. Receiving eggs and milk products.**

(a) *Liquid, frozen and dry eggs and egg products.* Liquid, frozen and dry eggs and egg products shall be obtained pasteurized.

(b) *Milk and milk products.* Milk and milk products shall be obtained pasteurized and received at a temperature of 7°C (45°F) or less, or as otherwise specified in PERMITTED UNDER the Milk Sanitation Law.

(c) *Frozen milk products.* Frozen milk products, ~~such as ice cream,~~ shall be obtained pasteurized ~~as specified in~~ OR AS OTHERWISE PERMITTED UNDER the Milk Sanitation Law.

(d) *Cheese.* Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are specified and published in the CFR. An example of acceptable alternative standards for curing certain cheese varieties is in 21 CFR 133 (relating to cheeses and related cheese products).

**§ 46.245. Package integrity of food upon receipt.**

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

**§ 46.246. Receiving shucked shellfish: packaging and identification.**

(a) *Label requirement.* Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the following:

(1) The name, address and certification number of the shucker-packer or repacker of the molluscan shellfish.

(2) For packages with a capacity of less than 1.87 L (1/2 gallon): the "sell by" OR "BEST IF USED BY" date.

(3) For packages with a capacity of 1.87 L (1/2 gallon) or more: the date shucked.

(b) *No label or inadequate label.* A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified in subsection (a) shall be subject to a detention, in accordance with section 6 of the act FOOD ACT (31 P. S. § 20.6).

**§ 46.247. Shellstock identification.**

(a) *Harvester's and dealer's source identification tags or labels.* Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each dealer that depurates, ships or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(1) *Contents of harvester's tag or label.* A harvester's tag or label shall list the following information, in the following order:

(i) The harvester's identification number as described in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that is assigned by the Department or other shellfish control authority having jurisdiction.

(ii) The date of harvesting.

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

(iv) The type and quantity of shellfish.

(v) The following statement in bold, capitalized type:

This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days.

(2) *Contents of dealer's tag or label.* A dealer's tag or label shall list the following information, in the following order:

(i) The dealer's name and address, and the certification number assigned by the Department or other shellfish control authority having jurisdiction.

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

(iii) The same information as specified for a harvester's tag under paragraph (1)(ii)--(iv).

(iv) The following statement in bold, capitalized type:

This tag is required to be attached until container is empty and thereafter kept on file for 90 days.

(b) *Missing or incomplete tag or label.* A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified in subsection (a) shall be subject to a detention, in accordance with section 6 of the act FOOD ACT (31 P. S. § 20.6).

(c) *Harvester's tag or label may SHALL include dealer information.* If a place is provided on the harvester's tag or label for a dealer's name, address and certification number, the dealer's information shall be listed first, notwithstanding subsection (a)(1).

(d) *Exception to requirement of separate dealer's tag or label.* If the harvester's tag or label is designed to accommodate each dealer's identification as specified in subsection (a)(2)(i) and (ii), individual dealer tags or labels need not be provided.

#### **§ 46.248. Shellstock: condition upon receipt.**

Shellstock shall be reasonably free of mud, dead shellfish and shellfish with broken shells when received by a food facility. Dead shellfish or shellstock with badly broken shells shall be discarded.

**§ 46.249. Molluscan shellfish: original container.**

(a) *General requirement.* Molluscan shellfish ~~may~~ SHALL not be removed from the container in which they are received other than immediately before sale or preparation for service. The two exceptions to this requirement are set forth in subsections (b) and (c).

(b) *Exception: shellstock.* Shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if both of the following occur:

(1) The source of the shellstock on display is identified as specified in § 46.247 (relating to shellstock identification) and recorded as specified in § 46.250 (relating to shellstock: maintaining identification)

(2) The shellstock are protected from contamination.

(c) *Exception: shucked shellfish.* Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if both of the following apply:

(1) The labeling information for the shellfish on display as specified in § 46.246 (relating to receiving shucked shellfish: packaging and identification) is retained and correlated to the date when, or dates during which, the shellfish are sold or served.

(2) The shellfish are protected from contamination.

**§ 46.250. Shellstock: maintaining identification.**

(a) *General requirement.* Shellstock tags shall remain attached to the container in which the shellstock are received until the container is empty. The exception to this requirement is set forth in subsection (b)(2).

(b) *Records of identification.* The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90-calendar days from the date the container is emptied by the following methods:

(1) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the shellstock are sold or served.

(2) Where shellstock are removed from their tagged or labeled container, ~~using either of the following methods:~~

~~(i) Using only one tagged or labeled container at a time.~~

~~(ii) Using more than one tagged or labeled container at a time and obtaining a variance from the Department as specified in § 46.1103(a) (relating to variances) based on a HACCP plan that:~~

~~(A) Is submitted by the permitholder and approved as specified in § 46.1103(b).~~

~~(B) Preserves~~ PRESERVING source identification by using a recordkeeping system as specified in paragraph (1)-, AND

~~(C) Ensures~~ ENSURING that shellstock from one tagged or labeled container are not commingled with shellstock from another container before being ordered by the consumer.

#### **§ 46.251. JUICE.**

PREPACKAGED JUICE SHALL BE OBTAINED FROM A PROCESSOR WITH A HACCP SYSTEM AS SPECIFIED IN 21 CFR 120 (RELATING TO HAZARD ANALYSIS AND CRITICAL CONTROL POINT HACCP SYSTEMS) AND BE ONE OF THE FOLLOWING:

(1) OBTAINED PASTEURIZED OR OTHERWISE TREATED TO ATTAIN A 5-LOG REDUCTION (A 99.999% REDUCTION) OF THE MOST RESISTANT MICROORGANISM OF PUBLIC HEALTH SIGNIFICANCE AS SPECIFIED IN 21 CFR 120.24 (RELATING TO PROCESS CONTROLS).

(2) BEAR A WARNING LABEL AS SPECIFIED IN 21 CFR 101.17(G) (RELATING TO FOOD LABELING WARNING, NOTICE, AND SAFE HANDLING STATEMENTS).

#### **PREVENTING CONTAMINATION BY EMPLOYEES**

##### **§ 46.261. Preventing contamination from food employees' hands.**

(a) *Hand washing required.* Food employees shall wash their hands as specified in § 46.131 (relating to cleanliness of hands and exposed portions of arms).

(b) *Hand contact with ready-to-eat food.* Except when washing fruits and vegetables as specified in § 46.285 (relating to washing raw fruits and vegetables) or when otherwise approved IN ACCORDANCE WITH SUBSECTION (D), food employees ~~may~~ SHALL not contact exposed, ready-to-eat food with their bare hands, ~~unless hands have been washed as specified in § 46.131(b)~~ and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves or dispensing equipment ~~whenever possible~~.

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

(D) *APPROVAL OF BARE-HAND CONTACT.* FOOD EMPLOYEES MAY CONTACT READY-TO-EAT FOODS WITH THEIR BARE HANDS IF THE FOOD FACILITY OPERATOR SUBMITS A WRITTEN PLAN TO THE DEPARTMENT AND THE DEPARTMENT PROVIDES THE FOOD FACILITY OPERATOR WRITTEN APPROVAL OF THE PLAN. THE WRITTEN PLAN AND RELATED DOCUMENTATION, AND THE DEPARTMENT'S WRITTEN APPROVAL MUST BE AVAILABLE AT THE FOOD FACILITY FOR USE BY THE PERSON IN CHARGE AND REVIEW BY THE DEPARTMENT UPON REQUEST. THE WRITTEN PLAN MUST CONTAIN THE FOLLOWING:

(1) THE REASON THE PERSON-IN-CHARGE OF THE FOOD FACILITY IS UNABLE TO COMPLY WITH SUBSECTION (B).

(2) A PROVISION IDENTIFYING THE PUBLIC HEALTH HAZARDS ASSOCIATED WITH BARE-HAND CONTACT SPECIFIC TO THE FOOD FACILITY, DEMONSTRATING THAT THESE HAZARDS ARE UNDERSTOOD BY THE FOOD FACILITY OPERATOR.

(3) VERIFICATION THAT THE FOOD FACILITY HAS IMPLEMENTED AND IS IN COMPLIANCE WITH ALL APPLICABLE SUPERVISION, EMPLOYEE HEALTH, PERSONAL CLEANLINESS AND HYGIENIC PRACTICES PROVISIONS REQUIRED UNDER SUBCHAPTER B.

(4) A PROVISION IDENTIFYING EXPOSED READY-TO-EAT FOODS THAT WILL BE CONTACTED WITH BARE HANDS AND THE PROCEDURES AND PRACTICES WHICH ARE IN PLACE TO ASSURE THAT FOOD EMPLOYEES WASH THEIR HANDS BEFORE RETURNING TO THEIR WORK STATION AND THAT CROSS-CONTAMINATION FROM TOUCHING RAW FOODS AND READY-TO-EAT FOODS IS PRECLUDED.

(5) AN EFFECTIVE TRAINING PLAN FOR FOOD EMPLOYEES THAT EMPHASIZES THE FOLLOWING SUBJECTS ADDRESSED IN THIS CHAPTER:

(I) NOT WORKING WHEN ILL.

(II) GOOD HYGIENIC PRACTICES AND PERSONAL CLEANLINESS.

(III) PROPER HANDWASHING PROCEDURES.

(IV) SAFE FOOD PREPARATION PROCEDURES.

THE TRAINING PLAN SHALL ACKNOWLEDGE MANAGEMENT RESPONSIBILITY FOR TRAINING, SPECIFY THE PROGRAM CONTENT AND TRAINING FREQUENCY (INCLUDING REFRESHER TRAINING),

(6) DOCUMENTATION DEMONSTRATING THAT SUBPARAGRAPHS (5)(I) THROUGH (5)(V) ARE IMPLEMENTED, AND ARE VERIFIED BY MANAGEMENT.

(7) AN ACTION PLAN IDENTIFYING CORRECTIVE ACTIONS TO BE TAKEN IN SITUATIONS IN WHICH THE PRACTICES AND PROCEDURES IN THE WRITTEN PLAN ARE NOT COMPLIED WITH.

#### **§ 46.262. Preventing contamination when tasting.**

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

### **PREVENTING FOOD AND INGREDIENT CONTAMINATION**

#### **§ 46.281. Preventing contamination of packaged and unpackaged food: separation, packaging and segregation.**

(a) *Required protective measures.* Food shall be protected from cross contamination by the following procedures, as applicable:

(1) Separating raw ~~animal~~ ANIMAL-DERIVED foods during storage, preparation, holding and display from:

(i) Raw ready-to-eat food including other raw ~~animal~~ ANIMAL-DERIVED food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as vegetables.



(ii) Cooked ready-to-eat food.

(2) Separating types of raw ~~animal~~ ANIMAL-DERIVED foods (such as beef, fish, lamb, pork and poultry) from each other during storage, preparation, holding and display, except when these raw ~~animal~~ ANIMAL-DERIVED foods are combined as ingredients, by doing the following:

(i) Using separate equipment for each type or arranging each type of food in equipment so that cross contamination of one type with another is prevented.

(ii) Preparing each type of food at different times or in separate areas.

(3) Cleaning equipment and utensils as specified in § 46.712(a) (relating to frequency of cleaning equipment food-contact surfaces and utensils) and sanitizing as specified in § 46.731(c) (relating to sanitization: requirement, frequency and methods).

(4) Storing the food in packages, covered containers or wrappings. The exception to this requirement is in subsection (b).

(5) Cleaning hermetically sealed containers of food of visible soil before opening.

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

(7) Storing damaged, spoiled or recalled food being held in the food facility as specified in § 46.964 (relating to distressed merchandise: segregated).

(8) Separating fruits and vegetables from ready-to-eat food before the fruits and vegetables are washed as specified in § 46.285 (relating to washing raw fruits and vegetables).

(b) *Exception to the requirement of storing foods in packages, covered containers or wrappings.* Subsection (a)(4) does not apply to the following:

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

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

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

(4) Food being cooled as specified in § 46.384(d)(2) (relating to potentially hazardous food: cooling).

(5) Shellstock.

#### **§ 46.282. Identification of content on food storage containers.**

Working containers holding food or food ingredients (such as cooking oils, flour, herbs, potato flakes, salt, spices and sugar) that are removed from their original packages for use in the food facility shall be identified with the common name of the food they contain. However, containers holding food that can be readily and unmistakably recognized (such as dry pasta) need not be identified.

**§ 46.283. Substituting pasteurized eggs for raw shell eggs in certain recipes.**

Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods such as Caesar salad, hollandaise or béarnaise sauce, mayonnaise, eggnog, ice cream and egg-fortified beverages that are not either of the following:

(1) Cooked as specified in § 46.361(a)(1) or (2) (relating to cooking raw ~~animal~~ ANIMAL-DERIVED foods).

(2) Included in § 46.361(d).

**§ 46.284. Protection from unapproved additives.**

(a) *Unapproved additives or unsafe levels of approved additives.* Food or food ingredients shall be protected from contamination that may result from the addition of unsafe or unapproved food or color additives, and from unsafe or unapproved levels of approved food and color additives, as described in § 46.242 (relating to additives).

(b) *Sulfiting agents.* A food employee ~~may~~ SHALL not do the following:

(1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1, as that term is defined in 21 CFR 101.54(c) (relating to nutrient content claims for "good source," "high," "more," and "high potency").

(2) Serve or sell a food specified in paragraph (1), other than grapes, that is treated with sulfiting agents before receipt by the food facility.

**§ 46.285. Washing raw fruits and vegetables.**

(a) *General.* Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served or offered for human consumption in ready-to-eat form.

(b) *Exception.* Whole, raw fruits and vegetables which are intended for washing by the consumer before consumption need not be washed before they are sold.

(c) *Chemical washing.* Fruits and vegetables may be washed by using chemicals as specified in § 46.1024(b) (relating to chemicals: use criteria).

**§ 46.286. Preventing contamination from ice used as a coolant.**

(a) *Ice used as exterior coolant is prohibited as ingredient.* Ice ~~may~~ SHALL not be used as food after it has been used as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment.

(b) *Storage or display of food in contact with water or ice.*

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

(2) *General prohibition.* Unpackaged foods other than those described in paragraphs (3) and (4) ~~may~~ SHALL not be stored in direct contact with undrained ice.

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

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

## **PREVENTING CONTAMINATION FROM EQUIPMENT, UTENSILS AND LINENS**

### **§ 46.301. Preventing contamination from food contact with equipment and utensils.**

Food shall only contact surfaces of equipment and utensils that are cleaned as specified in §§ 46.711--46.719 (relating to cleaning of equipment) and sanitized as specified in § 46.731 (relating to sanitization: requirement, frequency and methods).

### **§ 46.302. In-use utensils and between-use storage.**

(a) *General.* During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored in the food with their handles above the top of the food and the container, unless the food is non-potentially hazardous and within containers or equipment that can be closed, such as bins of sugar, flour or cinnamon--in which case the food preparation and dispensing utensils shall be stored with their handles above the top of the food within the containers.

(b) *Storage on cleaned and sanitized tables or equipment.* During pauses in food preparation or dispensing, food preparation and dispensing utensils may be stored on a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the table or equipment are cleaned and sanitized at a frequency specified in §§ 46.712 and 46.731 (relating to frequency of cleaning equipment food-contact surfaces and utensils; and sanitization: requirement, frequency and methods).

(c) *Storage in running water.* During pauses in food preparation or dispensing, food preparation and dispensing utensils may be stored in running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes.

(d) *Storage in clean, protected locations.* During pauses in food preparation or dispensing, food preparation and dispensing utensils may be stored in a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not potentially hazardous.

(e) *Storage in a container of water.* During pauses in food preparation or dispensing, food preparation and dispensing utensils may be stored in a container of water if the water is maintained at a temperature of at least 60°C (140°F) 58°C (135°F) and the

container is cleaned at frequency specified in § 46.712(d)(7) (relating to frequency of cleaning equipment food-contact surfaces and utensils)

**§ 46.303. Linens and napkins: use limitations.**

Linens and napkins ~~may~~ SHALL not be used in contact with food unless they are used FOR EITHER OF THE FOLLOWING PURPOSES:

(1) ~~to~~ TO line a container for the service of foods ~~and~~, WHERE the linens and napkins are replaced each time the container is refilled for a new consumer.

(2) FOR RETAIL DISPLAY OF NON-POTENTIALLY HAZARDOUS FOOD, WHERE THE LINENS AND NAPKINS ARE REPLACED WITH EACH RESTOCKING OF THE RETAIL DISPLAY.

**§ 46.304. Wiping cloths: use limitations.**

(a) *Cloths used for wiping food spills.* Cloths that are used for wiping food spills shall be used for no other purpose.

(b) *Wet and dry wiping cloths.* Cloths used for wiping food spills shall be one of the following.

(1) Dry and used for wiping food spills from tableware and carry-out containers.

(2) Wet and cleaned as specified in § 46.751(b)(4) (relating to requirement and frequency of laundering) stored in a chemical sanitizer at a concentration specified in § 46.674(a) (relating to warewashing equipment: mechanical or manual) and used for wiping spills from food-contact and nonfood-contact surfaces of equipment.

(c) *Wiping cloths used with raw ~~animal~~ ANIMAL-DERIVED foods.* Dry or wet cloths that are used with raw ~~animal~~ ANIMAL-DERIVED foods shall be kept separate from cloths used for other purposes, and wet cloths used with raw ~~animal~~ ANIMAL-DERIVED foods shall be kept in a separate sanitizing solution.

(d) *General cleanliness.* Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths shall be free of food debris and visible soil.

**§ 46.305. Gloves: use limitations.**

(a) *Single-use gloves.* Single-use gloves shall be used for only one task (such as working with ready-to-eat food or with raw ~~animal~~ ANIMAL-DERIVED food), used for no other purpose and discarded when damaged or soiled, or when interruptions occur in the operation.

(b) *Slash-resistant gloves: general.* Except as specified in subsection (c), slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified in §§ 46.361--46.365 (relating to destruction of organisms of public health concern), such as frozen food or a primal cut of meat.

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

(d) *Cloth gloves.* Cloth gloves ~~may~~ SHALL not be used in direct contact with food unless the food is subsequently cooked as required in §§ 46.361--46.365, such as frozen food or a primal cut of meat.

#### **§ 46.306. Using clean tableware for second portions and refills.**

(a) *General.* A food employee ~~may~~ SHALL not use tableware, including single-service articles, soiled by the consumer, to provide second portions or refills. However, a food employee may refill a consumer's drinking cup or container without contact between the pouring utensil and the lip-contact area of the drinking cup or container.

(b) *Use of soiled tableware by self-service consumers to obtain food from display or serving equipment prohibited.* Self-service consumers ~~may~~ SHALL not be allowed to use soiled tableware (including single-service articles) to obtain additional food from the display and serving equipment. The sole exception to this prohibition is described in subsection (c).

(c) *Use of soiled drinking cups by self-service consumers to obtain drinks.* Drinking cups and containers may be reused by self-service consumers if refilling is a contamination-free process as specified in § 46.583(1), (2) and (4) (relating to dispensing equipment: protection of equipment and food).

#### **§ 46.307. Refilling returnables.**

(a) *Refilling with potentially hazardous food prohibited.* A take-home food container returned to a food facility ~~may~~ SHALL not be refilled at a food facility with a potentially hazardous food.

(b) *Refilling with a cleaned container.* Except as specified in subsection (c), a take-home food container refilled with food that is not potentially hazardous shall be cleaned as specified in § 46.719(b) (relating to washing returnable containers for refilling).

(c) *Refilling certain containers by a contamination-free process.* Personal take-out beverage containers, such as thermally insulated bottles, non-spill coffee cups and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified in § 46.583(1), (2) and (3) (relating to dispensing equipment: protection of equipment and food).

### **PREVENTING CONTAMINATION FROM THE PREMISES**

#### **§ 46.321. Food storage.**

(a) *General storage requirements.* Except as specified in subsections (b) and (c), food shall be protected from contamination by storing as follows:

- (1) In a clean, dry location.
- (2) Where it is not exposed to splash, dust or other contamination.
- (3) At least 15 cm (6 inches) above the floor.

(b) *Exception for food stored on case lot handling equipment.* Food in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot

handling equipment as specified in § 46.595 (relating to case lot handling equipment: moveability).

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

(d) *Foods storage: prohibited areas.* Food ~~may~~ SHALL not be stored in any of the following locations:

- (1) A locker room.
- (2) A toilet room.
- (3) A dressing room.
- (4) A garbage room.
- (5) A mechanical room.
- (6) Under a sewer line that is not shielded to intercept potential drips.
- (7) Under a leaking water line (including a leaking automatic fire sprinkler head), or under a line on which water has condensed.
- (8) Under an open stairwell.
- (9) Under any OTHER source of contamination, SUCH AS PEELING PAINT, UNPROTECTED LIGHT BULBS, SOME VENTILATION UNITS OR OUTSIDE SHEDS.

**§ 46.322. Vended potentially hazardous food: original container.**

Potentially hazardous food dispensed through a vending machine shall be in the package in which it was placed at the food facility at which it was prepared.

**§ 46.323. Food preparation.**

During preparation, unpackaged food shall be protected from environmental sources of contamination, SUCH AS OUTSIDE DUST, CONSTRUCTION OR RENOVATION DEBRIS, OR VENTILATION DUST.

**PREVENTING CONTAMINATION BY CONSUMERS**

**§ 46.341. Food display.**

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line or salad bar food guards; display cases; or other effective means.

**§ 46.342. Protection of condiments.**

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

(b) *Condiments at a vending machine location.* Condiments at a vending machine location shall be in individual packages or provided in dispensers that are filled at an approved location, such as the food facility that provides food to the vending machine location, or a properly equipped food facility that is located on the site of the vending machine location.

#### **§ 46.343. Consumer self-service operations.**

(a) *Raw, unpackaged ~~animal~~ ANIMAL-DERIVED foods.* Raw, unpackaged ~~animal~~ ANIMAL-DERIVED food (such as beef, lamb, pork, poultry and fish) ~~may~~ SHALL not be offered for consumer self-service. This subsection does not apply to consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish; or ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue; or raw, frozen, shell-on shrimp or lobster.

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

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

#### **§ 46.344. Returned food and reservice of food.**

(a) *General prohibition of reuse of returned or unused food.* Except as specified in subsection (b), after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer ~~may~~ SHALL not be offered as food for human consumption.

(b) *Exception for certain foods and packages.* ~~Except as specified in § 46.461(e) (relating to additional safeguards for a food facility that serves a highly susceptible population), a~~ A container of food that is not potentially hazardous may be transferred from one consumer to another if either of the following occurs:

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

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

#### **~~§ 46.345. Miscellaneous sources of contamination.~~**

~~Food shall be protected from contamination that may result from a factor or source not specified in §§ 46.261, 46.262, 46.281–46.286, 46.301–46.307, 46.321–46.323 and 46.341–46.344.~~

## DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN

### § 46.361. Cooking raw ~~animal~~ ANIMAL-DERIVED foods.

(a) *General cooking requirement.* Except as specified in subsections (b)--(d), raw ~~animal~~ ANIMAL-DERIVED foods (such as eggs, fish, meat, poultry and foods containing these raw ~~animal~~ ANIMAL-DERIVED foods) shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods, based on the food that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for either of the following:

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

(ii) Except as specified in paragraphs (2) and (3), and subsection (b), fish, meat and pork, including game animals commercially raised for food as specified in § 46.221(a) (relating to game animals).

(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified in § 46.221(a); and raw eggs that are not broken and prepared in response to a consumer's order and for immediate service:

Minimum Temperature	Minimum Time
63°C (145°F)	3 Minutes
66°C (150°F)	1 Minute
70°C (158°F)	Less than 1 second (instantaneous)

(3) 74°C (165°F) or above for 15 seconds for poultry, wild game animals as specified in § 46.221(b) and (c), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites or stuffing containing fish, meat, poultry or ratites.

(b) *Certain roasts.* Whole beef roasts, corned beef roasts, pork roasts and cured pork roasts such as ham, shall be cooked as follows:

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

Oven Type	Oven Temperature for Roast Weighing less than 4.5 kg (10 lbs.)	Oven Temperature for Roast Weighing 4.5 kg (10 lbs.) or more
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity Cooking	121°C (250°F) or more	121°C (250°F) or more

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

Minimum Temperature	Minimum Time
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54°C (130°F)	121 112 Minutes
55.0°C (131°F)	89 MINUTES
56°C (132°F) 56.1°C (133°F)	77 56 Minutes
57°C (134°F) 57.2°C (135°F)	47 36 Minutes
58°C (136°F) 58.9°C (138°F)	32 28 Minutes
59°C (138°F)	19 Minutes
60°C 60.0°C (140°F)	12 Minutes
61°C 61.1°C (142°F)	8 Minutes
62°C 62.2°C (144°F)	5 Minutes
63°C 62.8°C (145°F)	3 4 Minutes
63.9°C (147°F)	134 SECONDS
65.0°C (149°F)	85 SECONDS
66.1°C (151°F)	54 SECONDS
67.2°C (153°F)	34 SECONDS
68.3°C (155°F)	22 SECONDS
69.4°C (157°F)	14 SECONDS
70.0°C (158°F)	< 1 SECOND

(c) *Raw or undercooked whole-muscle, intact beef steak.* A raw or undercooked whole-muscle, intact beef steak ~~may~~ SHALL NOT be served or offered for sale in a ready-to-eat form if UNLESS ALL OF the following apply:

- (1) The food facility serves a population that is not a highly susceptible population.
- (2) The steak is labeled to indicate that it meets the definition of "whole-muscle, intact beef" as specified in § 46.214 (relating to whole-muscle, intact beef).
- (3) The steak is cooked on both the top and bottom to a surface temperature of 63°C (145°F) or above and a cooked color change is achieved on all external surfaces.

(d) *Other raw ~~animal~~ ANIMAL-DERIVED foods.* A raw ~~animal~~ ANIMAL-DERIVED food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or undercooked meat other than whole-muscle, intact beef steaks as specified in subsection (c), ~~may~~ SHALL be served or offered for sale in a ready-to-eat form ONLY if either of the following occurs:

- (1) The food facility serves a population that is not a highly susceptible population, and the consumer is informed as specified in § 46.423 (relating to consumer advisory required with respect to ~~animal~~ ANIMAL-DERIVED foods that are raw, undercooked or not otherwise processed to eliminate pathogens) that to ensure its safety, the food should be cooked as specified in subsections (a) or (b).
- (2) The Department grants a variance from subsection (a) or (b) as specified in § 46.1103(a) (relating to variances), based on a HACCP plan that is all of the following:
  - (i) Submitted by the license holder and approved as specified in § 46.1103(b) (relating to variances).
  - (ii) Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food.

- (iii) Verifies that equipment and procedures for food preparation and training of food employees at the food facility meet the conditions of the variance.

**§ 46.362. Microwave cooking.**

Raw ~~animal~~ ANIMAL-DERIVED foods cooked in a microwave oven SHALL meet all of the following conditions:

- (1) Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat.
- (2) Covered to retain surface moisture.
- (3) Heated to a temperature of at least 74°C (165°F) in all parts of the food.
- (4) Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

**§ 46.363. Plant food cooking for hot holding.**

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 60°C (140°F) 58°C (135°F).

**§ 46.364. Parasite destruction in fish other than molluscan shellfish by freezing.**

(a) *General temperature requirement.* Except as specified in subsection (b), before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked or marinated-partially cooked fish other than molluscan shellfish shall be frozen throughout to a temperature of one of the following:

- (1) -20°C (-4°F) or below for 168 hours (7 days) in a freezer.
- (2) -35°C (-31°F) or below for 15 hours in a blast freezer.

(b) *Exception for certain tuna species.* If the fish are tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern), the fish may be served or sold in a raw, raw-marinated or partially cooked ready-to-eat form without freezing as specified in subsection (a).

(c) *Records: creation and retention.*

(1) Except as specified in subsection (b) and paragraph (2), if raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the food facility for 90-calendar days beyond the time of service or sale of the fish.

(2) If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified in subsection (a) may substitute for the records specified in paragraph (1).

### **§ 46.365. Reheating food.**

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

(b) *Reheating for hot holding.*

(1) Potentially hazardous food that is cooked, cooled and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74°C (165°F) for 15 seconds. Reheating for hot holding shall be done rapidly and the time the food is between the temperature specified in § 46.385(a)(2) or (3) (relating to potentially hazardous food: hot and cold holding) and 74°C (165°F) ~~may~~ SHALL not exceed 2 hours. Exceptions to these requirements are specified in paragraphs (2), (3) and (4).

(2) Except as specified in paragraph (3), reheating of potentially hazardous food in a microwave oven for hot holding shall be performed in accordance with § 46.362 (relating to microwave cooking).

(3) Ready-to-eat food taken from a commercially processed, hermetically sealed container or from an intact package from a food establishment that is inspected by the Department or other food regulatory authority AGENCY that has jurisdiction over the FOOD PROCESSING plant, shall be heated to a temperature of at least 60°C (~~140°F~~) 58°C (135°F) for hot holding.

(4) Remaining unsliced portions of roasts of beef that are cooked as specified in § 46.361(b) (relating to cooking raw animal ANIMAL-DERIVED foods) ~~may~~ SHALL be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified in § 46.361(b).

### **§ 46.366. TREATING JUICE.**

JUICE PACKAGED IN A FOOD FACILITY SHALL BE ONE OF THE FOLLOWING:

(1) TREATED UNDER A HACCP PLAN (AS DESCRIBED IN § 46.1122(B) – RELATING TO HACCP PLANS) TO ATTAIN A 5-LOG REDUCTION (A 99.999% REDUCTION) OF THE MOST RESISTANT MICROORGANISM OF PUBLIC HEALTH SIGNIFICANCE.

(2) IF NOT TREATED TO YIELD A 5-LOG REDUCTION OF THE MOST RESISTANT MICROORGANISM OF PUBLIC HEALTH CONCERN, LABELED AS SPECIFIED § 46.422 (RELATING TO LABELING) AND AS SPECIFIED IN 21 CFR 101.17(G) (RELATING TO FOOD LABELING WARNING, NOTICE, AND SAFE HANDLING STATEMENTS) WITH THE FOLLOWING:

*WARNING:* THIS PRODUCT HAS NOT BEEN PASTEURIZED AND, THEREFORE, MAY CONTAIN HARMFUL BACTERIA THAT CAN CAUSE SERIOUS ILLNESS IN CHILDREN, THE ELDERLY, AND PERSONS WITH WEAKENED IMMUNE SYSTEMS.

## **TEMPERATURE AND TIME CONTROL FOR LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN**

### **§ 46.381. Stored frozen food.**

Stored frozen foods shall be maintained frozen.

### **§ 46.382. Potentially hazardous food: slacking.**

Frozen potentially hazardous food that is slacked to moderate the temperature shall be held at one of the following:

(1) Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding).

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

### **§ 46.383. Potentially hazardous food: thawing.**

Except as specified in paragraph (4), potentially hazardous food shall be thawed by one of the procedures that follow:

(1) Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding).

(2) Completely submerged under running water at a water temperature of 21°C (70°F) or below; with sufficient water velocity to agitate and float off loose particles in an overflow, for one of the following:

(i) A period of time that does not allow thawed portions of ready-to-eat food to rise above 5°C (41°F), or 7°C (45°F) as specified in § 46.385(a)(3).

(ii) A period of time that does not allow thawed portions of a raw ~~animal~~ ANIMAL-DERIVED food requiring cooking as specified in § 46.361(a) or (b) (relating to cooking raw ~~animal~~ ANIMAL-DERIVED foods) to be above 5°C (41°F), or 7°C (45°F) as specified in § 46.385(a)(3) for more than 4 hours including both of the following:

(A) The time the food is exposed to the running water and the time needed for preparation for cooking.

(B) The time it takes under refrigeration to lower the food temperature to 5°C (41°F), or 7°C (45°F) as specified in § 46.385(a)(3).

(3) As part of a cooking process if the food that is frozen is one of the following:

(i) Cooked as specified in § 46.361(a) or (b) or § 46.362 (relating to microwave cooking).

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

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

#### **§ 46.384. Potentially hazardous food: cooling.**

(a) *Cooling cooked potentially hazardous food.* Cooked potentially hazardous food shall be cooled as follows:

- (1) Within 2 hours, from ~~60°C (140°F)~~ 58°C (135°F) to 21°C (70°F).
- (2) Within ~~4 hours~~ 6 HOURS, from ~~21°C (70°F)~~ 58°C (135°F) to 5°C (41°F) or less, or to 7°C (45°F) as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding).

(b) *Cooling potentially hazardous food prepared from ingredients at ambient temperature.* Potentially hazardous food shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) as specified in § 46.385(a)(3) if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.

(c) *Cooling methods.* Cooling shall be accomplished in accordance with the time and temperature criteria specified in subsection (a) by using one or more of the following methods, based on the type of food being cooled:

- (1) Placing the food in shallow pans.
- (2) Separating the food into smaller or thinner portions.
- (3) Using rapid cooling equipment.
- (4) Stirring the food in a container placed in an ice water bath.
- (5) Using containers that facilitate heat transfer.
- (6) Adding ice as an ingredient.
- (7) Other effective methods.

(d) *Food containers in which food is cooled.* When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be both of the following:

- (1) Arranged in the equipment to provide maximum heat transfer through the container walls.
- (2) Loosely covered, or uncovered if protected from overhead contamination as specified in § 46.321(a)(2) (relating to food storage), during the cooling period to facilitate heat transfer from the surface of the food.

#### **§ 46.385. Potentially hazardous food: hot and cold holding.**

(a) *GENERAL.* Except during preparation, cooking, or cooling, or when time is used as the public health control as specified in subsection (b) (C), potentially hazardous food shall be maintained at one of the following temperatures, as applicable:

- (1) At ~~60°C (140°F)~~ 58°C (135°F) or above, except that roasts cooked to a temperature and for a time specified in § 46.361(b) (relating to cooking raw ~~animal~~ ANIMAL-DERIVED foods) or reheated as specified in § 46.365(b)(5) (relating to reheating food) ~~may~~ SHALL be held at a temperature of 54°C (130°F) OR ABOVE.
- (2) At 5°C (41°F) or less except as specified in paragraphs (3)--(5), or § 46.584(b) (relating to vending machines).

(3) At 7°C (45°F) or between 7°C (45°F) and 5°C (41°F) in existing refrigeration equipment that is not capable of maintaining the food at 5°C (41°F) or less if either of the following is accurate:

(i) The equipment is in place and in use in the food facility; and by \_\_\_\_\_ WITHIN 5 YEARS OF THE EFFECTIVE DATE OF THIS CHAPTER, the equipment is upgraded or replaced so that it shall maintain food at a temperature of 5°C (41°F) or less.

(ii) A food facility operator can demonstrate to the Department that a hardship would result from meeting the requirements of this paragraph and a variance is applied for and granted by the Department. The variance will not relieve the applicant from meeting the food safety objectives of this chapter.

(4) At 7°C (45°F) or less for shell eggs, or as otherwise specified in SECTION 3 OF the Egg Refrigeration Law (~~31 P. S. §§ 300.1-300.9~~) (31 P. S. § 300.3).

(5) At 7°C (45°F) or less FOR MILK PRODUCTS, FOR A MAXIMUM PERIOD ALLOWED BY THE "SELL-BY" CODING REQUIRED BY § 59.22 (RELATING TO MILK DATING), or as otherwise specified in the Milk Sanitation Law.

*(B) DATE MARKING OF READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD.*

(1) EXCEPT AS SPECIFIED IN PARAGRAPHS (4) OR (5), REFRIGERATED, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD PREPARED AND HELD IN A FOOD FACILITY FOR MORE THAN 48 HOURS SHALL BE CLEARLY MARKED TO INDICATE EITHER OF THE FOLLOWING:

(I) THE DATE BY WHICH THE FOOD SHALL BE CONSUMED ON THE PREMISES, SOLD, OR DISCARDED.

(II) THE DATE ON WHICH THE FOOD WAS PREPARED.

(2) REFRIGERATED READY-TO-EAT POTENTIALLY HAZARDOUS FOOD PREPARED AND PACKAGED BY A FOOD PROCESSING PLANT SHALL BE CLEARLY MARKED WITH THE DATE THE ORIGINAL CONTAINER IS OPENED IN A FOOD FACILITY. EXCEPT AS SPECIFIED IN PARAGRAPHS (4) AND (5), ALL FOOD REPACKAGED FROM THE ORIGINAL CONTAINER BY THE FOOD FACILITY SHALL BE CLEARLY MARKED TO INDICATE THE DATE BY WHICH THE FOOD SHALL BE CONSUMED ON THE PREMISES, SOLD OR DISCARDED, AND IN NO CASE SHALL THIS DATE BE BEYOND THE MANUFACTURER'S USE-BY DATE.

(3) A REFRIGERATED, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD THAT IS FREQUENTLY REWRAPPED (SUCH AS LUNCHMEAT OR A ROAST), OR FOR WHICH DATE MARKING IS IMPRACTICAL (SUCH AS SOFT SERVE MIX OR MILK IN A DISPENSING MACHINE), SHALL BE MARKED AS IN PARAGRAPHS (1) OR (2), OR BY AN ALTERNATIVE METHOD ACCEPTABLE TO THE DEPARTMENT.

(4) PARAGRAPHS (1) AND (2) SHALL NOT APPLY TO INDIVIDUAL MEAL PORTIONS SERVED OR REPACKAGED FOR SALE FROM A BULK CONTAINER UPON A CONSUMER'S REQUEST.

(5) PARAGRAPH (2) SHALL NOT APPLY TO THE FOLLOWING:

(I) FERMENTED SAUSAGES PRODUCED IN A FEDERALLY INSPECTED FOOD PROCESSING PLANT THAT ARE NOT LABELED "KEEP

REFRIGERATED" AND WHICH RETAIN THE ORIGINAL CASING ON THE PRODUCT.

(II) SHELF STABLE, DRY FERMENTED SAUSAGES.

(II) SHELF STABLE SALT-CURED PRODUCTS SUCH AS PROSCIUTTO AND PARMA (HAM) PRODUCED IN A FEDERALLY INSPECTED FOOD PROCESSING PLANT THAT ARE NOT LABELED "KEEP REFRIGERATED"- PROVIDED THAT WHEN THE FACE IS CUT, THE REMAINING PORTION IS WHOLE AND INTACT.

(6) A REFRIGERATED, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD INGREDIENT OR A PORTION OF A REFRIGERATED, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD IS SUBSEQUENTLY COMBINED WITH ADDITIONAL INGREDIENTS OR PORTIONS OF FOOD, SHALL RETAIN THE DATE MARKING OF THE EARLIEST-PREPARED OR FIRST-PREPARED INGREDIENT.

~~(b)~~ (C) *Time as a public health control.*

(1) Except as specified in paragraph (2), if time--rather than temperature--is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption, all of the following shall be done:

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

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

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

(iv) Written procedures shall be maintained in the food facility and made available to the Department upon request, that ensure compliance with this subsection and § 46.384(a)--(b) (relating to potentially hazardous food: cooling) for food that is prepared, cooked and refrigerated before time is used as a public health control.

(2) In a food facility that serves a highly susceptible population, time only--rather than temperature--~~may~~ SHALL not be used as the public health control for raw eggs.

## **SPECIALIZED PROCESSING METHODS**

### **§ 46.401. Variance requirement for specialized processing methods.**

A food facility shall obtain a variance from the Department as specified in § 46.1103(a) and (b) (relating to variances) before using any specialized processing method not currently recognized by the Department as a safe method for processing food.

### **§ 46.402. Reduced oxygen packaging.**

(a) *General requirement.* A food facility that packages food using a reduced oxygen packaging method--where *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form of the food--shall ensure that there are at least two

barriers in place to control the growth and toxin formation of *Clostridium botulinum*. This requirement does not apply to a food facility that has obtained a variance under § 46.401 (relating to variance requirement for specialized processing methods).

(b) *HACCP plan requirement.* A food facility that packages food using a reduced oxygen packaging method--where *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form of the food--shall have a HACCP plan that contains the information specified in § 46.1122(b)(4) (relating to HACCP plans) and that does all of the following:

- (1) Identifies the food to be packaged.
- (2) Limits the food packaged to a food that does not support the growth of *Clostridium botulinum* because it complies with one of the following:
  - (i) Has an  $a_w$  of 0.91 or less.
  - (ii) Has a pH of 4.6 or less.
  - (iii) Is a meat or poultry product cured at a food establishment regulated by USDA using substances specified in 9 CFR 318.7 424.21 (relating to ~~approval of substances for use in the preparation of products~~ USE OF FOOD INGREDIENTS AND SOURCES OF RADIATION) and 9 CFR 381.147 (relating to ~~restrictions on the use of substances in poultry products~~), and is received in an intact package.
  - (iv) Is a food with a high level of competing organisms such as raw meat or raw poultry.
- (3) Specifies methods for maintaining food at 5°C (41°F) or below.
- (4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to do the following:
  - (i) Maintain the food at 5°C (41°F) or below.
  - (ii) ~~Discard~~ FOR FOOD HELD AT REFRIGERATION TEMPERATURES, DISCARD the food within 14-calendar days of its packaging if it is not served for on-premises consumption, or it is not consumed if served or sold for off-premises consumption.
- (5) Limits the REFRIGERATED shelf life to no more than 14-calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first.
- (6) Includes operational procedures that do all of the following:
  - (i) Prohibit contacting food with bare hands.
  - (ii) Identify a designated area and the method by which ~~the following occur:~~
    - (A) ~~Physical~~ PHYSICAL barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination: AND



(B) ~~Access~~ ACCESS to the processing equipment is ~~restricted~~ LIMITED to responsible trained personnel familiar with the potential hazards of the operation.

(iii) Cleaning and sanitization procedures for food-contact surfaces are delineated.

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

(i) ~~Concepts~~ CONCEPTS required for a safe operation.,

(ii) ~~Equipment~~ THE EQUIPMENT and facilities., AND THE

(iii) ~~Procedures~~ PROCEDURES specified in paragraph (6) and § 46.1122(b)(4).

(c) *Special ~~restriction~~ LIMITATION with respect to certain fish.* Except for fish that is frozen before, during, and after packaging, a food facility ~~may~~ SHALL not package fish using a reduced oxygen packaging method.

## **FOOD IDENTITY, PRESENTATION AND ON-PREMISES LABELING**

### **§ 46.421. Accurate representation.**

(a) *Standards of identity.* Packaged food shall comply with standard of identity requirements in the following:

(1) ~~The act~~ SECTIONS 9 AND 13(f) OF THE FOOD ACT (31 P.S. §§ 20.9 AND 20.13(f)).

(2) Definitions in 21 CFR 131–169 (~~relating to Food and Drug Administration, Department of Health and Human Services~~) 131 (RELATING TO MILK AND CREAM) THROUGH 169 (RELATING TO FOOD DRESSINGS AND FLAVORINGS) and 9 CFR 319 (relating to definitions and standards of identity or composition).

(3) 21 CFR 130 (relating to food standards: general).

(4) 9 CFR 319, Subpart A (~~relating to definitions and standards of identity or composition~~ GENERAL).

(b) *Food shall be honestly presented.*

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

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

### **§ 46.422. Labeling.**

(a) *Labels required on packaged foods.* Food packaged in a food facility shall be labeled as specified in ~~the act~~ §§ 9, 10 AND 13(f) OF THE FOOD ACT (31 P.S. §§ 20.9, 20.10 AND 20.13(f)), 21 CFR 101 (relating to food labeling), 9 CFR 317 (relating to labeling, marking devices, and containers) and 9 CFR 381, Subpart N (relating to ~~poultry products inspection regulations~~ labeling and containers).

(b) *Label information on packaged foods.* Label information on packaged foods shall include the following:

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

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

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

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

(5) Except as exempted in section 403(q)(3)--(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 343(q)(3)--(5)), nutritional labeling as specified in 21 CFR 101 (relating to food labeling) and 9 CFR 317, Subpart B (relating to nutrition labeling).

(6) DISCLOSURE OF THE USE OF CANTHAXANTHIN FOR ANY SALMONID FISH CONTAINING CANTHAXANTHIN AS A COLOR ADDITIVE, BY THE LABELING OF THE BULK FISH CONTAINER, INCLUDING A LIST OF INGREDIENTS, DISPLAYED ON THE RETAIL CONTAINER OR BY OTHER WRITTEN MEANS, SUCH AS A COUNTER CARD.

(c) *Labeling information on bulk foods available for consumer self-dispensing or on unpackaged foods portioned to consumer specifications.* Bulk food that is available for consumer self-dispensing or unpackaged foods portioned to consumer specifications shall be prominently labeled with one of the following in plain view of the consumer:

(1) The manufacturer's or processor's label that was provided with the food.

(2) A card, sign or other method of notification (SUCH AS A PRODUCT LABELING BOOK) that includes the information specified in subsection (b)(1), (2) and (5).

(d) *Labeling information on certain bakery products.* Bakery products need not be labeled if they are sold directly to the consumer and the following are accurate:

(1) The food is either manufactured or prepared on the premises of the food facility or at another food facility that is owned by the same person and is regulated by the Department or other food regulatory agency that has jurisdiction.

(2) The information specified in subsection (b)(1), (2) and (5) is available at the place of sale.

(3) A health, nutrient content or other claim is not made.

(e) ~~Other forms of information.~~ CONCEALED OR ALTERED LABELING INFORMATION.

~~(1) If required by law, consumer warnings shall be provided.~~

~~(2) Food facility or manufacturers' dating information on foods may SHALL not be concealed or altered.~~

**§ 46.423. Consumer advisory required with respect to ~~animal~~ ANIMAL-DERIVED foods that are raw, undercooked or not otherwise processed to eliminate pathogens.**

Except as specified in §§ 46.361(c) and (d)(3) and 46.461 (relating to cooking raw ~~animal~~ ANIMAL-DERIVED foods; and additional safeguards for a food facility that serves a highly susceptible population), if an ~~animal~~ ANIMAL-DERIVED food such as beef, eggs, fish, lamb, milk, pork, poultry or shellfish that is raw, undercooked or not ~~other-wise~~ OTHERWISE processed to eliminate pathogens is offered in a ready-to-eat form as a deli, menu, vended or other item; or as a raw ingredient in another ready-to-eat food, the food facility shall inform consumers by brochures, deli case or menu advisories, label statements, table tents, placards or other effective written means of the significantly increased risk associated with certain highly susceptible populations eating these foods in raw or undercooked form.

**UNSAFE, ADULTERATED OR CONTAMINATED FOOD**

**§ 46.441. Discarding, or reconditioning unsafe, adulterated or contaminated food.**

The following foods shall be discarded:

(1) A food that is unsafe, adulterated or not honestly presented as specified in § 46.201 (relating to food shall be safe, unadulterated and honestly presented), unless the food is reconditioned according to a procedure approved by the Department.

(2) Food that is not from an approved source as specified in §§ 46.211--46.221.

(3) Ready-to-eat food that may have been contaminated by an employee that has been restricted or excluded as specified in § 46.113 (relating to duty to impose exclusions and restrictions).

(4) Food that is contaminated by food employees, consumers or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means.

(5) A FOOD SPECIFIED IN § 46.385(B)(1) AND (2) (RELATING TO POTENTIALLY HAZARDOUS FOOD: HOT AND COLD HOLDING), IF ANY OF THE FOLLOWING OCCUR:

(I) THE FOOD EXCEEDS THE TEMPERATURE SPECIFIED IN § 46.385(A) FOR MORE THAN 4 HOURS OR FOR AN UNDETERMINED AMOUNT OF TIME.

(II) THE FOOD IS IN A CONTAINER OR PACKAGE THAT DOES NOT BEAR A DATE OR DAY.

(6) REFRIGERATED, READY-TO-EAT, POTENTIALLY HAZARDOUS FOOD PREPARED IN A FOOD FACILITY AND DISPENSED THROUGH A VENDING MACHINE WITH AN AUTOMATIC SHUTOFF CONTROL SHALL BE DISCARDED IF IT EXCEEDS A TEMPERATURE AS SPECIFIED IN § 46.385 (A).

## SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

### § 46.461. Additional safeguards for a food facility that serves a highly susceptible population.

(a) *Prepackaged juice bearing a warning label prohibited.* In a food facility that serves a highly susceptible population, prepackaged juice or a prepackaged beverage containing juice, that bears a warning label as specified in 21 CFR 101.17(g) (relating to FOOD labeling warning, and notice, AND SAFE HANDLING statements), ~~may~~ SHALL not be served or offered for sale.

(B) *UNPACKAGED JUICE PREPARED ON THE PREMISES.* IN A FOOD FACILITY THAT SERVES A HIGHLY SUSCEPTIBLE POPULATION, UNPACKAGED JUICE THAT IS PREPARED ON THE PREMISES FOR SERVICE OR SALE IN A READY-TO-EAT FORM SHALL BE PROCESSED UNDER A HACCP PLAN THAT CONTAINS THE INFORMATION SPECIFIED IN § 46.1122 (RELATING TO HACCP PLANS) AND AS SPECIFIED IN 21 CFR 120.24 (RELATING TO PROCESS CONTROLS).

~~(b)~~ (C) *Pasteurized eggs required in certain foods.* In a food facility that serves a highly susceptible population, pasteurized shell eggs or pasteurized liquid, frozen, or dry eggs or egg products shall be substituted for raw shell eggs in the preparation of the following:

(1) Foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, egg nog, ice cream and egg-fortified beverages.

(2) Except as specified in subsection (e), recipes in which more than one egg is broken and the eggs are combined.

~~(c) Food in unopened original packages.~~ In a food facility that serves a highly susceptible population, ~~food in an unopened original package may not be re-served.~~

(d) *Prohibited ready-to-eat foods.* In a food facility that serves a highly susceptible population, the following foods ~~may~~ SHALL not be served or offered for sale in a ready-to-eat form:

(1) Raw ~~animal~~ ANIMAL-DERIVED foods such as raw fish, raw-marinated fish, raw molluscan shellfish and steak tartare.

(2) A partially cooked ~~animal~~ ANIMAL-DERIVED food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw shell eggs, and meringue.

(3) Raw seed sprouts.

(e) *Limited exception allowing use of raw eggs.* In a food facility that serves a highly susceptible population, subsection (b)(2) does not apply in any of the following circumstances:

(1) The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified in § 46.361(a)(1) (relating to cooking raw ~~animal~~ ANIMAL-DERIVED foods), and served immediately, such as an omelet, soufflé or scrambled eggs.

(2) The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin or bread.

(3) The preparation of the food is conducted under a HACCP plan that accomplishes the following:

(i) Identifies the food to be prepared.

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

(iii) Includes specifications and practices that ensure the following:

(A) Salmonella Enteritidis growth is controlled before and after cooking.

(B) Salmonella Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in § 46.361(a)(2).

(iv) Contains the information specified in § 46.1122(b)(4) (relating to HACCP plans) including procedures that accomplish the following:

(A) Control cross contamination of ready-to-eat food with raw eggs.

(B) Delineate cleaning and sanitization procedures for food-contact surfaces.

(v) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

## **Subchapter D. EQUIPMENT, UTENSILS AND LINENS**

### **GENERAL STANDARD**

Sec.

46.501. Acceptability of food equipment certified or classified for sanitation by an ANSI-accredited certification program.

### **MATERIALS FOR USE IN CONSTRUCTION AND REPAIR**

46.521. Materials in multiuse utensils and ~~food-contact~~ FOOD-CONTACT surfaces.

46.522. Materials for surfaces that are nonfood-contact surfaces.

46.523. Single-service and single-use articles: required characteristics.

### **DESIGN AND CONSTRUCTION**

46.541. Durability and strength.

46.542. Cleanability of multiuse food-contact surfaces and CIP equipment.

46.543. "V" threads: use limitation.

46.544. Cleanability of hot oil filtering equipment, can openers, nonfood-contact surfaces, kick plates and ventilation hood systems.

### **ACCURACY**

46.561. Accuracy of temperature measuring devices for food.

46.562. Accuracy of temperature measuring devices for ambient air and water.

46.563. Accuracy of pressure measuring devices on mechanical warewashing equipment.

### **FUNCTIONALITY**

- 46.581. Ventilation hood systems, drip prevention.
- 46.582. Equipment openings, closures and deflectors.
- 46.583. Dispensing equipment: protection of equipment and food.
- 46.584. Vending machines.
- 46.585. Bearings and gear boxes: leakproof.
- 46.586. Beverage tubing: separation.
- 46.587. Ice units: separation of drains.
- 46.588. Condenser unit: separation.
- 46.589. Molluscan shellfish tanks.
- 46.590. Temperature measuring devices.
- 46.591. Warewashing machines.
- 46.592. Manual warewashing machines.
- 46.593. Warewashing sinks and drainboards: self-draining.
- 46.594. Equipment compartments: drainage.
- 46.595. Case lot handling equipment: moveability.

#### **NUMBERS AND CAPACITIES OF EQUIPMENT**

- 46.611. Cooling, heating and holding capacities.
- 46.612. Manual warewashing: sink compartment requirements.
- 46.613. Drainboards.
- 46.614. Ventilation hood systems: adequacy.
- 46.615. Clothes washers and dryers.

#### **NUMBERS AND CAPACITIES OF UTENSILS, TEMPERATURE MEASURING DEVICES AND TESTING DEVICES**

- 46.631. Consumer self-service utensils.
- 46.632. Food temperature measuring devices.
- 46.633. Temperature measuring devices for manual warewashing.
- 46.634. Sanitizing solution testing devices.

#### **LOCATION AND INSTALLATION OF EQUIPMENT**

- 46.651. Location of equipment, clothes washers and dryers and storage cabinets to prevent contamination.
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#### **GENERAL STANDARD**

##### **§ 46.501. Acceptability of food equipment certified or classified for sanitation by an ANSI-accredited certification program.**

Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program shall be deemed to comply with the applicable provisions of §§ 46.521--46.523, 46.541--46.544, 46.561--46.563 and 46.581--46.595.

#### **MATERIALS FOR USE IN CONSTRUCTION AND REPAIR**

##### **§ 46.521. Materials in multiuse utensils and ~~food-contact~~ FOOD-CONTACT surfaces.**

(a) *Required characteristics.* Materials that are used in the construction of utensils and food-contact surfaces of equipment may SHALL not allow the migration of deleterious

substances or impart colors, odors or tastes to food. Under normal use conditions these materials shall be all of the following:

- (1) Safe.
- (2) Durable, corrosion-resistant and nonabsorbent.
- (3) Sufficient in weight and thickness to withstand repeated warewashing.
- (4) Finished to have a smooth, easily cleanable surface.
- (5) Resistant to pitting, chipping, crazing, scratching, scoring, distortion and decomposition.

(b) *Cast iron: use limitation.* Except as specified in paragraphs (1) and (2), cast iron ~~may~~ SHALL not be used for utensils or food-contact surfaces of equipment.

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

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

Utensil Category	Description	Maximum Lead in Mg/L (ppm)
Hot Beverage Mugs	Coffee Mugs	0.5
Large Hollowware	Bowls $\geq$ 1.1 L (1.16 Qt.)	1.0
Small Hollowware	Bowls $<$ 1.1 L (1.16 Qt.)	2.0
Flat Utensils	Plates, Saucers	3.0

(d) *Copper: use limitation.*

(1) Except as specified in paragraph (2), copper and copper alloys (such as brass) ~~may~~ SHALL not be used in contact with a food that has a pH below 6 (such as vinegar, fruit juice or wine) or for a fitting or tubing installed between a backflow prevention device and a carbonator.

(2) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

(e) *Galvanized metal: use limitation.* Galvanized metal ~~may~~ SHALL not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.

(f) *Sponges: use limitation.* Sponges ~~may~~ SHALL not be used in contact with cleaned and sanitized or in-use food-contact surfaces.

(g) *Lead in pewter alloys: use limitation.* Pewter alloys containing lead in excess of 0.05% ~~may~~ SHALL not be used as a food-contact surface.

(h) *Lead in solder and flux; use limitation.* Solder and flux containing lead in excess of 0.2% ~~may~~ SHALL not be used as a food-contact surface.



(i) *Wood: use limitation.* Except as specified in paragraphs (1)--(3), wood and wood wicker **may** **SHALL** not be used as a food-contact surface.

(1) Hard maple or an equivalently hard, close-grained wood may be used for the following:

(i) Cutting boards; cutting blocks; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls, PIZZA PEELS and chopsticks.

(ii) Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.

(2) Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables or nuts are used.

(3) If the nature of the food requires removal of rinds, peels, husks or shells before consumption, the whole, uncut, raw food may be kept in the following:

(i) Untreated wood containers.

(ii) Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 (relating to preservatives for wood).

(j) *Nonstick coatings, use limitation.* Multiuse kitchenware (such as frying pans, griddles, sauce pans, cookie sheets and waffle bakers) that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching utensils and cleaning aids.

#### **§ 46.522. Materials for surfaces that are nonfood-contact surfaces.**

Surfaces of equipment that are nonfood-contact surfaces, but are exposed to splash, spillage or other food soiling or that require frequent cleaning shall be constructed of a corrosion-resistant, nonabsorbent and smooth material.

#### **§ 46.523. Single-service and single-use articles: required characteristics.**

Materials that are used to make single-service and single-use articles shall be safe and clean, and **may** **SHALL** not allow the migration of deleterious substances, or impart colors, odors or tastes to food.

### **DESIGN AND CONSTRUCTION**

#### **§ 46.541. Durability and strength.**

(a) *Equipment and utensils.* Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

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

**§ 46.542. Cleanability of multiuse food-contact surfaces and CIP equipment.**

(a) *Multiuse food-contact surfaces.* Multiuse food-contact surfaces shall be all of the following:

- (1) Smooth.
- (2) Free of breaks, open seams, cracks, chips, inclusions, pits and similar imperfections.
- (3) Free of sharp internal angles, corners and crevices.
- (4) Finished to have smooth welds and joints.
- (5) Except as specified in subsection (b), accessible for cleaning and inspection by one of the following methods:
  - (i) Without being disassembled.
  - (ii) By disassembling without the use of tools.
  - (iii) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel (such as screwdrivers, pliers, open-end wrenches and Allen wrenches).

(b) *Exception.* Subsection (a)(5) does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.

(c) *CIP equipment.* CIP equipment shall meet the characteristics specified in subsection (a) and shall be designed and constructed so that the following are accurate:

- (1) Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces.
- (2) The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions.
- (3) If the CIP equipment is not designed for disassembly during cleaning, it is designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

**§ 46.543. "V" threads: use limitation.**

Except for hot oil cooking or filtering equipment, "V" type threads ~~may~~ SHALL not be used on food-contact surfaces.

**§ 46.544. Cleanability of hot oil filtering equipment, can openers, nonfood-contact surfaces, kick plates and ventilation hood systems.**

(a) *Hot oil filtering equipment.* Hot oil filtering equipment shall meet the characteristics specified in § 46.542 (relating to cleanability of multiuse food-contact surfaces and CIP equipment), as applicable, and shall be readily accessible for filter replacement and cleaning of the filter.

(b) *Can openers.* Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

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

(d) *Kick plates, removable.* Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being both of the following:

(1) Removable by one of the methods specified in § 46.542(a)(5) or capable of being rotated open.

(2) Removable or capable of being rotated open without unlocking equipment doors.

(e) *Ventilation hood systems, filters.* Filters or other grease extracting equipment, if not designed to be cleaned in place, shall be designed to be readily removable for cleaning and replacement.

## ACCURACY

### § 46.561. Accuracy of temperature measuring devices for food.

(a) *Accuracy range for Celsius-scaled or Celsius/Fahrenheit-scaled devices.* Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to  $\pm 1^{\circ}\text{C}$  in the intended range of use.

(b) *Accuracy for Fahrenheit-scaled devices.* Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to  $\pm 2^{\circ}\text{F}$  in the intended range of use.

### § 46.562. Accuracy of temperature measuring devices for ambient air and water.

(a) *Accuracy range for Celsius-scaled or Celsius/Fahrenheit-scaled devices.* Ambient air and water temperature measuring devices that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to  $\pm 1.5^{\circ}\text{C}$  in the intended range of use.

(b) *Accuracy for Fahrenheit-scaled devices.* Ambient air and water temperature measuring devices that are scaled only in Fahrenheit shall be accurate to  $\pm 3^{\circ}\text{F}$  in the intended range of use.

### § 46.563. Accuracy of pressure measuring devices on mechanical warewashing equipment.

Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse on mechanical warewashing equipment shall have increments of 7 kilopascals (1 pounds per square inch) or smaller, and shall be accurate to  $\pm 14$  kilopascals ( $\pm 2$  pounds per square inch) in the 100--170 kilopascals (15--25 pounds per square inch) range.

## FUNCTIONALITY

### § 46.581. Ventilation hood systems, drip prevention.

Exhaust ventilation hood systems in food preparation and warewashing areas (including components such as hoods, fans, guards and ducting) shall be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.

### § 46.582. Equipment openings, closures and deflectors.

(a) *Overlap and slope of covers.* A cover or lid for equipment shall overlap the opening and be sloped to drain.

(b) *Flange requirement.* An opening located within the top of a unit of equipment that is designed for use with a cover or lid shall be flanged upward at least 5 millimeters (2/10 of an inch).

(c) *Watertight joint.* Except as specified in subsection (d), fixed piping, temperature measuring devices, rotary shafts and other parts extending into equipment shall be provided with a watertight joint at the point where the item enters the equipment.

(d) *Alternative to watertight joint.* If a watertight joint is not provided, the piping, temperature measuring devices, rotary shafts and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips and dust from openings into the food. The openings shall be flanged as specified in subsection (b).

### § 46.583. Dispensing equipment: protection of equipment and food.

In equipment that dispenses or vends liquid food or ice in unpackaged form, the following shall occur:

(1) The delivery tube, chute orifice and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food.

(2) The delivery tube, chute and orifice shall be protected from manual contact such as by being recessed.

(3) The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents and other contamination by a self-closing door if the equipment is either of the following:

(i) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents and other contaminants that are present in the environment.

(ii) Available for self-service during hours when it is not under the full-time supervision of a food employee.

(4) The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

#### **§ 46.584. Vending machines.**

(a) *Vending stage closure.* The dispensing compartment of a vending machine--including a machine that is designed to vend prepackaged snack food that is not potentially hazardous (such as chips, party mixes and pretzels)--shall be equipped with a self-closing door or cover if the machine is either of the following:

(1) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents and other contaminants that are present in the environment.

(2) Available for self-service during hours when it is not under the full supervision of a food employee.

(b) *Automatic shutoff.*

(1) A machine vending potentially hazardous food shall have an automatic control that prevents the machine from vending food under either of the following circumstances:

(i) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that ~~can not~~ CANNOT maintain food temperatures as specified in Subchapter C (relating to food).

(ii) If a condition specified in subparagraph (i) occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified in Subchapter C.

(2) When the automatic shutoff within a refrigerated vending machine ~~vending~~ DISPENSING potentially hazardous food is activated, the ambient temperature ~~may~~ SHALL not exceed 5°C (41°F) or 7°C (45°F) as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding) for more than 30 minutes immediately after the machine is filled, serviced or restocked.

(3) When the automatic shutoff within a hot holding vending machine ~~vending~~ DISPENSING potentially hazardous food is activated, the ambient temperature ~~may~~ SHALL not be less than ~~60°C (140°F)~~ 58°C (135°F) for more than 120 minutes immediately after the machine is filled, serviced or restocked.

(c) *Can openers.* Cutting or piercing parts of can openers on vending machines shall be protected from manual contact, dust, insects, rodents and other contamination.

(d) *Vending machines that dispense liquids in paper containers.* Vending machines designed to store beverages that are packaged in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(e) *Vending machines that dispense liquid food in bulk.* Vending machines that dispense liquid food in bulk shall be both of the following:

(1) Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow or other internal wastes.

(2) Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(f) *Requirements for a liquid shutoff device.* Shutoff devices described in subsection (e)(2) shall prevent water or liquid food from continuously running if there is a failure of a flow control device in the water or liquid food system or waste accumulation that could lead to overflow of the waste receptacle.

(g) *Doors and openings.*

(1) Vending machine doors and access opening covers to food and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than 1.5 millimeters or 1/16 inch by one or more of the following:

(i) Being covered with louvers, screens or materials that provide an equivalent opening of not greater than 1.5 millimeters or 1/16 inch. Screening of 12 or more mesh to 2.5 centimeters (12 mesh to 1 inch) meets this requirement.

(ii) Being effectively gasketed.

(iii) Having interface surfaces that are at least 13 millimeters or 1/2 inch wide.

(iv) Jambs or surfaces used to form an L-shaped entry path to the interface.

(2) Vending machine service connection openings through an exterior wall of the machine, shall be closed by sealants, clamps, or grommets so that the openings are no larger than 1.5 millimeters or 1/16 inch.

#### **§ 46.585. Bearings and gear boxes: leakproof.**

Equipment containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant ~~can not~~ CANNOT leak, drip or be forced into food or onto food-contact surfaces.

#### **§ 46.586. Beverage tubing: separation.**

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

#### **§ 46.587. Ice units: separation of drains.**

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

#### **§ 46.588. Condenser unit: separation.**

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

#### **§ 46.589. Molluscan shellfish tanks.**

(a) *General.* Except as specified in subsection (b), molluscan shellfish life support system display tanks ~~may~~ SHALL not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only.

(b) *Exception.* Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with the following:

(1) A variance granted by the Department in accordance with the procedure described in § 46.1103(a) (relating to variances).

(2) A HACCP plan that is submitted by the food facility operator and approved as specified in § 46.1103(b), ensuring the following:

(i) Water used with fish other than molluscan shellfish does not flow into the molluscan tank.

(ii) The safety and quality of the shellfish as they were received are not compromised by the use of the tank.

(iii) The identity of the source of the shellstock is retained as specified in § 46.250 (relating to shellstock: maintaining identification).

#### **§ 46.590. Temperature measuring devices.**

(a) *Location of device in storage unit.* In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature OR A SIMULATED PRODUCT TEMPERATURE in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.

(b) *General device requirement.* Except as specified in subsection (c), cold or hot holding equipment used for potentially hazardous food shall be designed to include--and shall be equipped with--at least one integral or permanently affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.

(c) *Exception to device requirement.* Subsection (b) does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers and salad bars.

(d) *Easily readable.* Temperature measuring devices shall be designed to be easily readable.

(e) *Devices on warewashing machines.* Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record or digital readout in increments no greater than 1°C or 2°F in the intended range of use.

## **§ 46.591. Warewashing machines.**

(a) *Data plate summarizing operating specifications.* A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operating specifications, including the following:

- (1) Temperatures required for washing, rinsing and sanitizing.
- (2) Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse.
- (3) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

(b) *Internal baffles.* Warewashing machine wash and rinse tanks shall be equipped with baffles, curtains or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

(c) *Temperature measuring devices.* A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature in the following locations or instances:

- (1) In each wash and rinse tank.
- (2) As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.

(d) ~~Sanitizer~~ **DETERGENT AND SANITIZER level indicator.** A warewashing machine ~~that uses a chemical for sanitization and that is installed after the effective date of this chapter shall be DESIGNED AND equipped with a device that indicates audibly or visually when more chemical sanitizer needs to be added~~ **TO AUTOMATICALLY DISPENSE DETERGENTS AND SANITIZERS AND INCORPORATE A VISUAL MEANS TO VERIFY THAT DETERGENTS AND SANITIZERS ARE DELIVERED OR A VISUAL OR AUDIBLE ALARM TO SIGNAL IF THE DETERGENTS AND SANITIZERS ARE NOT DELIVERED TO THE RESPECTIVE WASHING AND SANITIZING CYCLES.**

(e) *Flow pressure device.* Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine. If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device shall be mounted in a 6.4 millimeter or 1/4 inch Iron Pipe Size (IPS) valve. This subsection does not apply to a machine that uses only a pumped or recirculated sanitizing rinse.

## **§ 46.592. Manual warewashing machines.**

If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall comply with the following:

- (1) Be designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F).



(2) Be provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

**§ 46.593. Warewashing sinks and drainboards: self-draining.**

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

**§ 46.594. Equipment compartments: drainage.**

Equipment compartments that are subject to accumulation of moisture due to conditions such as condensation, food or beverage drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

**§ 46.595. Case lot handling equipment: moveability.**

Equipment, such as dollies, pallets, racks and skids used to store and transport large quantities of packaged foods received from a supplier in a cased or over-wrapped lot, shall be designed to be moved by hand or by conveniently available equipment such as hand trucks and forklifts.

## **NUMBERS AND CAPACITIES OF EQUIPMENT**

**§ 46.611. Cooling, heating and holding capacities.**

Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity to provide food temperatures as specified in Subchapter C (relating to food).

**§ 46.612. Manual warewashing: sink compartment requirements.**

(a) *General: three compartments required.* Except as specified in subsection (c), a sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.

(b) *Large equipment and utensils.* Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils THAT REQUIRE CLEANING BY IMMERSION. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in subsection (c) shall be used.

(c) *Exception for approved alternative equipment.* Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved by the Department. Alternative manual warewashing equipment may include any of the following:

- (1) High-pressure detergent sprayers.
- (2) Low- or line-pressure spray detergent foamers.
- (3) Other task-specific cleaning equipment, SUCH AS UTENSILS SUPPLIED BY AN EQUIPMENT MANUFACTURER.
- (4) Brushes or ~~other~~ SIMILAR BRISTLED implements.

(5) Two-compartment sinks as specified in ~~subsection (d)~~ § 46.676 (F) (RELATING TO MANUAL WAREWASHING EQUIPMENT).

(6) Receptacles that substitute for the compartments of a multi-compartment sink.

~~(d) Use of two-compartment sink. A two-compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process. A two-compartment sink may be used when all of the following are accurate:~~

~~(1) The food facility operator has obtained approval from the Department to use the two-compartment sink.~~

~~(2) The nature of warewashing is limited to batch operations for cleaning kitchenware (such as between cutting one type of raw meat and another or cleanup at the end of a shift) and the following are accurate:~~

~~(i) The number of items to be cleaned is limited.~~

~~(ii) The cleaning and sanitizing solutions are made up immediately before use and drained immediately after use.~~

~~(iii) Either a detergent sanitizer is used to sanitize and is applied as specified in § 46.676(e) (relating to manual warewashing equipment), or a hot water sanitization immersion step is used as specified in § 46.718(3) (relating to rinsing procedures).~~

#### **§ 46.613. Drainboards.**

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.

#### **§ 46.614. Ventilation hood systems: adequacy.**

Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and, ceilings AND FIXTURES.

#### **§ 46.615. Clothes washers and dryers.**

A mechanical clothes washer and dryer shall be provided and used at a food facility if work clothes or linens are laundered on the premises. This section does not apply if on-premises laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified in § 46.772 (relating to wiping cloths: air-drying locations).

### **NUMBERS AND CAPACITIES OF UTENSILS, TEMPERATURE MEASURING DEVICES AND TESTING DEVICES**

#### **§ 46.631. Consumer self-service utensils.**

A food-dispensing utensil shall be available for each container displayed at a consumer self-service unit (such as a buffet or salad bar).

#### **§ 46.632. Food temperature measuring devices.**

Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified in Subchapter C (relating to food). A FOOD TEMPERATURE MEASURING DEVICE WITH A SUITABLE SMALL-DIAMETER PROBE THAT IS DESIGNED TO MEASURE THE TEMPERATURE OF THIN MASSES SHALL BE PROVIDED AND READILY ACCESSIBLE TO ACCURATELY MEASURE THE TEMPERATURE OF THIN FOODS, SUCH AS MEAT PATTIES OR FISH FILLETS.

#### **§ 46.633. Temperature measuring devices for manual warewashing.**

In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

#### **§ 46.634. Sanitizing solution testing devices.**

A test kit or other device that accurately measures the concentration in mg/L or ppm, of sanitizing solutions shall be provided.

### **LOCATION AND INSTALLATION OF EQUIPMENT**

#### **§ 46.651. Location of equipment, clothes washers and dryers and storage cabinets to prevent contamination.**

(a) *Prohibited locations.* Except as specified in subsection (b), equipment, a cabinet used for the storage of food, or a cabinet that is used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles ~~may~~ SHALL not be located in the following:

- (1) Locker rooms.
- (2) Toilet rooms.
- (3) Garbage rooms.
- (4) Mechanical rooms.
- (5) Under sewer lines that are not shielded to intercept potential drips.
- (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed.
- (7) Under open stairwells.
- (8) Under other sources of contamination.

(b) *Exception.* A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.

(c) *Mechanical clothes washer or dryer.* If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed food; clean equipment, utensils and linens; and unwrapped single-service and single-use articles.

**§ 46.652. Installation of fixed equipment, fixed table-mounted equipment and fixed floor-mounted equipment.**

(a) *Fixed equipment: spacing or sealing.* Equipment that is fixed because it is not easily movable shall be installed so that it is both of the following:

(1) Spaced to allow access for cleaning along the sides, behind and above the equipment.

(2) Spaced from adjoining equipment, walls and ceilings a distance of not more than 1 millimeter or 1/32 inch or--if the equipment is exposed to spillage or seepage--sealed to adjoining equipment or walls.

(b) *Fixed table-mounted equipment.* Table-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being one of the following:

(1) Sealed to the table.

(2) Elevated on legs that provide at least one of the following:

(i) 10 centimeters (4 inches) clearance between the table and the equipment.

(ii) 7.5 centimeters (3 inches) clearance between the table and the equipment if the horizontal distance of the table top under the equipment is no more than 50 centimeters (20 inches) from the point of access for cleaning.

(iii) 5 centimeters (2 inches) clearance between the table and the equipment if the horizontal distance of the table top under the equipment is no more than 7.5 centimeters (3 inches) from the point of access for cleaning.

(c) *Fixed floor-mounted equipment.*

(1) Except as specified in paragraph (2) or (3), floor-mounted equipment that is not easily movable shall be sealed to the floor or elevated on legs that provide at least a 15 centimeters (6 inches) clearance between the floor and the equipment.

(2) If no part of the floor under the floor-mounted equipment is more than 15 centimeters (6 inches) from the point of cleaning access, the clearance space may be only 10 centimeters (4 inches).

(3) This section does not apply to display shelving units, display refrigeration units and display freezer units located in the consumer shopping areas of a retail food store, if the floor under the units is maintained clean.

**MAINTENANCE AND OPERATION OF EQUIPMENT**

**§ 46.671. Equipment: good repair and proper adjustment.**

(a) *General.* Equipment shall be maintained in a state of repair and condition that meets the requirements specified in §§ 46.501, 46.521--46.523, 46.541--46.544, 46.561--46.563 and 46.581--46.595.

(b) *Equipment components.* Equipment components such as doors, seals, hinges, fasteners and kick plates shall be kept intact, tight and adjusted in accordance with manufacturer's specifications.

(c) *Cutting or piercing parts of can openers.* Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

#### **§ 46.672. Cutting surfaces.**

Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded if they are not capable of being resurfaced.

#### **§ 46.673. Microwave ovens.**

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 (relating to microwave ovens).

#### **§ 46.674. Warewashing equipment: mechanical or manual.**

(a) *Cleaning frequency.* A warewashing machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, or raw foods, or laundering wiping cloths; and drainboards or other equipment used to substitute for drainboards as specified in § 46.613 (relating to drainboards) shall be cleaned as follows:

(1) Before use.

(2) Throughout the day at a frequency necessary to prevent recontamination of equipment and utensils and to ensure that the equipment performs its intended function.

(3) If used, at least every 24 hours.

(b) *Cleaning agents.* When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in § 46.612(c) (relating to manual warewashing: sink compartment requirements), shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner or other cleaning agent according to the cleaning agent manufacturer's label instructions.

(c) *Clean solutions.* The wash, rinse and sanitize solutions shall be maintained clean.

(d) *Chemical sanitization: temperature, pH, concentration and hardness.* A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at exposure times specified in § 46.731(c)(3) (relating to sanitization: requirement, frequency and methods) shall be listed in 21 CFR 178.1010 (relating to sanitizing solutions), shall be used in accordance with the EPA-approved manufacturer's label use instructions, and shall be used as follows:

(1) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart:

<b>Minimum Concentration</b>	<b>Minimum Temperature for Solution with pH of 10 or less</b>	<b>Minimum Temperature for Solution with pH of 8 or less</b>
25 mg/L (ppm)	49°C (120°F)	49°C (120°F)

50 mg/L (ppm)	38°C (100°F)	24°C (75°F)
100 mg/L (ppm)	13°C (55°F)	13°C (55°F)

(2) An iodine solution shall have the following:

(i) A minimum temperature of 24°C (75°F).

(ii) A pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective.

(iii) A concentration between 12.5 mg/L (ppm) and 25 mg/L (ppm).

(3) A quaternary ammonium compound solution shall:

(i) Have a minimum temperature of 24°C (75°F).

(ii) Have a concentration as specified in ~~§ 46.713 (relating to chemicals: use criteria)~~ § 46.731 (RELATING TO SANITIZATION: REQUIREMENT, FREQUENCY AND METHODS) and as indicated by the manufacturer's use directions included in the labeling.

(iii) Be used only in water with 500 mg/L (ppm) hardness or less or in water having a hardness no greater than specified by the manufacturer's label.

(4) If another solution of a chemical specified in paragraphs (1)--(3) is used, the food facility operator shall demonstrate to the Department that the solution achieves sanitization and the use of the solution may be approved by the Department.

(5) If a chemical sanitizer other than chlorine, iodine or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer use directions included in the labeling.

(e) *Determining chemical sanitizer concentration.* Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.

#### **§ 46.675. Mechanical warewashing equipment.**

(a) *Manufacturers' operating instructions.*

(1) A warewashing machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.

(2) A warewashing machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

(b) *Wash solution temperature where hot water is used to sanitize.* The temperature of the wash solution in spray type warewashers that use hot water to sanitize ~~may~~ **SHALL** not be less than the following temperature, as applicable:

(1) For a stationary rack, single temperature machine, 74°C (165°F).

(2) For a stationary rack, dual temperature machine, 66°C (150°F).

(3) For a single tank, conveyor, dual temperature machine, 71°C (160°F).

(4) For a multitank, conveyor, multitemperature machine, 66°C (150°F).

(c) *Wash solution temperature where chemicals are used to sanitize.* The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize ~~may~~ SHALL not be less than 49°C (120°F).

(d) *Sanitizing rinse temperature where hot water is used to sanitize.*

(1) Except as specified in paragraph (2), in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold ~~may~~ SHALL not be more than 90°C (194°F), or less than the following, as applicable:

(i) For a stationary rack, single temperature machine: 74°C (165°F).

(ii) For all other machines: 82°C (180°F).

(2) The maximum temperature specified in paragraph (1) does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.

(e) *Sanitization pressure.* The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine ~~may~~ SHALL not be less than 100 kilopascals (15 pounds per square inch) or more than 170 kilopascals (25 pounds per square inch) as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve.

#### **§ 46.676. Manual warewashing equipment.**

(a) *Warewashing sinks: use limitation.* A warewashing sink ~~may~~ SHALL not be used for handwashing. WAREWASHING SINKS SHALL NOT BE USED FOR FOOD PREPARATION UNLESS THE USE IS APPROVED BY THE DEPARTMENT, THE PROCEDURES SPECIFIED IN SUBSECTION (B) ARE FOLLOWED AND LIMITED FOOD PREPARATION OR WAREWASHING OCCURS.

(b) *Sanitizing warewashing sink after other uses.* If a warewashing sink is used to wash wiping cloths, wash produce or thaw food, the sink shall be cleaned as specified in § 46.674(a) (relating to warewashing equipment: mechanical or manual) before and after each time it is used to wash wiping cloths, wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified in § 46.731 (relating to sanitization: requirement, frequency and methods) before and after using the sink to wash produce or thaw food.

(c) *Wash solution temperature.* The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions.

(d) *Hot water sanitization temperatures.* If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above.

(e) *Chemical sanitization using detergent-sanitizers.* If a detergent-sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step shall be the same detergent-sanitizer that is used in the washing step.

(F) *USE OF TWO-COMPARTMENT SINK.* A TWO-COMPARTMENT SINK SHALL NOT BE USED FOR WAREWASHING OPERATIONS WHERE CLEANING AND SANITIZING SOLUTIONS ARE USED FOR A CONTINUOUS OR INTERMITTENT FLOW OF KITCHENWARE OR TABLEWARE IN AN ONGOING WAREWASHING PROCESS. A TWO-COMPARTMENT SINK MAY BE USED FOR WAREWASHING WHEN ALL OF THE FOLLOWING ARE ACCURATE:

(1) THE FOOD FACILITY OPERATOR HAS OBTAINED APPROVAL FROM THE DEPARTMENT TO USE THE TWO-COMPARTMENT SINK.

(2) THE NATURE OF WAREWASHING IS LIMITED TO BATCH OPERATIONS FOR CLEANING KITCHENWARE (SUCH AS BETWEEN CUTTING ONE TYPE OF RAW MEAT AND ANOTHER OR CLEANUP AT THE END OF A SHIFT) AND THE FOLLOWING ARE ACCURATE:

(I) THE NUMBER OF ITEMS TO BE CLEANED IS LIMITED.

(II) THE CLEANING AND SANITIZING SOLUTIONS ARE MADE UP IMMEDIATELY BEFORE USE AND DRAINED IMMEDIATELY AFTER USE.

(III) EITHER A DETERGENT-SANITIZER IS USED TO SANITIZE AND IS APPLIED IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS AND AS SUBSECTION (E) (RELATING TO MANUAL WAREWASHING EQUIPMENT), OR A HOT WATER SANITIZATION IMMERSION STEP IS USED AS SPECIFIED IN § 46.718(3) (RELATING TO RINSING PROCEDURES).

## **MAINTENANCE AND OPERATION OF UTENSILS AND TEMPERATURE AND PRESSURE MEASURING DEVICES**

### **§ 46.691. Utensils and temperature and pressure measuring devices: repair and calibration.**

(a) *General requirement of good repair and calibration.* Utensils shall be maintained in a state of repair or condition that complies with the requirements specified in §§ 46.501--46.521, 46.523, 46.541--46.544, 46.561--46.563, 46.581--46.595 or shall be discarded.

(b) *Food temperature measuring devices.* Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

(c) *Ambient air temperature, water pressure and water temperature measuring devices.* Ambient air temperature, water pressure and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use.

### **§ 46.692. Single-service and single-use articles.**

(a) *Required use.* A food facility without facilities specified in §§ 46.711--46.719 (relating to cleaning of equipment and utensils) for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers.



(b) *Use limitation.*

(1) Single-service and single-use articles ~~may~~ SHALL not be reused.

(2) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than 1 inch protruding from the chilled dispensing head.

**§ 46.693. Mollusk and crustacean shells used as serving containers.**

Mollusk and crustacean shells ~~may~~ SHALL not be used more than once as serving containers.

**CLEANING OF EQUIPMENT AND UTENSILS**

**§ 46.711. Objective of cleaning equipment and utensils.**

(a) *General cleanliness requirement.* Equipment food-contact surfaces and utensils shall be clean to sight and touch.

(b) *Grease and soil accumulations.* The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.

(c) ~~Nonfood-contact~~ **NONFOOD-CONTACT** surfaces. Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue and other debris.

**§ 46.712. Frequency of cleaning equipment food-contact surfaces and utensils.**

(a) *General requirements.* Equipment food-contact surfaces and utensils shall be cleaned as follows:

(1) Except as specified in subsection (b), before each use with a different type of raw ~~animal~~ **ANIMAL-DERIVED** food such as beef, fish, lamb, pork or poultry.

(2) Each time there is a change from working with raw foods to working with ready-to-eat foods.

(3) Between uses with raw fruits and vegetables and with potentially hazardous food.

(4) Before using or storing a food temperature measuring device.

(5) At any time during the operation when contamination may have occurred.

(b) *Exception.* Subsection (a)(1) does not apply if the food-contact surface or utensil is in contact with a succession of different raw ~~animal~~ **ANIMAL-DERIVED** foods each requiring a higher cooking temperature as specified in § 46.361 (relating to cooking raw ~~animal~~ **ANIMAL-DERIVED** foods) than the previous food (such as preparing raw fish followed by cutting raw poultry on the same cutting board).

(c) *Maximum cleaning interval for equipment food-contact surfaces and utensils in contact with potentially hazardous food.* Except as specified in subsection (d), if used with potentially hazardous food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every 4 hours.

(d) *Exceptions.* Surfaces of utensils and equipment contacting potentially hazardous food may be cleaned less frequently than every 4 hours under any of the following circumstances:

(1) In storage, containers of potentially hazardous food and their contents are maintained at temperatures specified in Subchapter C (relating to food characteristics) and the containers are cleaned when they are empty.

(2) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the chart in subparagraph (i) and both of the following occur:

(i) The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature:

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

(ii) The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food facility.

(3) Containers in serving situations such as salad bars, delis and cafeteria lines hold ready-to-eat potentially hazardous food that is maintained at the temperatures specified in Subchapter C, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are EMPTIED AND cleaned at least every 24 hours.

(4) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified in Subchapter C.

(5) Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues.

(6) The cleaning schedule is approved by the Department based on consideration of the following:

(i) Characteristics of the equipment and its use.

(ii) The type of food involved.

(iii) The amount of food residue accumulation.

(iv) The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease.

(7) In-use utensils are intermittently stored in a container of water in which the water is maintained at ~~60°C (140°F)~~ 58°C (135°F) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

(e) *Maximum cleaning interval for equipment food-contact surfaces and utensils in contact with food that is not potentially hazardous.* Except when dry cleaning methods are used as specified in § 46.715(a) (relating to methods of cleaning) surfaces of utensils and equipment contacting food that is not potentially hazardous shall be cleaned as follows:

(1) At any time when contamination may have occurred.

(2) At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops or ladles.

(3) Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers.

(4) In equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders and water vending equipment as follows:

(i) At a frequency specified by the manufacturer.

(ii) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

#### **§ 46.713. Frequency of cleaning cooking and baking equipment.**

(a) ~~Food-contact~~ **FOOD-CONTACT** surfaces. The food-contact surfaces of cooking and baking equipment shall be cleaned at least every 24 hours. This requirement does not apply to hot oil cooking and filtering equipment if it is cleaned as specified in § 46.712(d)(6) (relating to frequency of cleaning equipment food-contact surfaces and utensils).

(b) *Microwave ovens.* The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

#### **§ 46.714. Frequency of cleaning nonfood-contact surfaces.**

Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

#### **§ 46.715. Methods of cleaning.**

(a) *Dry cleaning.*

(1) If used, dry cleaning methods such as brushing, scraping and vacuuming shall contact only surfaces that are soiled with dry food residues that are not potentially hazardous.

(2) Cleaning equipment used in dry cleaning food-contact surfaces ~~may~~ SHALL not be used for any other purpose.

(b) *Precleaning.*

(1) Food debris on equipment and utensils shall be ~~scrapped~~ SCRAPED over a waste disposal unit ~~scraper~~, or garbage receptacle or may be removed in a warewashing machine with a prewash cycle.

(2) If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked or scrubbed with abrasives.

(c) *Wet cleaning.*

(1) Equipment food-contact surfaces and utensils shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary, such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(2) The washing procedures selected shall be based on the type and purpose of the equipment or utensil, and on the type of soil to be removed.

**§ 46.716. Washing: loading of soiled items into warewashing machines.**

Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that exposes the items to the unobstructed spray from all cycles, and allows the items to drain.

**§ 46.717. Washing procedures for alternative warewashing equipment.**

If washing in sink compartments or a warewashing machine is impractical (such as when the equipment is fixed or the utensils are too large) washing shall be done by using alternative manual warewashing equipment as specified in § 46.612(c) (relating to manual warewashing: sink compartment requirements) in accordance with the following procedures:

(1) Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts.

(2) Equipment components and utensils shall be scrapped or rough cleaned to remove food particle accumulation.

(3) Equipment and utensils shall be washed as specified in § 46.715(c)(1) (relating to methods of cleaning).

**§ 46.718. Rinsing procedures.**

Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one of the following procedures:

(1) Use of a distinct, separate water rinse after washing and before sanitizing if using any of the following:

(i) A three-compartment sink.

(ii) Alternative manual warewashing equipment equivalent to a three-compartment sink as specified in § 46.612(c) (relating to manual warewashing: sink compartment requirements).

(iii) A three-step washing, rinsing and sanitizing procedure in a warewashing system for CIP equipment.

(2) Use of a detergent-sanitizer as specified in § 46.676(f) (relating to manual warewashing equipment) if using either of the following:

(i) Alternative warewashing equipment as specified in § 46.612(c) that is approved for use with a detergent-sanitizer.

(ii) A warewashing system for CIP equipment.

(3) Use of a nondistinct water rinse that is integrated in the hot water sanitization immersion step of a two-compartment sink operation.

(4) If using a warewashing machine that does not recycle the sanitizing solution as specified in paragraph (5), or alternative manual warewashing equipment (such as sprayers), use of a nondistinct water rinse that is the following:

(i) Integrated in the application of the sanitizing solution.

(ii) Wasted immediately after each application.

(5) If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the sanitizing solution.

#### **§ 46.719. Washing returnable containers for refilling.**

(a) *General requirement.* Except as specified in subsections (b) and (c), returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food establishment.

(b) *Exception.* A food-specific container for beverages may be refilled at a food facility if all of the following are accurate:

(1) Only a beverage that is not a potentially hazardous food is used as specified in § 46.307(a) (relating to refilling returnables).

(2) The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food facility.

(3) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system.

(4) The consumer-owned container returned to the food facility for refilling is refilled for sale or service only to the same consumer.

(5) The container is refilled by either of the following:

(i) An employee of the food facility.

- (ii) The owner of the container if the beverage system includes a contamination-free transfer process that cannot be bypassed by the container owner.
- (c) *Exception.* Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

## **SANITIZATION OF EQUIPMENT AND UTENSILS**

### **§ 46.731. Sanitization: requirement, frequency and methods.**

- (a) *Requirement.* Equipment food-contact surfaces and utensils shall be sanitized in accordance with this section.
- (b) *Frequency.* Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning.
- (c) *Methods: hot water and chemical.* After being cleaned, equipment food-contact surfaces and utensils shall be sanitized by the following methods, based upon the type of operation:
  - (1) In hot water manual operations: by immersion for at least 30 seconds and as specified in § 46.676(d) (relating to manual warewashing equipment).
  - (2) In hot water mechanical operations: by being cycled through equipment that is set up as specified in § 46.675(a), (d) and (e) (relating to mechanical warewashing equipment) and achieving a utensil surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator.
  - (3) In chemical manual or mechanical operations: including the application of sanitizing chemicals by immersion, manual swabbing, brushing or pressure spraying methods, using a solution as specified in § 46.674(d) (relating to warewashing equipment: mechanical or manual) for the following exposure time, as applicable:
    - (i) Except as specified in subparagraph (ii), an exposure time of at least 10 seconds for a chlorine solution specified in § 46.674(d)(1).
    - (ii) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L (ppm) that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F).
    - (iii) An exposure time of at least 30 seconds for other chemical sanitizing solutions.
    - (iv) An exposure time used in relationship with a combination of temperature, concentration and pH that, when evaluated for efficacy, yields sanitization.

## **LAUNDERING**

### **§ 46.751. Requirement and frequency of laundering.**

- (a) *Requirement.* Clean linens shall be free from food residues and other soiling matter.

(b) *Frequency of laundering.*

(1) Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky or visibly soiled.

(2) Cloth gloves used as specified in § 46.305(d) (relating to gloves: use limitations) shall be laundered before being used with a different type of raw ~~animal~~ ANIMAL-DERIVED food such as beef, lamb, pork and fish.

(3) Linens and napkins that are used as specified in § 46.303 (relating to linens and napkins: use limitations) and cloth napkins shall be laundered between each use.

(4) Wet wiping cloths shall be laundered daily.

(5) Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

**§ 46.752. Methods of laundering.**

(a) *Storage of soiled linens.* Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single-service and single-use articles.

(b) *Mechanical washing.* All linens shall be mechanically washed, except in food facilities where only wiping cloths are laundered as specified in § 46.615(b) (relating to clothes washers and dryers), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a warewashing or food preparation sink that is cleaned as specified in § 46.674(a) (relating to warewashing equipment: mechanical or manual).

**§ 46.753. Use of laundry facilities.**

(a) *General requirement.* Except as specified in subsection (b), laundry facilities on the premises of a food facility shall be used only for the washing and drying of items used in the operation of the facility.

(b) *Exception.* Separate laundry facilities located on the premises for the purpose of general laundering (such as for institutions providing boarding and lodging) may also be used for laundering food facility items.

**PROTECTION OF CLEAN ITEMS**

**§ 46.771. Drying clean equipment and utensils.**

(a) *Air-drying or adequate draining required.* After cleaning and sanitizing, equipment and utensils shall be air-dried or used after adequate draining as specified in paragraph (a) of 21 CFR ~~78.1010~~ 178.1010 (relating to sanitizing solutions) before contact with food.

(b) *Cloth drying.* After cleaning and sanitizing, equipment and utensils ~~may~~ SHALL not be cloth-dried, except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

**§ 46.772. Wiping cloths: air-drying locations.**

(a) *General.* Except as provided in subsection (b), wiping cloths laundered in a food facility that does not have a mechanical clothes dryer as specified in § 46.615(b) (relating to clothes washers and dryers) shall be air-dried in a location and in a manner that prevents contamination of food, equipment, utensils, linens, and single-service and single-use articles and the wiping cloths.

(b) *Exception.* This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified in § 46.674(d) (relating to warewashing equipment: mechanical or manual).

**§ 46.773. Lubricating and reassembling clean ~~food-contact~~ FOOD-CONTACT surfaces and equipment.**

(a) *Food-contact surfaces.* Lubricants shall be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces.

(b) *Equipment.* Equipment shall be reassembled so that food-contact surfaces are not contaminated.

**§ 46.774. Storing clean items.**

(a) *General requirement for equipment, utensils, linens, and single-service and single-use articles.* Except as specified in subsection (d), cleaned equipment and utensils, laundered linens, and single-service and single-use articles shall be stored as follows:

- (1) In a clean, dry location.
- (2) Where they are not exposed to splash, dust or other contamination.
- (3) At least 15 cm (6 inches) above the floor.

(b) *Additional storage requirements for equipment and utensils.* Clean equipment and utensils shall be stored as specified in subsection (a) and shall be stored covered or inverted, and in a self-draining position that allows air drying.

(c) *Additional storage requirements for single-service and single-use articles.* Single-service and single-use articles shall be stored as specified in subsection (a) and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(d) *Items in closed packages.* Items that are kept in closed packages may be stored less than 15 cm (6 inches) above the floor on dollies, pallets, racks and skids that are designed as specified in § 46.595 (relating to case lot handling equipment: moveability).

(e) *Prohibited storage locations.* Except as specified in subsection (f), cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may SHALL not be stored in any of the following locations:

- (1) A locker rooms.
- (2) A toilet room.
- (3) A garbage room.



- (4) A mechanical room.
- (5) Under a sewer line that is not shielded to intercept potential drips.
- (6) Under a leaking water line--including a leaking automatic fire sprinkler head--or under a line on which water has condensed.
- (7) Under an open stairwell.
- (8) Under another source of contamination.
- (f) *Limited exception for a locker room.* Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

#### **§ 46.775. Handling clean items.**

##### **(a) *Kitchenware and tableware.***

(1) Single-service and single-use articles and cleaned and sanitized utensils shall be handled, displayed and dispensed so that contamination of food- and lip-contact surfaces is prevented.

(2) Knives, forks and spoons that are not prewrapped shall be presented so that only the handles are touched by employees and by consumers if consumer self-service is provided.

(3) Except as specified in paragraph (2), single-service articles that are intended for food- or lip-contact shall be furnished for consumer self-service with the original individual wrapper intact or from an approved dispenser.

(b) *Preset tableware.* If tableware is preset, it shall be protected from contamination by being wrapped, covered or inverted. Exposed, unused settings shall be either removed when a consumer is seated, or cleaned and sanitized before further use if the settings are not removed when a consumer is seated.

(c) *Soiled and clean tableware.* Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated.

### **Subchapter E. WATER, PLUMBING AND WASTE**

#### **WATER**

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- 46.881. Storage areas and receptacles for refuse, recyclables and returnables: materials, design, construction and installation.
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- 46.885. Removal of refuse, recyclable and returnables.
- 46.886. Facilities for disposal and recycling refuse, recyclables and returnables.

### **WATER**

#### **§ 46.801. Sources of drinking water.**

Drinking water shall be obtained from an approved source that is either of the following:

(1) A public water system.

(2) A nonpublic water system that is constructed, maintained and operated in accordance with 25 Pa. Code Chapter 109 (relating to safe drinking water). For the purpose of approval of a nonpublic water system that serves a food facility, a nonpublic water system shall be required to conform to the construction, maintenance and operation requirements established for a transient noncommunity water system as defined in 25 Pa. Code Chapter 109.

**§ 46.802. Drinking water system flushing and disinfection.**

A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system. A FOOD FACILITY SHALL OBTAIN VERIFICATION THAT THE WATER MEETS THE QUALITY STANDARDS FOR PUBLIC DRINKING WATER ESTABLISHED IN 25 PA. CODE CHAPTER 109 (RELATING TO SAFE DRINKING WATER) BEFORE PLACING A DRINKING WATER SYSTEM IN SERVICE, AND SHALL RETAIN THAT VERIFICATION AND PROVIDE IT TO THE DEPARTMENT UPON REQUEST.

**§ 46.803. Bottled drinking water.**

Bottled drinking water used or sold in a food facility shall be obtained from approved sources in accordance with 25 Pa. Code Chapter 109 (relating to safe drinking water).

**§ 46.804. Quality of water.**

(a) *Standards for drinking water.* Except as specified in subsection (b), water obtained from either a public water system or a nonpublic water system for use in a food facility shall meet the quality standards for public drinking water established in 25 Pa. Code Chapter 109 (relating to safe drinking water).

(b) *Nondrinking water.*

(1) A nondrinking water supply shall be used only if approved by the Department.

(2) Nondrinking water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, fire protection and irrigation.

(c) *Sampling of water from nonpublic water systems.* Except when used as nondrinking water as specified in subsection (b), water from a nonpublic water system shall be sampled and tested for contamination at the same frequency and for the same contaminants as established in 25 Pa. Code Chapter 109 for a transient noncommunity public water system that serves 25 people daily. All analytical work must be performed in accordance with 25 Pa. Code Chapter 109.

(d) *Sample report for nonpublic water system to be retained at food facility.* If a food facility receives all of its drinking water from a nonpublic water system, the results from all required self-monitoring samples collected during the previous 12 months or, if less frequent than annual monitoring is approved by the Department for the facility, the most recent sample report for the nonpublic water system shall be retained on file in the food facility. Food facilities that use a Department of Environmental Protection approved self-contained public water system shall maintain test result records in accordance with 25 Pa. Code Chapter 109.

**§ 46.805. Quantity and availability of water: capacity and pressure.**

(a) *Capacity.*

(1) The water source and system shall be of sufficient capacity to meet the peak water demands of the food facility.

(2) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the food facility.

(b) *Pressure.* Water under pressure shall be provided to all fixtures, equipment and nonfood equipment that are required to use water, ~~except that~~. HOWEVER, water supplied as specified in § 46.806(b)(1) and (2) (relating to distribution, delivery and retention of water) to a temporary food facility or in response to a temporary interruption of a water supply need not be under pressure.

#### **§ 46.806. Distribution, delivery and retention of water.**

(a) *Delivery system.* Water shall be received from the source through the use of one or more of the following:

(1) A properly constructed and maintained service connection or lateral from a public water system that is approved by the Department of Environmental Protection in accordance with 25 Pa. Code Chapter 109 (relating to safe drinking water).

(2) One or more of the following that shall be constructed, maintained and operated in accordance with 25 Pa. Code Chapter 109:

(i) Nonpublic water main, water pumps, pipes, hoses, connections and other appurtenances.

(ii) Water transport vehicles.

(iii) Water containers.

(b) *Alternative water supply.* Water meeting the applicable requirements in §§ 46.801-46.805 and subsection (a) shall be made available for a mobile food facility, for a temporary food facility without a permanent water supply, and for a food facility with a temporary interruption of its water supply through one or more of the following sources:

(1) A supply of containers of commercially bottled drinking water.

(2) One or more closed portable water containers.

(3) An enclosed vehicular water tank.

(4) An on-premises water storage tank.

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

### **PLUMBING SYSTEM**

#### **§ 46.821. Approved materials to be used in plumbing systems.**

(a) *Approved materials required.* A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to CHAPTER 3 OF the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304).

(b) *Safe materials for water filters.* A water filter shall be made of safe materials.

#### **§ 46.822. Design, construction and installation of plumbing systems.**

(a) *Approved system and cleanable fixtures.*

(1) A plumbing system shall be designed, constructed and installed according to CHAPTER 3 OF the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304).

(2) A plumbing fixture such as a handwashing facility, toilet ~~for~~ OR urinal shall be easily cleanable.

(b) *Handwashing facility: installation.*

(1) A handwashing ~~lavatory~~ SINK shall be equipped to provide water at a temperature of at least ~~32°C (90°F)~~ 38°C (100°F) through a mixing valve or combination faucet.

(2) A steam mixing valve ~~may~~ SHALL not be used at a handwashing ~~lavatory~~ SINK.

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

(4) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

(c) *Air gap requirement for backflow prevention.* An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment or nonfood equipment shall be at least twice the diameter of the water supply inlet and ~~may~~ SHALL not be less than 25 mm (1 inch).

(d) *Design standard for backflow prevention device.* A backflow or backsiphonage prevention device installed on a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection and testing for that specific application and type of device.

(e) *Design of conditioning device.* A water filter, screen and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

#### **§ 46.823. Numbers and capacities of plumbing facilities.**

(a) *Handwashing facilities FOR EMPLOYEES AND CONSUMERS.*

(1) Except as specified in paragraphs (2) and (3), at least one handwashing ~~lavatory~~ SINK--and a number of handwashing ~~lavatories~~ SINKS necessary for their convenient use by employees in areas specified in § 46.824(a) (relating to location and placement of plumbing facilities) shall be provided.

(2) If approved by the Department and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing ~~lavatories~~ SINKS in a food facility that has at least one handwashing ~~lavatory~~ SINK.

(3) If approved by the Department, when food exposure is limited TO PREPACKAGED FOODS and handwashing ~~lavatories~~ SINKS are not conveniently available, such as in some ~~mobile or~~ temporary food facilities or at some vending machine locations, employees may use chemically treated towelettes for handwashing.

(4) AT LEAST ONE HANDWASHING SINK AND A NUMBER OF HANDWASHING SINKS NECESSARY FOR THE CONVENIENT USE BY CONSUMERS SHALL BE

PROVIDED IN FOOD FACILITIES WHICH ALLOW CONSUMPTION OF FOOD ON THE FOOD FACILITY PREMISES. HANDWASH SINKS FOR CONSUMERS SHALL BE LOCATED IN EASILY ACCESSIBLE AREAS AND AS REQUIRED IN § 46.824(A)(2), BUT SHALL NOT REQUIRE ACCESS THROUGH FOOD PREPARATION, FOOD DISPENSING, FOOD, EQUIPMENT AND UTENSIL STORAGE AREAS, OR WAREWASHING AREAS.

(b) *Toilets and urinals.* At least one toilet and not fewer than the toilets (and urinals, if used) required by the ~~Department or the~~ Department of Labor and Industry shall be provided.

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

(d) *Backflow prevention device: when required.* A plumbing system shall be installed to preclude backflow of a solid, liquid or gas contaminant into the water supply system at each point of use at the food facility, including on a hose bib if a hose is attached, or on a hose bib if a hose is not attached ~~and backflow prevention is required by 25 Pa. Code Chapter 109 (relating to safe drinking water), by doing either of the following:~~

(1) ~~Providing an air gap as specified in § 46.822(c) (relating to design, construction and installation of plumbing systems);~~

(2) ~~Installing~~ BUT CAN BE ATTACHED, BY an approved backflow prevention device as specified in § 46.822(d).

(E) **BACKFLOW PREVENTION DEVICE ON CARBONATORS.** IF NOT PROVIDED WITH AN AIR GAP AS SPECIFIED IN SUBSECTION 46.822(C), A DOUBLE CHECK VALVE WITH AN INTERMEDIATE VENT PRECEDED BY A SCREEN OF NOT LESS THAN 100 MESH TO 25.4MM (100 MESH TO 1 INCH) SHALL BE INSTALLED UPSTREAM FROM A CARBONATING DEVICE AND DOWNSTREAM FROM ANY COPPER IN THE WATER SUPPLY LINE. A SINGLE OR DOUBLE CHECK VALVE ATTACHED TO THE CARBONATOR NEED NOT BE OF THE VENTED TYPE IF AN AIR GAP OR VENTED BACKFLOW PREVENTION DEVICE HAS BEEN OTHERWISE PROVIDED.

#### **§ 46.824. Location and placement of plumbing facilities.**

(a) *Handwashing facilities.* A handwashing facility shall be located as follows:

(1) In food preparation, food dispensing and warewashing areas to allow convenient use by employees.

(2) In, or immediately adjacent to, toilet rooms.

(b) *Location of backflow prevention device.* A backflow prevention device shall be located so that it ~~may~~ CAN be serviced and maintained.

(c) *Location of conditioning device.* A water filter, screen and other water-conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

## **§ 46.825. Operation and maintenance of plumbing facilities.**

### *(a) Using a handwashing facility.*

(1) A handwashing facility shall be maintained so that it is accessible at all times for employee use.

(2) A handwashing facility ~~may~~ SHALL not be used for purposes other than handwashing.

(3) An automatic handwashing facility shall be used in accordance with manufacturer's instructions.

### *(b) Cross connection prohibited.*

(1) Except for firefighting, a person ~~may~~ SHALL not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.

(2) The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.

(c) *Scheduling inspection and service for a water system device.* A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge.

### *(d) Cleaning the water reservoir of water devices such as fogging devices.*

(1) A reservoir that is used to supply water to a device such as a produce fogger shall be both of the following:

(i) Maintained in accordance with manufacturer's specifications.

(ii) Cleaned in accordance with manufacturer's specifications or according to the procedures specified in paragraph (2), whichever is more stringent.

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

(i) Draining and complete disassembly of the water and aerosol contact parts.

(ii) Brush-cleaning the reservoir, aerosol tubing and discharge nozzles with a suitable detergent solution.

(iii) Flushing the complete system with water to remove the detergent solution and particulate accumulation.

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

(e) *System maintained in good repair.* A plumbing system shall be repaired according to CHAPTER 3 OF the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304), and shall be maintained in good repair.

## **MOBILE WATER TANK AND MOBILE FOOD FACILITY WATER TANK**

### **§ 46.841. Materials used in construction of mobile water tanks and mobile food facility water tanks.**

Materials that are used in the construction of a mobile water tank, mobile food facility water tank and appurtenances shall be ALL OF the following:

- (1) Safe MATERIALS.
- (2) Durable, corrosion-resistant and nonabsorbent.
- (3) Finished to have a smooth, easily cleanable surface.

### **§ 46.842. Design and construction of mobile water tanks and mobile food facility water tanks.**

(a) *Requirement: enclosed system sloped to drain.* A mobile water tank shall be the following:

- (1) Enclosed from the filling inlet to the discharge outlet.
- (2) Sloped to an outlet that allows complete drainage of the tank.

(b) *Requirement: inspection and cleaning port protected and secured.* If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and both of the following:

- (1) Flanged upward at least 13 mm (1/2 inch).
- (2) Equipped with a port cover assembly that is both of the following:
  - (i) Provided with a gasket and a device for securing the cover in place.
  - (ii) Flanged to overlap the opening and sloped to drain.

(c) *"V" type threads: use limitation.* A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

(d) *Requirement: tank vent protected.* If provided, a water tank vent shall terminate in a downward direction and shall be covered with the following, as applicable:

- (1) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area.
- (2) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

(e) *Requirement: inlet and outlet sloped to drain.* A water tank and its inlet and outlet shall be sloped to drain, and a water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil or grease.

(f) *Hose: construction and identification.* A hose used for conveying drinking water from a water tank shall be all of the following:

- (1) Safe CONSTRUCTED OF SAFE MATERIALS.



- (2) Durable, corrosion-resistant and nonabsorbent.
- (3) Resistant to pitting, chipping, crazing, scratching, scoring, distortion and decomposition.
- (4) Finished with a smooth interior surface.
- (5) Clearly and durably identified as to its use if not permanently attached.

**§ 46.843. Numbers and capacities of mobile water tanks and mobile food facility water tanks.**

(a) *Filter requirement where compressed air pressurizes the water tank system.* A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is used to pressurize the water tank system.

(b) *Protective cover or device.* A cap and keeper chain, closed cabinet, closed storage tube or other approved protective cover or device shall be provided for a water inlet, outlet and hose.

(c) *Mobile food facility tank inlet.* A mobile food facility's water tank inlet shall be both of the following:

- (1) 19.1 mm (3/4 inch) in inner diameter or less.
- (2) Provided with a hose connection of a size or type that will prevent its use for any other service.

**§ 46.844. Operation and maintenance of mobile water tanks and mobile food facility water tanks.**

(a) *System flushing and disinfection.* A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification and periods of nonuse.

(b) *Preventing backflow while using a pump and hoses.* A person shall operate a water tank, pump and hoses so ~~that~~ AS TO PREVENT backflow and other contamination of the water supply ~~are prevented~~.

(c) *Protecting inlet, outlet and hose fitting.* If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified in § 46.843(b) (relating to numbers and capacities of mobile water tanks and mobile food facility water tanks).

(d) *Tank, pump and hoses, dedication.* A water tank, pump and hoses used for conveying drinking water shall be used for no other purpose, except that water tanks, pumps and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

## **SEWAGE, OTHER LIQUID WASTE AND RAINWATER**

### **§ 46.861. Capacity and drainage of a sewage holding tank in a mobile food facility.**

A sewage holding tank in a mobile food facility shall be both of the following:

(1) Sized 15 % larger in capacity than the water supply tank.

(2) Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.

### **§ 46.862. Retention, drainage and delivery of sewage, other liquid waste and rainwater.**

(a) *Facility drainage system.* Food facility drainage systems, including grease traps, that convey sewage shall be designed and installed as specified in § 46.822(a) (relating to design, construction and installation of plumbing systems).

(b) *Backflow prevention.*

(1) Except as specified in paragraphs (2) and (3), a direct connection ~~may~~ SHALL not exist between the sewage system and a drain originating from equipment in which food, portable equipment or utensils are placed.

(2) If allowed under CHAPTER 3 OF the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304), a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

(3) If allowed under CHAPTER 3 OF the Pennsylvania Construction Code Act, a warewashing or culinary sink may have a direct connection.

(c) *Grease trap.* If used, a grease trap shall be located to be easily accessible for cleaning.

(d) *Conveying sewage.* Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses and connections that are constructed, maintained and operated according to CHAPTER 3 OF the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304) AND § 7 OF THE PENNSYLVANIA SEWAGE FACILITIES ACT (35 P.S. § 750.7).

(e) *Removing mobile food facility wastes.* Sewage and other liquid wastes shall be removed from a mobile food facility at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created.

(f) *Flushing a waste retention tank.* A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

### **§ 46.863. Disposal of sewage and nonsewage.**

(a) *Disposal of sewage.* Sewage shall be disposed through an approved facility that is either of the following:

- (1) A public sewage treatment plant.
- (2) An individual sewage disposal system that is sized, constructed, maintained, and operated according to the Pennsylvania Construction Code § 7 OF THE PENNSYLVANIA SEWAGE FACILITIES act (35 P.S. § 750.7)
- (b) *Other liquid wastes and rainwater.* Condensate drainage and other non-sewage liquids and rainwater shall be drained from point of discharge to disposal according to CHAPTER 3 OF the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304).

## **REFUSE, RECYCLABLES AND RETURNABLES**

### **§ 46.881. Storage areas and receptacles for refuse, recyclables and returnables: materials, design, construction and installation.**

- (a) *Indoor storage area.* If located within the food facility, a storage area for refuse, recyclables and returnables shall meet the requirements specified in §§ 46.901, 46.921 and 46.922(e) and (f) (relating to indoor areas of food facilities: surface characteristics; cleanability of floors, walls and ceilings; and functionality of various physical features of a food facility).
- (b) *Outdoor storage surface.* An outdoor storage surface for refuse, recyclables and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be smooth, durable and sloped to drain.
- (c) *Outdoor enclosure.* If used, an outdoor enclosure for refuse, recyclables and returnables shall be constructed of durable and cleanable materials.
- (d) *Receptacles.* Receptacles and waste handling units for refuse, recyclables and returnables and for use with materials containing food residue shall be durable, cleanable, insect- and rodent-resistant, leakproof and nonabsorbent. Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the food facility, or within closed outside receptacles.
- (e) *Receptacles in vending machines.* A refuse receptacle ~~may~~ **SHALL** not be located within a vending machine, except that a receptacle for beverage bottle crown closures may be located within a vending machine.
- (f) *Outside receptacles.*
  - (1) Receptacles and waste handling units for refuse, recyclables and returnables used with materials containing food residue and used outside the food facility shall be designed and constructed to have tight-fitting lids, doors or covers.
  - (2) Receptacles and waste handling units for refuse and recyclables such as an onsite compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

**§ 46.882. Storage areas and receptacles for refuse, recyclables and returnables: numbers and capacities.**

(a) *Storage areas, rooms and receptacles: capacity and availability.*

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

(2) A receptacle shall be provided in each area of the food facility or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.

(3) If disposable towels are used at handwashing lavatories SINKS, a waste receptacle shall be located at each lavatory SINK or group of adjacent lavatories SINKS.

(b) *Toilet room receptacle for sanitary napkins.* A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

(c) *Cleaning implements and supplies.* Suitable cleaning implements and supplies (such as high-pressure pumps, hot water, steam and detergent) shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables and returnables, except that approved off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.

**§ 46.883. Location of storage areas, redeeming machines, receptacles and waste handling units.**

(a) *General requirement.* An area designated for refuse, recyclables, returnables and--except as specified in subsection (b)--a redeeming machine for recyclables or returnables shall be located so that it is separate from food, equipment, utensils, linens, and single-service and single-use articles and a public health hazard or nuisance is not created.

(b) *Redeeming EXCEPTION FOR REDEEMING machine.* A redeeming machine may be located in the packaged food storage area or consumer area of a food facility if food, equipment, utensils, linens, and single-service and single-use articles are not subject to contamination from the machines and a public health hazard or nuisance is not created.

(c) *Receptacles.* The location of receptacles and waste handling units for refuse, recyclables and returnables ~~may~~ SHALL not create a public health hazard or nuisance or interfere with the cleaning of adjacent space.

**§ 46.884. Operation and maintenance of storage areas, redeeming machines, receptacles and waste handling units.**

(a) *Storing refuse, recyclables and returnables.* Refuse, recyclables and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

(b) *Keeping areas, enclosures and receptacles in good repair.* Storage areas, enclosures and receptacles for refuse, recyclables and returnables shall be maintained in good repair.

(c) *Outside storage prohibitions.*

(1) Except as specified in paragraph (2), refuse receptacles not meeting the requirements specified in § 46.881(d) (relating to storage areas and receptacles for refuse, recyclables and returnables: materials, design, construction and installation) (such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue) may SHALL not be stored outside.

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

(d) *Covering receptacles.* Receptacles and waste handling units for refuse, recyclables and returnables shall be kept covered as follows:

(1) Inside the food facility if the receptacles and units are filled or contain food residue and are not in continuous use.

(2) With tight-fitting lids or doors if kept outside the food facility.

(e) *Using drain plugs.* Drains in receptacles and waste handling units for refuse, recyclables and returnables shall have drain plugs in place.

(f) *Maintaining refuse areas and enclosures.* A storage area and enclosure for refuse, recyclables or returnables shall be maintained free of unnecessary items, as specified in § 46.981(n) (relating to premises, structures, attachments and fixtures: methods), and clean.

(g) *Cleaning receptacles.*

(1) Receptacles and waste handling units for refuse, recyclables and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of as specified in § 46.862(e) (relating to retention, drainage and delivery of sewage, other liquid waste and rainwater).

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

**§ 46.885. Removal of refuse, recyclable and returnables.**

(a) *Frequency.* Refuse, recyclables and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

(b) *Receptacles or vehicles.* Refuse, recyclables and returnables shall be removed from the premises by way of either of the following:

(1) Portable receptacles adequately constructed and maintained to contain the refuse, recyclables or returnables placed therein.

(2) A transport vehicle adequately constructed and maintained to contain the refuse, recyclables or returnables transported therein.

**§ 46.886. Facilities for disposal and recycling refuse, recyclables and returnables.**

Solid waste not disposed of through the sewage system such as through grinders and pulpers shall be recycled or disposed of in an approved public or private community recycling or refuse facility; or solid waste shall be disposed of in an individual refuse facility such as a lawfully-operated landfill or incinerator.

**Subchapter F. PHYSICAL FACILITIES**  
**MATERIALS FOR CONSTRUCTION AND REPAIR**

Sec.

- 46.901. Indoor areas of food facilities: surface characteristics.
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**DESIGN, CONSTRUCTION AND INSTALLATION**

- 46.921. Cleanability of floors, walls and ceilings.
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**NUMBERS AND CAPACITIES**

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- 46.944. Mechanical ventilation as needed.
- 46.945. Requirement and designation of dressing areas and storage areas.
- 46.946. Utility sinks.

**LOCATION AND PLACEMENT**

- 46.961. Handwashing facilities: located for convenience.
- 46.962. Toilet rooms: located for convenience.
- 46.963. Employee accommodations: located to prevent contamination.
- 46.964. Distressed merchandise: segregated.
- 46.965. Refuse, recyclables and returnables: receptacles, waste handling units and designated storage areas.

**MAINTENANCE AND OPERATION**

- 46.981. Premises, structures, attachments and fixtures: methods.
- 46.982. Limitations on animals.

**MATERIALS FOR CONSTRUCTION AND REPAIR**

**§ 46.901. Indoor areas of food facilities: surface characteristics.**

(a) *General requirement.* Except as specified in subsection (b), materials for indoor floor, wall and ceiling surfaces of a food facility under conditions of normal use shall be all of the following:

(1) Smooth, durable and easily cleanable for areas where food facility operations are conducted.

(2) Closely woven and easily cleanable carpet for carpeted areas.

(3) Nonabsorbent for areas subject to moisture such as food preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, mobile food facility servicing areas, and areas subject to flushing or spray cleaning methods.

(b) *Exception for a temporary food facility.*

(1) If graded to drain, a floor in a temporary food facility may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other suitable approved materials that are effectively treated to control dust and mud.

(2) Walls and ceilings in a temporary food facility shall be constructed of a material that protects the interior from the weather and windblown dust and debris.

#### **§ 46.902. Outdoor areas of food facilities: surface characteristics.**

(a) *Walking and driving areas.* The outdoor walking and driving areas of a food facility shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(b) *Exterior surfaces.* Exterior surfaces of food facility buildings and mobile food facilities shall be of weather-resistant materials and shall comply with CHAPTER 3 OF the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304).

(c) *Certain outdoor storage areas.* Outdoor storage areas of a food facility used for storing refuse, recyclables or returnables shall be of materials specified in § 46.525(b) and (c) (relating to storage areas and receptacles for refuse, recyclables and returnables: materials, design, construction and installation).

### **DESIGN, CONSTRUCTION AND INSTALLATION**

#### **§ 46.921. Cleanability of floors, walls and ceilings.**

(a) *General requirement.* Except as specified in subsection (d), the floors, floor coverings, walls, wall coverings and ceilings of a food facility shall be designed, constructed and installed so they are smooth and easily cleanable, except that antislip floor coverings or applications may be used for safety reasons.

(b) *Utility lines.*

(1) Utility service lines and pipes in a food facility ~~may~~ SHALL not be unnecessarily exposed.

(2) Exposed utility service lines and pipes in a food facility shall be installed so they do not obstruct or prevent cleaning of the floors, walls or ceilings.

(3) Exposed horizontal utility service lines and pipes in a food facility ~~may~~ SHALL not be installed on the floor.

(c) *Floor and wall junctures: coved, and enclosed or sealed.*

(1) In food facilities in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1 mm (1/32 inch).

(2) The floors in food facilities in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and sealed.

(d) *Floor carpeting: ~~restrictions~~ LIMITATIONS and installation.*

(1) A floor covering such as carpeting or similar material ~~may~~ SHALL not be installed as a floor covering in food preparation areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing lavatories SINKS, toilets and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing or spray cleaning methods.

(2) If carpeting is installed as a floor covering in areas other than those specified in paragraph (1), it shall be both of the following:

(i) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method.

(ii) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

(e) *Floor covering: mats and duckboards.* Mats and duckboards in a food facility shall be designed to be removable and easily cleanable.

(f) *Wall and ceiling coverings and coatings.*

(1) Wall and ceiling covering materials in a food facility shall be attached so that they are easily cleanable.

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

(g) *Attachments to walls and ceilings.* Attachments to walls and ceilings (such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items and other attachments) in a food facility shall be easily cleanable, except that in a consumer area of a food facility, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.

(h) *Studs, joists and rafters in walls and ceilings.* Studs, joists and rafters in a food facility ~~may~~ SHALL not be exposed in areas subject to moisture. This requirement does not apply to temporary food facilities.

## **§ 46.922. Functionality of various physical facilities of a food facility.**

(a) *Light bulbs: protective shielding.*



(1) Except as specified in paragraph (2), light bulbs in use in a food facility shall be shielded, coated or otherwise shatter-resistant in areas where there is exposed food; clean equipment, utensils and linens; or unwrapped single-service and single-use articles.

(2) Shielded, coated or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages, if both of the following are accurate:

(i) The integrity of the packages ~~can not~~ CANNOT be affected by broken glass falling onto them.

(ii) The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

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

(b) *Heating, ventilating and air conditioning system vents.* Heating, ventilating and air conditioning systems in a food facility shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment or utensils.

(c) *Design and installation of insect control devices.*

(1) Insect control devices that are used in a food facility to electrocute or stun flying insects shall be designed to retain the insect within the device.

(2) Insect control devices shall be installed so that they meet the following requirements:

(i) The devices are not located over a food preparation area.

(ii) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed food; clean equipment, utensils and linens; and unwrapped single-service and single-use articles.

(d) *Toilet rooms shall be enclosed.* A toilet room located on the premises of a food facility shall be completely enclosed and provided with a tight-fitting and self-closing door. This requirement does not apply to a toilet room that is located outside a food facility and does not open directly into the food facility (such as a toilet room that is provided by the management of a shopping mall).

(e) *Outer openings shall be protected.*

(1) Except as specified in paragraphs (2)--(5), outer openings of a food facility shall be protected against the entry of insects and rodents by use of the following:

(i) Filling or closing holes and other gaps along floors, walls and ceilings.

(ii) Having closed, tight-fitting windows;

(iii) Having solid, self-closing, tight-fitting doors.

(2) Paragraph (1) does not apply if a food facility opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.

(3) Exterior doors used as exits need not be self-closing if they are all of the following:

(i) Solid and tight-fitting;

(ii) Designated for use only when an emergency exists;

(iii) ~~Restricted~~, AND LIMITED so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.

(4) Except as specified in paragraphs (2) and (5), if the windows or doors of a food facility, or of a larger structure within which a food facility is located, are kept open for ventilation or other purposes or a temporary food facility is not provided with windows and doors as specified in paragraph (1), the openings shall be protected against the entry of insects and rodents by one or more of the following:

(i) 16 mesh to 25.4mm (16 mesh to 1 inch) screens;

(ii) Properly designed and installed air curtains TO CONTROL FLYING INSECTS;

(iii) Other effective means.

(5) Paragraph (4) does not apply if ~~flying insects and other pests~~ INSECTS, RODENTS AND OTHER ANIMALS are absent due to the location of the facility, the weather or other limiting condition.

(f) *Exterior walls and roofs: protective barrier.* Perimeter walls and roofs of a food facility shall effectively protect the facility from the weather and the entry of insects, rodents and other animals.

(g) *Outdoor food vending areas, overhead protection.* If located outside, a machine used to vend food shall be provided with overhead protection except that machines vending canned beverages need not meet this requirement.

(h) *Outdoor servicing areas: overhead protection.* Servicing areas of a food facility shall be provided with overhead protection. However, if the area is used only for the loading of water or the discharge of sewage and other liquid waste, through the use of a closed system of hoses, the area need not be provided with overhead protection.

(i) *Outdoor walking and driving surfaces: graded to drain.* Exterior walking and driving surfaces of a food facility shall be graded to drain.

(j) *Outdoor refuse areas: curbed and graded to drain.* Outdoor refuse areas shall be constructed in accordance with CHAPTER 3 OF the Pennsylvania Construction Code Act (35 P.S. §§ 7210.301 – 7210.304) and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the refuse and from cleaning the area and waste receptacles.

(k) *Living or sleeping quarters, use prohibition.* A room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters ~~may~~ SHALL not be used for conducting food facility operations.

(l) *Living or sleeping quarters: separation.* Living or sleeping quarters located on the premises of a food facility such as those provided for lodging registration clerks or

resident managers shall be separated from rooms and areas used for food facility operations by complete partitioning and solid self-closing doors.

## NUMBERS AND CAPACITIES

### § 46.941. Handwashing facilities: numbers and capacities.

(a) *Minimum number.* Handwashing facilities shall be provided in a food facility as specified in § 46.823(a) (relating to numbers and capacities of plumbing facilities).

(b) *Availability of handwashing cleanser.* Each handwashing ~~lavatory~~ SINK or group of two adjacent ~~lavatories~~ SINKS shall be provided with a supply of hand cleaning liquid, powder or bar soap.

(c) *Availability of hand drying.* Each handwashing ~~lavatory~~ SINK or group of adjacent ~~lavatories~~ SINKS shall be provided with one or more of the following:

- (1) Individual, disposable towels.
- (2) A continuous towel system that supplies the user with a clean towel.
- (3) A heated-air hand drying device.

(d) ~~Restrictions~~ *LIMITATIONS on use of handwashing aids and devices.* A sink used for food preparation or utensil washing, or a utility sink or curbed cleaning facility used for the disposal of mop water or similar wastes, ~~may~~ SHALL not be provided with the handwashing aids and devices required for a handwashing ~~lavatory~~ SINK as specified in subsections (b) and (c) and § 46.882(a)(3) (relating to storage areas and receptacles for refuse, recyclables and returnables: numbers and capacities).

(e) *Handwashing signage.* A sign or poster that notifies food employees to wash their hands shall be provided at all handwashing ~~lavatories~~ SINKS used by food employees and shall be clearly visible to food employees.

(f) *Disposable towels, waste receptacle.* A handwashing ~~lavatory~~ SINK or group of adjacent ~~lavatories~~ SINKS that is provided with disposable towels shall be provided with a waste receptacle as specified in § 46.882(a)(3).

### § 46.942. Toilets and urinals: numbers and capacities.

(a) *Minimum number.* Toilets and urinals shall be provided in a food facility as specified in § 46.823(b) (relating to numbers and capacities of plumbing facilities).

(b) *Availability of toilet tissue.* A supply of toilet tissue shall be available at each toilet.

### § 46.943. Lighting: intensity.

The light intensity in a food facility shall be all of the following:

(1) At least 110 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration units and dry food storage areas and in other areas and rooms during periods of cleaning.

(2) At least 220 lux (20 foot candles) at each of the following locations:

(i) At a surface where food is provided for consumer self-service such as buffets and salad bars or where fresh produce or packaged foods are sold or offered for consumption.

(ii) Inside equipment such as reach-in and under-counter refrigerators.

(iii) At a distance of 75 cm (30 inches) above the floor in areas used for handwashing, warewashing, and equipment and utensil storage, and in toilet rooms.

(3) At least 540 lux (50 foot candles) at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders or saws where employee safety is a factor.

#### **§ 46.944. Mechanical ventilation as needed.**

If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke and fumes in a food facility, mechanical ventilation of sufficient capacity shall be provided.

#### **§ 46.945. Requirement and designation of dressing areas and storage areas.**

(a) *Designation.* Dressing rooms or dressing areas shall be designated in a food facility if employees routinely change their clothes in that facility.

(b) *Storage of employees' clothing and possessions.* Lockers or other suitable facilities shall be provided for the orderly storage of employees' clothing and other possessions.

#### **§ 46.946. Utility sinks.**

A utility sink or curbed cleaning facility shall be provided as specified in § 46.823(c) (relating to numbers and capacities of plumbing facilities).

### **LOCATION AND PLACEMENT**

#### **§ 46.961. Handwashing facilities: located for convenience.**

Handwashing facilities in a food facility shall be conveniently located as specified in § 46.824(a) (relating to location and placement of plumbing facilities).

#### **§ 46.962. Toilet rooms: located for convenience.**

Toilet rooms in a food facility shall be conveniently located and accessible to employees during all hours of operation.

#### **§ 46.963. Employee accommodations: located to prevent contamination.**

(a) *Designated eating, drinking and smoking areas.* Areas designated for employees to eat, drink and use tobacco shall be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.

(b) *Lockers and other facilities.* Lockers or other suitable facilities shall be located in a designated room or area where contamination of food, equipment, utensils, linens, and single-service and single-use articles cannot occur.

**§ 46.964. Distressed merchandise: segregated.**

Products that are held by the food facility operator for credit, redemption or return to the distributor; such as damaged, spoiled or recalled products, shall be segregated and held in designated areas that are separate from food, equipment, utensils, linens, and single-service and single-use articles.

**§ 46.965. Refuse, recyclables and returnables: receptacles, waste handling units and designated storage areas.**

Units, receptacles, and areas designated for storage of refuse and recyclable and returnable containers shall be located as specified in § 46.883 (relating to location of storage areas, redeeming machines, receptacles and waste handling units).

**MAINTENANCE AND OPERATION**

**§ 46.981. Premises, structures, attachments and fixtures: methods.**

(a) *General requirement.* The physical facilities of a food facility shall be maintained in good repair.

(b) *Cleaning: frequency and ~~restrictions~~ LIMITATIONS.*

(1) The physical facilities of a food facility shall be cleaned as often as necessary to keep them clean.

(2) Cleaning shall be done during periods when the least amount of food is exposed such as after closing. This requirement does not apply to cleaning that is necessary due to a spill or other accident.

(c) *Cleaning floors by dustless methods.*

(1) Except as specified in paragraph (2), only dustless methods of cleaning shall be used (such as wet cleaning, vacuum cleaning, mopping with treated dust mops or sweeping using a broom and dust-arresting compounds).

(2) Spills or drippage on floors that occur between normal floor cleaning times shall be cleaned as follows:

(i) Without the use of dust-arresting compounds.

(ii) In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.

(d) *Cleaning ventilation systems without causing contamination, health hazard or nuisance.*

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

(2) If vented to the outside, ventilation systems ~~may~~ SHALL not create a public health hazard or nuisance or unlawful discharge.

(e) *Preventing contamination by cleaning maintenance tools.* Food preparation sinks, handwashing lavatories SINKS and warewashing equipment may SHALL not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials or the disposal of mop water and similar liquid wastes.

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

(g) *Absorbent materials on floors: use limitation.* Except as specified in subsection (c)(2), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth or similar materials may SHALL not be used on floors.

(h) *Maintaining and using handwashing facilities.* Handwashing facilities shall be kept clean, and maintained and used as specified in § 46.825(a) (relating to operation and maintenance of plumbing facilities).

(i) *Closing toilet room doors.* Toilet room doors as specified in § 46.922(d) (relating to functionality of various physical facilities at a food facility) shall be kept closed except during cleaning and maintenance operations.

(j) *Using dressing rooms and lockers.* Dressing rooms shall be used by employees if the employees regularly change their clothes in the facility. Lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.

(k) *Controlling pests.* The presence of insects, rodents and other pests shall be controlled to minimize their presence on the premises by all of the following:

(1) Routinely inspecting incoming shipments of food and supplies.

(2) Routinely inspecting the premises for evidence of pests.

(3) Using methods, if pests are found, such as trapping devices or other means of pest control as specified in § 46.1026(b) and (c) (relating to pesticides).

(4) Eliminating harborage conditions.

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

(m) *Storing maintenance tools.* Maintenance tools (such as brooms, mops, vacuum cleaners and similar items) shall be stored so that they do not contaminate food, equipment, utensils, linens, and single-service and single-use articles, and in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

(n) *Removing unnecessary items and litter from the premises.* The premises of a food facility shall be free of items that are unnecessary to the operation or maintenance of the facility, such as equipment that is nonfunctional or no longer used, and litter.

## **§ 46.982. Limitations on animals.**

(a) *General.* Live animals may SHALL not be allowed on the premises of a food facility, unless under an exception specified in subsection (b).

(b) *Exceptions.*

(1) Live animals may be allowed ONLY in any of the following situations, AND if the contamination of food; clean equipment, utensils and linens; and unwrapped single-service and single-use articles ~~can not~~ CANNOT result:

(i) Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems.

(ii) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas.

(iii) Service animals that are controlled by the disabled employee or person, in areas that are not used for food preparation and that are usually open for customers (such as dining and sales areas), if a health or safety hazard will not result from the presence or activities of the service animal.

(iv) Pets in the common dining areas of ~~group residences~~ INSTITUTIONAL CARE FACILITIES (SUCH AS NURSING HOMES, ASSISTED LIVING FACILITIES, GROUP HOMES OR RESIDENTIAL CARE FACILITIES), at times other than during meals if all of the following are accurate:

(A) Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas.

(B) Condiments, equipment and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present.

(C) Dining areas including tables, countertops and similar surfaces are effectively cleaned before the next meal service.

(v) Caged animals or animals that are similarly ~~restricted~~ RESTRAINED, in areas that are not used for food preparation, storage, sales, display or dining, such as in a variety store that sells pets or a tourist park that displays animals.

(2) Live or dead fish bait may be stored if contamination of food, clean equipment, utensils and linens; and unwrapped single-service and single-use articles cannot result.

## **Subchapter G. POISONOUS OR TOXIC MATERIALS**

### **LABELING AND IDENTIFICATION**

Sec.

46.1001. Poisonous or toxic substances: original containers to display identifying information.

46.1002. Poisonous or toxic substances: working containers labeled with common name.

### **OPERATIONAL SUPPLIES AND APPLICATIONS**

46.1021. Poisonous or toxic substances: storage.

46.1022. Poisonous or toxic substances: limitations on presence and use.

46.1023. Prohibition of use of poisonous or toxic material containers to store food.

46.1024. Chemicals: use criteria.

- 46.1025. Lubricants that have incidental contact with food: criteria.
- 46.1026. Pesticides.
- 46.1027. Medicines.
- 46.1028. First aid supplies: storage.
- 46.1029. Other personal care items: storage.

#### **STOCK AND RETAIL SALE**

- 46.1041. Storage and display: separation of poisonous or toxic materials from food.

### **LABELING AND IDENTIFICATION**

#### **§ 46.1001. Poisonous or toxic substances: original containers to display identifying information.**

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

#### **§ 46.1002. Poisonous or toxic substances: working containers labeled with common name.**

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

### **OPERATIONAL SUPPLIES AND APPLICATIONS**

#### **§ 46.1021. Poisonous or toxic substances: storage.**

Poisonous or toxic materials shall be stored so they ~~can not~~ CANNOT contaminate food, equipment, utensils, linens, and single-service and single-use articles by taking both of the following measures:

- (1) Separating the poisonous or toxic materials by spacing or partitioning.
- (2) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This paragraph does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

#### **§ 46.1022. Poisonous or toxic substances: limitations on presence and use.**

(a) ~~Restriction~~ *LIMITATION*. Only those poisonous or toxic materials that are required for the operation and maintenance of a food facility, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a food facility. This section does not apply to packaged poisonous or toxic materials that are for retail sale.



(b) *Conditions of use.* Poisonous or toxic materials shall be used in a lawful manner according to the following:

(1) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food facility.

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

(3) Additional conditions that may be ~~established~~ APPROVED by the Department.

(c) *Conditions of application.* Poisonous or toxic materials shall be applied so that the following are accurate:

(1) A hazard to employees or other persons is not constituted.

(2) Contamination (including toxic residues due to drip, drain, fog, splash or spray on food, equipment, utensils, linens, and single-service and single-use articles) is prevented, and for a restricted-use pesticide, this is achieved by doing all of the following:

(i) Removing the items.

(ii) Covering the items with impermeable covers, or taking other appropriate preventive actions.

(iii) Cleaning and sanitizing equipment and utensils after the application.

(d) *Applicator.* A restricted use pesticide shall be applied only by an applicator certified in accordance with the Pennsylvania Pesticide Control Act of 1973 (3 P. S. §§ 111.21--111.61) or a person under the direct supervision of a certified applicator.

#### **§ 46.1023. Prohibition of use of poisonous or toxic material containers to store food.**

A container previously used to store poisonous or toxic materials ~~may~~ SHALL not be used to store, transport or dispense food.

#### **§ 46.1024. Chemicals: use criteria.**

(a) *Sanitizers.* Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010 (relating to sanitizing solutions).

(b) *Chemicals for washing fruits and vegetables.* Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 (relating to chemicals used in washing or to assist in the peeling of fruits and vegetables).

(c) *Boiler water additives.* Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310 (relating to boiler water additives).

(d) *Drying agents.*

(1) Drying agents used in conjunction with sanitization shall contain only components that are listed as one or more of the following:

(i) Generally recognized as safe for use in food as specified in 21 CFR 182 (relating to substances generally recognized as safe), or 21 CFR 184 (relating to direct food substances affirmed as generally recognized as safe).

(ii) Generally recognized as safe for the intended use as specified in 21 CFR 186 (relating to indirect food substances affirmed as generally recognized as safe).

(iii) Approved for use as a drying agent under a prior sanction specified in 21 CFR 181 (relating to prior-sanctioned food ingredients).

(iv) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175–178 (relating to indirect food additives: ADHESIVES AND COMPONENTS OF COATINGS) THROUGH 178 (RELATING TO INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS).

(v) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 (relating to threshold of regulation for substances used in food-contact articles).

(2) When sanitization is with chemicals, the approval required in paragraph (1)(iii) or (v), or the regulation as an indirect food additive required in paragraph (1)(iv), shall be specifically for use with chemical sanitizing solutions.

#### **§ 46.1025. Lubricants that have incidental contact with food: criteria.**

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

#### **§ 46.1026. Pesticides.**

(a) *Restricted use pesticides: criteria.* Restricted use pesticides specified in § 46.1022(d) (relating to poisonous or toxic substances: limitations on presence and use) shall meet the requirements of a restricted use pesticide as specified in § 128.2 (relating to definitions). This section requires restricted use pesticides be one of the following:

(1) Classified for restricted use under section 3(d) of the Federal Insecticide, Fungicide and Rodenticide Act of 1947 (~~7 U.S.C.A. § 136(d)~~) (7 U.S.C.A. § 136a(d)).

(2) A pesticide designated by the Secretary for restricted use under section 7(b)(6) of the Pennsylvania Pesticide Control Act of 1973 (3 P. S. § 111.27(b)(6)).

(b) *Rodent bait stations.* Rodent bait shall be contained in a covered, tamper-resistant bait station.

(c) *Tracking powders: pesticides and nontoxics.* A tracking powder pesticide ~~may~~ SHALL not be used in a food facility. A nontoxic tracking powder (such as talcum or flour) may be used in a food facility if it will not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

#### **§ 46.1027. Medicines.**

(a) ~~Restriction~~ *LIMITATION and storage.*

(1) Only those medicines that are necessary for the health of employees shall be allowed in a food facility. This section does not apply to medicines that are stored or displayed for retail sale.

(2) Medicines that are in a food facility for the employees' use shall be labeled as specified in § 46.1001 (relating to poisonous or toxic substances: original containers to display identifying information) and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.

(b) *Refrigerated medicines: storage.* Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be in compliance with the following:

(1) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines.

(2) Located so they are inaccessible to children.

#### **§ 46.1028. First aid supplies: storage.**

First aid supplies that are in a food facility for the employees' use shall be both of the following:

(1) Labeled as specified in § 46.1001 (relating to poisonous or toxic substances: original containers to display identifying information).

(2) Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils and linens, and single-service and single-use articles.

#### **§ 46.1029. Other personal care items: storage.**

Except as specified in § 46.1027(b) and 46.1028 (relating to medicines; and first aid supplies: storage), employees shall store their personal care items in facilities as specified in § 46.945(b) (relating to requirement and designation of dressing areas and storage areas).

### **STOCK AND RETAIL SALE**

#### **§ 46.1041. Storage and display: separation of poisonous or toxic materials from food.**

Poisonous or toxic materials shall be stored and displayed for retail sale so they ~~can~~ **CANNOT** contaminate food, equipment, utensils, linens, and single-service and single-use articles by one or both of the following:

(1) Separating the poisonous or toxic materials by spacing or partitioning.

(2) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.

## **Subchapter H. ADMINISTRATIVE PROCEDURES**

### **CHAPTER ~~APPLICABILITY~~ ACCESS, APPROVALS AND VARIANCES**

Sec.

- 46.1101. ~~Application for intended purpose: public health protection~~ ACCESS TO FOOD FACILITIES.
- 46.1102. ~~Access to food facilities~~ OBTAINING DEPARTMENT OR LICENSOR APPROVAL.
- 46.1103. Variances.

#### **PLAN SUBMISSION AND APPROVAL**

- 46.1121. Facility and operating plans.
- 46.1122. HACCP plans.
- 46.1123. Confidentiality of trade secrets.
- 46.1124. Preoperational inspection of construction.

#### **REQUIREMENTS FOR OPERATION**

- 46.1141. Requirement: ~~permit~~, license or registration.
- 46.1142. Application procedure for appropriate ~~permit~~, license or registration.
- 46.1143. Issuance.
- 46.1144. Conditions of retention: responsibilities of the food facility operator.

### **CHAPTER ~~APPLICABILITY~~ ACCESS, APPROVALS AND VARIANCES**

#### **§ 46.1101. ~~Application for intended purpose: public health protection~~ ACCESS TO FOOD FACILITIES.**

~~The Department will apply this chapter to promote its underlying purpose as specified in § 46.1 (relating to purpose) of safeguarding public health and ensuring that food is safe, unadulterated and honestly presented when offered to the CONSUMER~~ AFTER THE DEPARTMENT OR LICENSOR PRESENTS IDENTIFICATION, THE PERSON IN CHARGE SHALL ALLOW THE DEPARTMENT OR LICENSOR TO DETERMINE IF THE FOOD FACILITY IS IN COMPLIANCE WITH THIS CHAPTER BY ALLOWING ACCESS TO THE FACILITY, ALLOWING INSPECTION, AND PROVIDING INFORMATION AND RECORDS SPECIFIED IN THIS CHAPTER AND TO WHICH THE DEPARTMENT OR LICENSOR IS ENTITLED UNDER THE PUBLIC EATING AND DRINKING PLACES LAW, THE FOOD ACT, AND ANY OTHER RELEVANT STATUTORY OR FOOD REGULATORY AUTHORITY, DURING THE FOOD FACILITY'S HOURS OF OPERATION AND OTHER REASONABLE TIMES IF THE FACILITY IS NOT OPEN DURING NORMAL BUSINESS HOURS.

**§ 46.1102. Access to food facilities OBTAINING DEPARTMENT OR LICENSOR APPROVAL.**

~~After the Secretary presents credentials, the person in charge shall allow the Secretary to determine if the food facility is in compliance with this chapter by allowing access to the facility, allowing inspection, and providing information and records specified in this chapter and to which the Secretary is entitled under the Public Eating and Drinking Places Law, the act, and any other relevant statutory or regulatory authority, during the food facility's hours of operation and other reasonable times.~~

(A) *GENERAL*. THIS SECTION DESCRIBES THE PROCESS BY WHICH A PERSON MAY OBTAIN AN APPROVAL FROM THE DEPARTMENT OR A LICENSOR REQUIRED BY ANY OTHER PROVISION OF THIS CHAPTER.

(B) *WRITTEN REQUEST*. A PERSON SEEKING AN APPROVAL FROM THE DEPARTMENT OR A LICENSOR UNDER THIS CHAPTER SHALL SUBMIT A WRITTEN REQUEST FOR APPROVAL TO THE ENTITY FROM WHICH APPROVAL IS SOUGHT. IF APPROVAL IS SOUGHT FROM THE DEPARTMENT, THE WRITTEN REQUEST SHALL BE MAILED OR DELIVERED TO THE FOLLOWING ADDRESS:

PENNSYLVANIA DEPARTMENT OF AGRICULTURE  
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES  
ATTN: CHIEF, DIVISION OF FOOD SAFETY  
2301 NORTH CAMERON STREET  
HARRISBURG, PS 17110-9408

(C) *CONTENTS OF REQUEST*. THE WRITTEN REQUEST FOR APPROVAL DESCRIBED IN SUBSECTION (B) SHALL SPECIFY THE PROVISION OF THIS CHAPTER PURSUANT TO WHICH APPROVAL IS SOUGHT, THE REASON APPROVAL IS SOUGHT AND RELEVANT DOCUMENTATION IN SUPPORT OF THE REQUEST.

(D) *PROCESSING A REQUEST*. THE DEPARTMENT OR LICENSOR WILL, WITHIN 30 DAYS OF RECEIPT OF A WRITTEN REQUEST FOR APPROVAL UNDER THIS SECTION, MAIL OR OTHERWISE PROVIDE THE REQUESTER WITH A WRITTEN GRANT OR DENIAL OF THE REQUEST, OR A SPECIFIC REQUEST FOR ADDITIONAL INFORMATION. IF A WRITTEN REQUEST FOR ADDITIONAL INFORMATION IS MADE, THE DEPARTMENT OR LICENSOR SHALL HAVE AN ADDITIONAL 30 DAYS FROM THE DATE IT RECEIVES THE ADDITIONAL INFORMATION WITHIN WHICH TO MAIL OR OTHERWISE PROVIDE THE REQUESTER WITH A WRITTEN GRANT OR DENIAL OF THE REQUEST.

(E) *STANDARD FOR APPROVAL*. THE DEPARTMENT OR LICENSOR SHALL GRANT APPROVAL IF IT DETERMINES THE APPROVAL WOULD NOT CONSTITUTE OR CAUSE A VIOLATION OF THE FOOD ACT, THE PUBLIC EATING AND DRINKING PLACES LAW OR THIS CHAPTER, AND THAT NO HEALTH HAZARD WOULD RESULT FROM THE APPROVAL.

### **§ 46.1103. Variances.**

(a) *Modifications and waivers.* The Department may grant a variance by modifying or waiving the requirements of this chapter if--in the opinion of the Department--a health hazard will not result from the variance. If a variance is granted, the Department will retain the information specified in subsection (b) in its records for the food facility.

(b) *Documentation of proposed variance and justification.* Before a variance from a requirement of this chapter is approved, the information that shall be provided by the person requesting the variance and retained in the Department's file on the food facility includes the following:

(1) A statement of the proposed variance of the chapter requirement citing relevant chapter section numbers.

(2) An analysis of the rationale for how the potential public health hazards addressed by the relevant chapter sections will be alternatively addressed by the proposal.

(3) A HACCP plan--if required as specified in § 46.1122(a)(1) (relating to HACCP plans)--that includes the information specified in § 46.1122(b) as it is relevant to the variance requested.

(c) *Conformance with approved procedures.* If the Department grants a variance as specified in subsection (a), or a HACCP plan is otherwise required as specified in § 46.1122(a), the food facility operator shall do the following:

(1) Comply with the HACCP plans and procedures that are submitted as specified in § 46.1122(b) and approved as a basis for the modification or waiver.

(2) Maintain and provide to the Department, upon request, records specified in § 46.1122(b)(4) and (5) that demonstrate that the following are routinely employed:

(i) Procedures for monitoring critical control points.

(ii) Monitoring of the critical control points.

(iii) Verification of the effectiveness of an operation or process.

(iv) Necessary corrective actions if there is failure at a critical control point.

## **PLAN SUBMISSION AND APPROVAL**

### **§ 46.1121. Facility and operating plans.**

(a) *When plans are required.* A food facility licensing applicant or food facility operator ~~required by the Public Eating and Drinking Place Law to~~ SHALL have plans and specifications reviewed by the Department OR LICENSOR AND will submit these properly prepared plans and specifications (as described in subsection (b)) to the Department OR LICENSOR for review and approval (USING THE PROCEDURE DESCRIBED IN § 46.1142 (RELATING TO APPLICATION PROCEDURE FOR APPROPRIATE LICENSE OR REGISTRATION)) before any of the following:

(1) The construction of a food facility.

(2) The conversion of an existing structure for use as a food facility.

(3) The remodeling of a food facility (INCLUDING INSTALLATION AND USE OF ANY NEW MAJOR FOOD EQUIPMENT FOR HEATING, COOLING AND HOT AND COLD HOLDING FOOD) or a change of type of food facility or food operation if the Department OR LICENSOR determines that plans and specifications are necessary to ensure compliance with this chapter.

(4) A CHANGE OF OWNERSHIP OF A FOOD FACILITY.

(b) *Contents of the plans and specifications.* The plans and specifications for a food facility, ~~including a food facility specified in § 46.1122(a) (relating to HACCP plans),~~ shall include (as required by the Department OR LICENSOR based on the type of operation, type of food preparation and foods prepared) the following information to demonstrate conformance with this chapter:

(1) Intended menu AND CONSUMER ADVISORY INTENTIONS, IF A CONSUMER ADVISORY IS REQUIRED UNDER § 46.423 (RELATING TO CONSUMER ADVISORY REQUIRED WITH RESPECT TO ANIMAL-DERIVED FOODS THAT ARE RAW, UNDERCOOKED OR NOT OTHERWISE PROCESSED TO ELIMINATE PATHOGENS).

(2) Anticipated volume of food to be stored, prepared, and sold or served.

(3) Proposed layout, mechanical schematics, construction materials and finish schedules.

(4) Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities and installation specifications.

(5) ~~Other information that may be required by the Department for the proper review of the proposed construction, conversion or modification of a food facility~~ SOURCE OF WATER SUPPLY, MEANS OF SEWAGE DISPOSAL AND REFUSE DISPOSAL.

(6) A HACCP PLAN, IF REQUIRED UNDER § 46.1122 (RELATING TO HACCP PLANS).

(7) OTHER INFORMATION THAT MAY BE REQUIRED BY THE DEPARTMENT OR LICENSOR FOR THE PROPER REVIEW OF THE PROPOSED CONSTRUCTION, CONVERSION OR MODIFICATION OF A FOOD FACILITY, AND REQUESTED BY THE DEPARTMENT OR LICENSOR IN WRITING.

#### **§ 46.1122. HACCP plans.**

(a) *When a HACCP plan is required.*

(1) Before engaging in an activity that requires a HACCP plan, a food facility applicant or food facility operator shall submit to the Department OR LICENSOR for approval a properly prepared HACCP plan as specified in subsection (b) and the relevant provisions of this chapter if any of the following occurs:

(i) Submission of an A HACCP plan is required according to applicable Federal or State laws.

(ii) A variance is required as specified in §§ 46.250(b)(2)(ii), ~~46.345(d)(3)~~ 46.361(d)(2), 46.401 or 46.589(b).

(iii) The Department OR LICENSOR determines that a food preparation or processing method requires a variance based on a plan submittal specified in § 46.1121(b) (relating to facility and operating plans), an inspectional finding, or a variance request.

(2) A food facility applicant or food facility operator shall have a properly prepared HACCP plan as specified in § 46.402 (relating to reduced oxygen packaging).

(b) *Contents of an A HACCP plan.* For a food facility that is required in subsection (a) to have an A HACCP plan, the plan and specifications shall indicate the following:

(1) A categorization of the types of potentially hazardous foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the Department OR LICENSOR.

(2) A flow diagram by specific food or category type identifying critical control points and providing information on the following:

(i) Ingredients, materials and equipment used in the preparation of that food.

(ii) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

(3) Food employee and supervisory training plan that addresses the food safety issues of concern.

(4) A statement of standard operating procedures for the plan under consideration including clearly identifying the following:

(i) Each critical control point.

(ii) The critical limits for each critical control point.

(iii) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge.

(iv) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points.

(v) Action to be taken by the person in charge if the critical limits for each critical control point are not met.

(vi) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed.

(5) Additional scientific data or other information, as required by the Department OR LICENSOR, supporting the determination that food safety is not compromised by the proposal.

### **§ 46.1123. Confidentiality of trade secrets.**

The Department will treat as confidential information that meets the criteria specified in law for a trade secret and is contained on inspection report forms and in the plans and



specifications submitted as specified in §§ 46.1121(b) and 46.1122(b) (relating to facility and operating plans; and HACCP plans).

**§ 46.1124. Preoperational inspection of construction.**

The Department OR LICENSOR will conduct one or more preoperational inspections to verify that the food facility is constructed and equipped in accordance with the approved plans and approved modifications of those plans, and variances granted under § 46.1103 (relating to variances). The Department OR LICENSOR will also verify the food facility is otherwise in compliance with this chapter, THE FOOD ACT and the Public Eating and Drinking Place PLACES Law.

**REQUIREMENTS FOR OPERATION**

**§ 46.1141. Requirement: ~~permit~~, license or registration.**

(A) *GENERAL REQUIREMENT.* A person ~~may~~ SHALL not operate a food facility without a valid ~~permit, license or~~ registration issued by the Department, OR LICENSE ISSUED BY THE DEPARTMENT OR LICENSOR, UNLESS OTHERWISE PROVIDED IN SUBSECTION (B).

(B) EXCEPTIONS.

(1) ANY BUILDING, STRUCTURE OR PLACE OWNED, LEASED OR OTHERWISE IN POSSESSION OF A PERSON OR MUNICIPAL CORPORATION OR PUBLIC OR PRIVATE ORGANIZATION, USED OR INTENDED TO BE USED BY TWO OR MORE FARMERS OR AN ASSOCIATION OF FARMERS FOR THE PURPOSE OF SELLING FOOD DIRECTLY TO CONSUMERS—OTHERWISE KNOWN AS A FARMER'S MARKET--SHALL BE CONSIDERED TO BE A SINGLE RETAIL FOOD ESTABLISHMENT FOR PURPOSES OF REGISTRATION UNDER § 14 OF THE FOOD ACT.

(2) THE FOLLOWING FOOD ESTABLISHMENTS ARE EXEMPT FROM REGISTRATION REQUIREMENTS UNDER § 14 OF THE FOOD ACT:

(I) VEHICLES USED PRIMARILY FOR THE TRANSPORTATION OF ANY CONSUMER COMMODITY IN BULK OR QUANTITY TO MANUFACTURERS, PACKERS, PROCESSORS OR WHOLESALE OR RETAIL DISTRIBUTORS.

(II) ANY FOOD ESTABLISHMENT IN WHICH AT LEAST 50% OF THE COMMODITIES SOLD WERE PRODUCED ON THE FARM ON WHICH THE FOOD ESTABLISHMENT IS LOCATED.

(III) ANY FOOD ESTABLISHMENT IN WHICH FOOD OR BEVERAGES ARE SOLD ONLY THROUGH A VENDING MACHINE.

(IV) ANY FOOD ESTABLISHMENT IN WHICH ONLY PREPACKAGED, NONPOTENTIALLY HAZARDOUS FOOD OR BEVERAGES ARE SOLD.

**§ 46.1142. Application procedure for appropriate ~~permit~~, license or registration.**

Prior to the opening of a food facility, the operator shall contact the Department OR LICENSOR to obtain the appropriate application form for the required ~~permit~~, license or

registration. The Department OR LICENSOR will supply the applicant the appropriate form, based upon the type of food facility involved. IF THE FOOD FACILITY IS A PUBLIC EATING AND DRINKING PLACE, THE APPLICANT MUST OBTAIN A LICENSE. IF THE FOOD FACILITY IS A RETAIL FOOD ESTABLISHMENT, THE APPLICANT MUST OBTAIN A REGISTRATION. A SINGLE LOCATION (SUCH AS A GROCERY STORE THAT ALSO SERVES HOT READY-TO-EAT FOODS) MIGHT REQUIRE BOTH A LICENSE AND A REGISTRATION.

#### **§ 46.1143. Issuance.**

*(a) New, converted or remodeled food facilities.*

~~(1)~~ For food facilities that are required to submit plans as specified in § 46.1121(a) (relating to facility and operating plans), the Department will issue a ~~license or permit~~ REGISTRATION, OR THE DEPARTMENT OR LICENSOR WILL ISSUE A LICENSE to the applicant after the following occur:

~~(i)~~ (1) The required plans, specifications, and information are reviewed and approved.

~~(ii)~~ (2) A preoperational inspection, as described in § 46.1124 (relating to preoperational inspection of construction) shows that the facility is built or remodeled in accordance with the approved plans and specifications and that the facility is in compliance with this chapter.

~~(iii)~~ (3) A properly completed application is submitted.

~~(iv)~~ (4) The required fee is submitted.

~~(2)~~ For food facilities that are not required to submit plans as specified in § 46.1121(a), the Department will issue a registration to the applicant after the following occur:

~~(i)~~ A properly completed application is submitted.

~~(ii)~~ The required fee is submitted.

*(b) License or permit REGISTRATION renewal.* The food facility operator of an existing FOOD facility shall submit an application, the required fee, and be in compliance with this chapter prior to issuance by the Department of a renewed REGISTRATION OR ~~license or permit~~, OR THE ISSUANCE OF A RENEWED LICENSE BY THE DEPARTMENT OR A LICENSOR.

~~(c) Registration renewal.~~ The food facility operator of an existing facility shall submit an application and the required fee prior to issuance by the Department of a renewed registration.

~~(d)~~ (C) *Change of ownership.* Licenses AND registrations and shellfish permits are nontransferable. New owners shall apply to the Department OR LICENSOR in accordance with § 46.1142 (relating to application procedure for appropriate permit, license or registration).

**§ 46.1144. Conditions of retention: responsibilities of the food facility operator.**

To retain a license, OR registration or ~~shellfish permit~~ issued by the Department OR LICENSOR under this chapter, a food facility operator shall do the following:

(1) Post the license, OR registration or ~~shellfish permit~~ in a location in the food facility that is conspicuous to consumers and the Department OR LICENSOR.

(2) Comply with this chapter--including the conditions of a granted variance as specified in § 46.1103(c) (relating to variances)--and approved plans as specified in § 46.1121(b) (relating to facility and operating plans).

(3) If a food facility is required in § 46.1122(a) (relating to HACCP plans) to operate under a HACCP plan, comply with the plan as specified in § 46.1103(c) (relating to variances).

(4) Immediately contact the Department OR LICENSOR to report an illness of an A FOOD employee as specified in § 46.111(b) (relating to duty to report disease or medical condition).

(5) Immediately discontinue operations and notify the Department OR LICENSOR if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger public health. A food facility operator need not discontinue operations in an area of a facility that is unaffected by the imminent health hazard.

(6) Not resume operations discontinued in accordance with paragraph (5) or otherwise according to the Public Eating and Drinking Place PLACES Law or the aet FOOD ACT until approval is obtained from the Department OR LICENSOR.

(7) Allow representatives of the ~~Secretary~~ DEPARTMENT OR LICENSOR access to the food facility as specified in § 46.1102 46.1101 (relating to access to food facilities).

(8) Except as specified in paragraph (9), replace existing facilities and equipment with facilities and equipment that comply with this chapter if either of the following occurs:

(i) The Department OR LICENSOR directs the replacement because the facilities and equipment constitute a public health hazard or no longer comply with the criteria upon which the facilities and equipment were accepted.

(ii) The facilities and equipment are replaced in the normal course of operation.

(9) Upgrade or replace refrigeration equipment as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding), by NO LATER THAN FIVE YEARS AFTER THE EFFECTIVE DATE OF THIS CHAPTER, if the circumstances specified in paragraph (8)(i) and (ii) do not occur first, and unless a variance has been approved as specified in § 46.1103.

(10) Comply with directives of the Department OR LICENSOR including time frames for corrective actions specified in inspection reports, notices, orders, warnings and other

directives issued by the Department OR LICENSOR in regard to the operator's food facility or in response to community emergencies.

(11) Accept notices issued and served by the Department OR LICENSOR according to the Public Eating and Drinking Place PLACES Law or the act FOOD ACT.

#### **CHAPTER 47. (Reserved)**

**§§ 47.1--47.3. (Reserved).**

#### **CHAPTER 49. (Reserved)**

##### **Subchapter A. (Reserved)**

**§§ 49.1--49.6. (Reserved).**

##### **Subchapter B. (Reserved)**

**§§ 49.11--49.20. (Reserved).**

##### **Subchapter C. (Reserved)**

**§§ 49.31--49.36.1. (Reserved).**

##### **Subchapter D. (Reserved)**

**§§ 49.41--49.47. (Reserved).**

##### **Subchapter E. (Reserved)**

**§§ 49.51--49.56. (Reserved).**

##### **Subchapter F. (Reserved)**

**§ 49.61. (Reserved).**

**§ 49.62. (Reserved).**

#### **Subpart B. LIQUID FOODS**

#### **CHAPTER 53. (Reserved)**

**§§ 53.1--53.7. (Reserved).**

**§§ 53.11--53.19. (Reserved).**

§ 53.21. (Reserved).

§ 53.22. (Reserved).

**CHAPTER 55. (Reserved)**

§§ 55.1--55.5. (Reserved).

**CHAPTER 61. (Reserved)**

**Subchapter A. (Reserved)**

§§ 61.1--61.7. (Reserved).

§§ 61.11--61.13. (Reserved).

§ 61.21. (Reserved).

§ 61.22. (Reserved).

§§ 61.31--61.34. (Reserved).

§§ 61.41--61.43. (Reserved).

**Subchapter B. (Reserved)**

§§ 61.51--61.53. (Reserved).

§§ 61.61--61.65. (Reserved).

§ 61.71. (Reserved).

§ 61.72. (Reserved).

**CHAPTER 63. (Reserved)**

§§ 63.1--63.4. (Reserved).

**Subchapter C. MISCELLANEOUS PROVISIONS**

**CHAPTER 78. (Reserved)**

**Subchapter A. (Reserved)**

§§ 78.1--78.3. (Reserved).

**Subchapter B. (Reserved)**

§§ 78.11--78.14. (Reserved).

§§ 78.21--78.24. (Reserved).

§ 78.31. (Reserved).

§ 78.32. (Reserved).

§§ 78.41--78.43. (Reserved).

§§ 78.51--78.53. (Reserved).

§§ 78.61--78.65. (Reserved).

§§ 78.71--78.78. (Reserved).

§§ 78.91--78.97. (Reserved).

§ 78.101. (Reserved).

**CHAPTER 79. (Reserved)**

§ 79.1. (Reserved).

**CHAPTER 80. (Reserved)**

§ 80.1. (Reserved).

§§ 80.11--80.13. (Reserved).

§§ 80.21--80.23. (Reserved).

§ 80.31. (Reserved).

§ 80.32. (Reserved).

§§ 80.41--80.48. (Reserved).

§ 80.51. (Reserved).

§ 80.52. (Reserved).

**§§ 80.61--80.63. (Reserved).**

**§ 80.71. (Reserved).**

**§ 80.72. (Reserved).**

**§§ 80.81--80.84. (Reserved).**

**CHAPTER 81. (Reserved).**

**§ 81.1. (Reserved).**

**§ 81.11. (Reserved).**

**§ 81.12. (Reserved).**

**§ 81.21. (Reserved).**

# PROPOSED RULEMAKING

## DEPARTMENT OF AGRICULTURE

[7 PA. CODE CHS. 31, 35, 41, 43, 45—47, 49, 53, 55, 61, 63 AND 78—81]

### Food Code

The Department of Agriculture (Department) proposes to adopt Chapter 46 (relating to food code) to read as set forth in Annex A. The Department also proposes to delete Chapters 31 (relating to bakeries and bakery products), 35 (relating to condiments, spices, pickles and related products), 41 (relating to fruit and fruit products, butters, jellies and preserves), 43 (relating to flavoring materials), 45 (relating to general foods), 47 (relating to oleaginous materials; animal and vegetable fats and oils), 49 (relating to shellfish), 53 (relating to cider and vinegar standards), 55 (relating to coffee and tea standards), 61 (relating to packaged nonalcoholic drinks), 63 (relating to salad dressing and related products), 78 (relating to food establishments), 79 (relating to food service), 80 (relating to food vending machines) and 81 (relating to public places).

### Statutory Authority

The Food Act (act) (31 P.S. §§ 20.1—20.18), the Public Eating and Drinking Place Law (law) (35 P.S. §§ 655.1—655.13) and section 1705(d) of The Administrative Code of 1929 (71 P.S. § 445(d)) provide the legal authority for this proposed rulemaking.

The act charges the Department with the responsibility to: (1) regulate, register and inspect "food establishments" in this Commonwealth under section 14 (a) of the act (31 P.S. § 20.14(a)); (2) promulgate regulations and food safety standards necessary to the proper enforcement of the food safety requirements under section 13(a) of the act (31 P.S. § 20.13(a)); and (3) construe the statute and its attendant regulations in a manner that is as consistent with Federal statutory and regulatory authority as practicable under section 16 of the act (31 P.S. § 20.16).

The law charges the Department with the responsibility to regulate, license and inspect "public eating and drinking places" in this Commonwealth under sections 2 and 6(a) of the law (35 P.S. §§ 655.2 and 655.6(a)), and to regulate the cleanliness and sanitation of these public eating and drinking places under section 9 of the law (35 P.S. § 655.9). This responsibility had originally been assigned the former Department of Environmental Resources, but was transferred to the Department by the act of December 12, 1994 (P.L. 903, No. 131).

Section 1705(d) of The Administrative Code of 1929 requires the Department to establish regulatory standards necessary to enforce food safety laws.

### Purpose

This proposed rulemaking would draw authority from several food safety statutes to establish a comprehensive Food Code for this Commonwealth. The primary purpose of this proposed rulemaking is to achieve the public health goal of reducing foodborne illness to the fullest extent possible.

This proposed rulemaking would bring the Commonwealth's food safety standards into step with the current National standards for food safety in the 1999 edition of

the *United States Public Health Service Food Code* (1999 Federal Recommended Food Code).

Food safety science is an evolving body of knowledge. It is the Department's intention to adopt regulatory food safety standards that reflect current recommended National standards, and to revise these standards in the future as necessary to track with relevant revisions to these National standards.

Food safety considerations and procedures are essentially the same, whether the entity being regulated is a "food establishment" as described in the act or a "public eating and drinking place" as described in the law. For this reason, the proposed rulemaking would merge the definitions of these two terms into a single new term—"food facility"—and establish sanitation and food safety standards and procedures for these facilities.

### Background

The 1999 Federal Recommended Food Code is the product of a collaborative effort among the Department, the Food and Drug Administration, the Food Safety Inspection Service, the Centers for Disease Control, various State and local public health and food control agencies, food industry representatives, academia and consumers. It represents the state-of-the-science with respect to food handling and food safety.

The proposed rulemaking would establish the food safety standards, procedures and requirements of the 1999 Federal Recommended Food Code as those of the Commonwealth. The provisions have been reformatted and revised to track with the underlying statutory authority for the proposed rulemaking, as well as the administrative requirements of the Department.

The standards in the proposed rulemaking are consistent with the content of many of the food safety training courses offered to food industry employees over the years. For this reason, the proposed rulemaking presents a set of standards with which a large segment of this Commonwealth's food industry is already familiar.

### Need for the Proposed Rulemaking

The proposed rulemaking is needed to reduce foodborne illness to the fullest extent possible. This public health and safety objective is the primary reason for the proposed rulemaking.

The food safety standards in the proposed rulemaking should also serve the regulated community by helping to lower the number of claims and lawsuits related to foodborne illness.

The Department is satisfied there are no reasonable alternatives to proceeding with the proposed rulemaking. The Department is also satisfied the proposed rulemaking meets the requirements of Executive Order No. 1996-1, "Regulatory Review and Promulgation."

### Overview of the Major Provisions of the Proposed Rulemaking

Proposed § 46.3 (relating to definitions) would define numerous terms, including "food facility." The majority of these definitions have their origin in the 1999 Federal Recommended Food Code, the act or the law.

Proposed Subchapter B (relating to management and personnel) would require a food facility have a designated person in charge of the facility, and ascribe specific duties and responsibilities to that person. In addition, the



Subchapter would prescribe disease/illness reporting standards, personal cleanliness requirements and other hygienic practices to limit incidents of foodborne illness.

Proposed Subchapter C (relating to food) would establish handling and preparation requirements that track food from its point of origin to its point of consumption.

Proposed §§ 46.211—46.221 would establish limitations and restrictions with respect to the sources from which a food facility may obtain various foods.

Proposed §§ 46.241—46.301 (relating to specifications for receiving, original containers and records) would specify the conditions at which various types of food are to be received by a food facility. These conditions include the maximum receiving temperatures for potentially hazardous foods, pasteurization requirements for milk and milk products and mandatory labeling/origin information for shellfish and shellstock.

Proposed §§ 46.261, 46.262, 46.281—46.286 and 46.301—46.307 (relating to preventing contamination by employees; preventing food and ingredient contamination; and preventing contamination from equipment, utensils and linens) would prescribe various practices intended to keep food from being contaminated after it has reached a food facility. These practices include measures to prevent contamination from hands and skin, the commingling of foods, misuse of food preparation equipment, utensils and linens and other potential sources of contamination.

Proposed §§ 46.321—46.323 and 46.341—46.345 (relating to preventing contamination from the premises; and preventing contamination by consumers) would establish requirements to help prevent contamination of food from the premises of the food facility or from contact with consumers.

Proposed §§ 46.361—46.365 (relating to destruction of organisms of public health concern) would establish procedures intended to destroy harmful organisms that can live in food. These provisions would establish minimum time/temperature standards for the cooking of meat and vegetables, for foods cooked by microwave and for cooked foods that are reheated. In addition, proposed § 46.364 (relating to parasite destruction in fish other than molluscan shellfish by freezing) would establish specific freezing time/temperature requirements and recordkeeping requirements for fish.

Proposed §§ 46.381—46.385 (relating to temperature and time control for limitation of growth of organisms of public health concern) would require certain procedures and standards intended to limit the growth of harmful organisms in potentially hazardous foods (foods capable of supporting the rapid growth of infectious or toxic microorganisms), such as, milk, eggs, meat and poultry.

The proposed rulemaking would allow for food to be processed by a specialized method (such as, by smoking or processing in a reduced-oxygen atmosphere) if the processor first obtains a variance from the Department. This would be addressed in proposed § 46.401 (relating to variance requirement for specialized processing methods).

Proposed § 46.422 (relating to labeling) would require particular label information on packaged foods and certain bulk foods. Proposed § 46.423 (relating to consumer advisory required with respect to animal foods that are raw, undercooked or not otherwise processed to eliminate pathogens) would require a vendor to provide a special warning to consumers if it sells a ready-to-eat food that has as a component a food that is raw, undercooked or not otherwise processed to eliminate pathogens. The warning

would advise members of certain highly-susceptible populations (the very young, the very old and other immunocompromised groups) of the potential health hazards involved in consuming raw or undercooked foods. In addition, food served to these highly-susceptible populations would have additional requirements imposed under proposed § 46.461 (relating to additional safeguards for a food facility that serves a highly-susceptible population).

In summary, proposed Subchapter D (relating to equipment, utensils and linens) would address the facilities, equipment and articles that come into contact or proximity with food and that have the demonstrated potential to cause or harbor foodborne illness. This includes utensils and surfaces with which food comes into contact. It also includes the design and construction of the food facility, the accuracy of temperature measuring devices, the design and cleanliness of food dispensing equipment, the design and operation of warewashing machines, the maximum capacities of various pieces of equipment, the location of equipment, the maintenance of equipment and the cleaning and sanitization of equipment and utensils.

Proposed Subchapter E (relating to water, plumbing and waste) would establish standards for the quantity and quality of drinking water and water used in food preparation at a food facility. The subchapter would also address the construction, number, location, operation and maintenance of plumbing systems at food facilities, as well as refuse storage.

Proposed Subchapter F (relating to physical facilities) would establish a set of general standards intended to ensure that a food facility is designed and constructed so as to minimize foodborne illness. These standards entail a food facility having cleanable food surfaces, cleanable floors, walls and ceilings, adequate handwashing facilities and adequate lighting and ventilation.

Proposed Subchapter G (relating to poisonous or toxic materials) would establish requirements for the safe labeling, storage and use of toxic substances in a food facility. These substances might include pesticides, medicines, cleaners, lubricants and other materials.

Proposed Subchapter H (relating to administrative provisions) would establish a process by which a food facility might obtain a variance from the Department to allow a practice or procedure not otherwise permitted under the chapter. This would only be done when a health hazard would not result from the variance. The subchapter would also address the process by which a food facility can obtain the registration required of a food establishment under the act or the license required of a public eating or drinking place under the law.

#### *Affected Individuals and Organizations*

The proposed rulemaking would impact upon the public by reducing the number of foodborne illness outbreaks originating from food facilities.

Food establishments and public eating or drinking places, collectively referred to as "food facilities" in the proposed rulemaking, would also be affected by this proposed rulemaking. These food facilities would be expected to comply with the standards of this chapter.

#### *Fiscal Impact*

*Commonwealth.* The proposed rulemaking would impose no costs and have no fiscal impact on the Commonwealth. The Department currently registers and inspects food establishments under the act and issues licenses allowing the operation of public eating and drinking places under the law. The proposed rulemaking would

merge the Department's regulatory functions into a single set of standards applicable to all "food facilities" in this Commonwealth.

**Political Subdivisions.** The proposed rulemaking would impose no costs and have no fiscal impact upon political subdivisions.

**Private Sector.** The proposed rulemaking might impose some initial cost on the private sector, although this cannot be readily quantified. Since the food safety standards prescribed by the proposed rulemaking reflect rather widely-known food safety concerns, the Department expects most food facilities in operation within this Commonwealth are currently meeting these standards or would have relatively little difficulty meeting them. In addition, the proposed rulemaking is likely to result in a decrease in the number of lawsuits relating to foodborne illness originating from food facilities, with a resultant savings in costs attributable to litigation and awards of damages. These savings are not readily quantifiable.

**General Public.** The proposed rulemaking would enhance public health and safety. It is expected to reduce the number of cases of foodborne illness attributable to food originating from food facilities in this Commonwealth. This should result in some indeterminate cost savings to the general public.

#### **Paperwork Requirements**

The proposed rulemaking is not likely to appreciably impact upon the paperwork generated by the Department or food facilities.

#### **Effective Date**

The proposed rulemaking will be effective upon publication in the *Pennsylvania Bulletin* as final-form rulemaking.

#### **Sunset Date**

There is no sunset date for the proposed rulemaking. The Department will review the efficacy of these regulations on an ongoing basis.

#### **Public Comment Period/Contact Person**

Interested persons are invited to submit written comments regarding the proposed rulemaking within 30 days following publication in the *Pennsylvania Bulletin*.

Comments are to be submitted to the Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: Sheri Dove.

#### **Regulatory Review**

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on February 8, 2002, the Department submitted a copy of the proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs. The Department also provided IRRC and the Committees a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has an objection to any portion of the proposed rulemaking, it must so notify the Department within 10 days of the close of the Committees' review period. The notification shall specify the regulatory review criteria that have not been met by that portion. The Regulatory Review Act sets forth detailed procedures for review of

these objections by the Department, the General Assembly and the Governor prior to the final publication of the proposed rulemaking.

SAMUEL E. HAYES, Jr.,  
Secretary

**Fiscal Note:** 2-137. No fiscal impact; (8) recommends adoption.

#### **Annex A**

#### **TITLE 7. AGRICULTURE.**

#### **PART III. BUREAU OF FOOD SAFETY AND LABORATORY SERVICES**

*(Editor's Note: The Department is proposing to delete Chapter 31, Pa. Code pages 31-1 to 31-9, serial pages (217445) to (217453).)*

#### **CHAPTER 31. (Reserved)**

§ 31.1. (Reserved).

§§ 31.11—31.23. (Reserved).

§§ 31.31—31.39. (Reserved).

*(Editor's Note: The Department proposes to delete Chapter 35, Pa. Code pages 35-1 and 35-2, serial pages (217455) to (217456).)*

#### **CHAPTER 35. (Reserved)**

§§ 35.1—35.11. (Reserved).

*(Editor's Note: The Department is proposing to delete Chapter 41, Pa. Code pages 41-1—41-6, serial pages (217537) to (217542).)*

#### **CHAPTER 41. (Reserved)**

§§ 41.1—41.4. (Reserved).

§§ 41.11—41.14. (Reserved).

§§ 41.21—41.24. (Reserved).

*(Editor's Note: The Department proposes to delete Chapter 43, Pa. Code pages 43-1—43-5, serial pages (217543) to (217547).)*

#### **CHAPTER 43. (Reserved)**

§§ 43.1—43.8. (Reserved).

*(Editor's Note: The Department proposed to delete Chapter 45, Pa. Code pages 45-1—45-11, serial pages (217549) to (217559).)*

§§ 45.1—45.7. (Reserved).

§§ 45.21—45.24. (Reserved).

§§ 45.31—45.33. (Reserved).

§§ 45.41—45.44. (Reserved).

§§ 45.51—45.54. (Reserved).

§§ 45.61—45.64. (Reserved).

§ 45.71. (Reserved).

§ 45.72. (Reserved).

§§ 45.81—45.87. (Reserved).

§§ 45.91—45.93. (Reserved).

#### **CHAPTER 46. FOOD CODE**

- A. PURPOSE AND DEFINITIONS
- B. MANAGEMENT AND PERSONNEL
- C. FOOD
- D. EQUIPMENT, UTENSILS AND LINENS
- E. WATER, PLUMBING AND WASTE
- F. PHYSICAL FACILITIES

G. POISONOUS OR TOXIC MATERIALS  
H. ADMINISTRATIVE PROCEDURES

Subchapter A. PURPOSE AND DEFINITIONS

Sec.	Purpose.
46.1.	Scope.
46.2.	Definitions.
46.3.	

§ 46.1. Purpose.

The purpose of this chapter is to safeguard public health and ensure that consumers are provided food that is safe, unadulterated and honestly presented.

§ 46.2. Scope.

This chapter establishes definitions; sets standards for management and personnel, food operations, and equipment and facilities; and provides for food facility plan review, permitting, licensing, registration, inspection and employee restriction.

§ 46.3. Definitions.

The following terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

*Act*—The Food Act (31 P. S. §§ 20.1—20.18).

*Additive*—A food additive or a color additive.

*Adulterated*—Food with respect to which one or more of the following is accurate:

(i) The food bears or contains any poisonous or deleterious substance, which may render it injurious to health. However, if the substance is not an added substance, the food will not be considered adulterated if the quantity of the substance in the food does not ordinarily render it injurious to health.

(ii) The food bears or contains any added poisonous or added deleterious substance, which is unsafe within the meaning of section 11 of the act (31 P. S. § 20.11). This subparagraph does not apply to a pesticide chemical in or on a raw agricultural commodity, a food additive or a color additive.

(iii) The food is a raw agricultural commodity and bears or contains a pesticide chemical which is unsafe within the meaning of section 11 of the act, except that, when a pesticide chemical has been used in or on a raw agricultural commodity with an exception granted or tolerance prescribed under section 11 of the act or under any of the Federal acts and the raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating or milling, the residue of the pesticide remaining in or on the processed food will, notwithstanding section 11 of the act and this subparagraph, not be deemed unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity.

(iv) The food bears or contains any food additive, which is unsafe within the meaning of section 11 of the act or any of the Federal acts.

(v) The food consists in whole or in part of any diseased, contaminated, filthy, putrid or decomposed substance or is otherwise unfit for food.

(vi) The food has been produced, prepared, packed or held under unsanitary conditions so that it may have become contaminated with filth or may have been rendered diseased, unwholesome or injurious to health.

(vii) The food is, in whole or part, the product of a diseased animal or of an animal which has died otherwise than by slaughter.

(viii) The food is in a container composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health, unless the container is fabricated or manufactured with good manufacturing practices as that standard is defined and delineated by any of the Federal acts and their regulations.

(ix) The food has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption under section 11 of the act or under one of the Federal acts.

(x) The food has had any valuable constituent, in whole or part, omitted or abstracted therefrom.

(xi) The food has had any substance substituted wholly or in part.

(xii) Damage or inferiority of the food is concealed in any manner.

(xiii) A substance has been added to the food and it is mixed or packed so as to increase its bulk or weight or reduce its quality or strength or make it appear better or of greater value than it is.

(xiv) The food bears or contains any color additive which is unsafe within the meaning of section 11 of the act or under one of the Federal acts.

(xv) The food bears or contains eggs processed by or egg products derived from a manufacturing, processing or preparing method wherein whole eggs are broken using a centrifuge-type egg breaking machine that separates the egg's liquid interior from the shell.

*Approved*—Acceptable to the Department based on a determination of conformity with principles, practices and generally recognized standards that protect public health.

*Bed and breakfast homestead or inn*—A private residence which contains 10 or fewer bedrooms used for providing overnight accommodations to the public, and in which breakfast is the only meal served and is included in the charge for the room.

*Beverage*—A liquid for drinking, including water.

*Bottled drinking water*—Water that is sealed in bottles, packages or other containers and offered for sale for human consumption. The term includes bottled mineral water.

*CIP*—cleaned in place—

(i) Cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine.

(ii) The term does not include the cleaning of equipment such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

*Certification number*—A unique combination of letters and numbers assigned by the Department or other shellfish control authority having jurisdiction to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

*Color additive*—A material which is a dye, pigment or other substance made by a process of synthesis or similar

artifice or extracted, isolated or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral or other source and when added or applied to a food is capable, alone or through reaction with other substances, of imparting color thereto.

(i) The term includes black, white and intermediate grays.

(ii) The term does not include materials, which the Secretary, by regulation, determines is used, or intends to be used, solely for a purpose other than coloring.

(iii) The term does not include any pesticide chemical, soil or plant nutrient or other agricultural chemical solely because of its effect in aiding, retarding or otherwise affecting, directly or indirectly, the growth or otherwise natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

**Comminuted**—A food that is reduced in size by methods including chopping, flaking, grinding or mincing. The term includes fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef and sausage; and a mixture of two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.

**Confirmed disease outbreak**—A foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness.

**Controlled atmosphere packaging**—A type of reduced oxygen packaging in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food and impermeable packaging material.

**Consumer**—A person, who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food facility and does not offer the food for resale.

**Corrosion-resistant material**—A material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

**Critical control point**—A point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

**Critical limit**—The maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

**Department**—The Department of Agriculture of the Commonwealth.

**Drinking water, potable water or water**—Safe drinking water as defined in the Pennsylvania Safe Drinking Water Act (35 P. S. §§ 721.1—721.17). The term does not include water such as boiler water, mop water, rainwater, wastewater and "nondrinking" water.

**Dry storage area**—A room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous and dry goods such as single service items.

**EPA**—The United States Environmental Protection Agency.

**Easily cleanable**—

(i) A characteristic of a surface that:

(A) Allows effective removal of soil by normal cleaning methods.

(B) Is dependent on the material, design, construction and installation of the surface.

(C) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose and use.

(ii) The term includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in subparagraph (i) to different situations in which varying degrees of cleanability are required, such as one of the following:

(A) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining.

(B) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

**Easily movable**—A unit of equipment that is both of the following:

(i) Portable; mounted on casters, gliders or rollers; or provided with a mechanical means to safely tilt the unit of equipment for cleaning.

(ii) Has no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

**Employee**—The permit, license or registration holder, person in charge, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food facility.

**Equipment**—

(i) An article that is used in the operation of a food facility such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine or warewashing machine.

(ii) The term does not include items used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks and skids.

**FDA**—The United States Food and Drug Administration.

**Fish**—The term includes:

(i) Fresh or saltwater finfish, crustaceans, all mollusk and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of those animals), other than birds or mammals, the animal life is intended for human consumption.

(ii) The term includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.

**Food**—An article used for food or drink by humans, including chewing gum and articles used for components of any article. The term does not include medicines and drugs.

**Foodborne disease outbreak**—One of the following:

(i) An incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiological analysis implicates the food as the source of the illness.

(ii) An incident in which one or more persons experience illness from botulism or chemical poisoning.

**Food-contact surface**—One of the following:

(i) A surface of equipment or a utensil with which food normally comes into contact.

(ii) A surface of equipment or a utensil from which food may drain, drip or splash into a food, or onto a surface normally in contact with food.

**Food additive**—

(i) A substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, with respect to which one or more of the following is correct:

(A) The substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.

(B) The substance has been used in food prior to January 1, 1958, and is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures or experience based on common use in food, to be safe under the conditions of its intended use.

(ii) The term does not include the following:

(A) A pesticide chemical in or on a raw agricultural commodity.

(B) A pesticide chemical to the extent that it is intended for use or is used in the production, storage or transportation of any raw agricultural commodity.

(C) A color additive.

(D) A substance used in accordance with a sanction or approval granted prior to the enactment of this subparagraph under a statute repealed by the act, under the Poultry Products Inspection Act (21 U.S.C.A. §§ 451–471) or under the Wholesome Meat Inspection Act (21 U.S.C.A. §§ 476a–467f and 470).

(E) A new animal drug.

**Food employee**—An individual working with unpackaged food, food equipment or utensils, or food contact surfaces.

**Food establishment**—

(i) A retail food store and a room, building or place or portion thereof or vehicle maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, baking, canning, freezing, packing or otherwise preparing or transporting or handling food.

(ii) The term includes those portions of public eating and drinking licensees which offer food for sale for

off-premises consumption, except those portions of establishments operating exclusively under milk or milk products permits.

**Food facility**—A public eating or drinking place or a food establishment. The term includes food service facilities provided by an organized camp or campground.

**Food facility operator**—The entity that is legally responsible for the operation of the food facility, such as the owner, owner's agent or other person.

**Food facility premises**—The food facility, its contents and the contiguous land or property under the control of the food facility operator. If a food facility is a component of a larger operation, such as a hotel, motel, school or recreation camp, and that larger operation is also under the control of the food facility operator, that larger operation is part of the food facility premises to the extent it may impact the food facility, its personnel or its operations.

**Game animal**—

(i) An animal, the products of which are food, that is not classified as any of the following:

(A) Fish, as that term is defined in this chapter.

(B) Cattle, sheep, swine, goat, horse, mule or other equine, as those terms are used in 9 CFR Chapter III, Subchapter A (relating to agency organization and terminology; mandatory meat and poultry products inspection and voluntary inspection and certification), or any subsequent revision or restatement thereof.

(C) Poultry, as that term is used in 9 CFR Chapter III, Subchapter A (relating to mandatory poultry products inspection) or any subsequent revision or restatement thereof.

(D) Ratites, such as ostriches, emus or rheas.

(ii) The term includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

**General use pesticide**—A pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175 (relating to pesticides classified for restricted use), or any subsequent revision or restatement thereof.

**HACCP—Hazard Analysis Critical Control Point**—A system developed by the National Advisory Committee on Microbiological Criteria for Foods that identifies and monitors specific foodborne hazards that can adversely affect the safety of the food products.

**HACCP plan**—A written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

**Hazard**—A biological, chemical or physical property that may cause an unacceptable consumer health risk.

**Hermetically sealed container**—A container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

**High humidity cooking**—Cooking in an oven that attains relative humidity of greater than 90% for at least 1

hour as measured in the cooking chamber or exit of the oven, or cooking in a moisture-impermeable bag that provides 100% humidity.

**Highly susceptible population**—A group of persons who are more likely than other populations to experience foodborne disease because they are immunocompromised.

**Imminent health hazard**—A significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on one or more of the following:

- (i) The number of potential injuries.
- (ii) The nature, severity and duration of the anticipated injury.

**Injected**—Manipulating a meat so that infectious or toxigenic microorganisms may be introduced from its surface to its interior through tenderizing with deep penetration, or injecting the meat such as with juices which may be referred to as "injecting," "pinning" or "stitch pumping."

**Juice**—When used in the context of food safety, the term refers to the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate of the liquid or purée. This definition does not apply to standards of identity established by the FDA or USDA.

**Kitchenware**—Food preparation and storage utensils.

**Linens**—Fabric items such as cloth hampers, cloth napkins, tablecloths, wiping cloths and work garments, including cloth gloves.

**mg/L**—Milligrams per liter, which is the metric equivalent of parts per million (ppm).

**Meat**—The flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals. The term does not include fish, poultry and wild game animals as specified under § 46.221(b) and (c) (relating to game animals).

**Milk Sanitation Law**—The act of July 2, 1935 (P. L. 589, No. 210) (31 P. S. §§ 645—660e).

**Modified atmosphere packaging**—

(i) A type of reduced oxygen packaging in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food.

(ii) The term includes: reduction in the proportion of oxygen, total replacement of oxygen, or an increase in the proportion of other gases such as carbon dioxide or nitrogen.

**Molluscan shellfish**—An edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

**pH**—The symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between 0 and 7 indicate acidity and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral.

**Packaged**—

(i) Bottled, canned, cartoned, securely bagged or securely wrapped in a food facility.

(ii) The term does not include a wrapper, carryout box or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer.

**Pennsylvania Construction Code Act**—35 P. S. §§ 7210.101—7210.1103.

**Person**—A corporation, partnership, limited liability company, business trust, other association, government entity (other than the Commonwealth), estate, trust, foundation or natural person.

**Person in charge**—The individual present at a food facility responsible for the operation at the time of inspection.

**Personal care items**—

(i) Items or substances that may be poisonous, toxic or a source of contamination and are used to maintain or enhance a person's health, hygiene or appearance.

(ii) The term includes items such as medicines, first aid supplies, cosmetics, toiletries (such as toothpaste and mouthwash) and similar items.

**Physical facilities**—The structure and interior surfaces of a food facility, including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

**Plumbing fixture**—A receptacle or device that is one or more of the following:

(i) Permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system.

(ii) Discharges used water, waste materials or sewage directly or indirectly to the drainage system of the premises.

**Plumbing system**—The water supply and distribution pipes; plumbing fixtures and traps; soil, waste and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices and appurtenances within the premises; and water-treating equipment.

**Poisonous or toxic material**—A substance that is not intended for ingestion and that fits within one or more of the following categories:

(i) Cleaners and sanitizers, including cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes and other chemicals.

(ii) Pesticides.

(iii) Substances necessary for the operation and maintenance of the establishment, such as nonfood grade lubricants, solvents and personal care items that may be deleterious to health.

(iv) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

**Potentially hazardous food**—

(i) A food which consists in whole or part of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustacea or other ingredients, including synthetic ingre-



2dients, which is in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms.

(ii) The term does not include foods that have a pH level of 4.6 or below or a water activity of 0.85 or less under standard conditions or food products in hermetically sealed containers processed to maintain commercial sterility.

**Poultry**—One or more of the following:

(i) A domesticated bird (chickens, turkeys, ducks, geese or guineas), whether live or dead, as defined in 9 CFR Chapter III, Subchapter A, Part 381 or any subsequent revision or restatement thereof.

(ii) A migratory waterfowl, game bird or squab such as pheasant, partridge, quail, grouse or guineas, whether live or dead, as defined in the USDA regulations in 9 CFR Chapter III, Subchapter A, Part 362 (relating to voluntary poultry inspection program) or any subsequent revision or restatement thereof.

(iii) The term does not include ratites.

**Primal cut**—A basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank or veal breast.

**Private water system**—A system for the provision of piped water for human consumption that is not a public water system.

**Public Eating and Drinking Place Law**—The act of May 23, 1945 (P. L. 926, No. 369) (35 P. S. §§ 655.1—655.13).

**Public eating and drinking places license**—A grant to a licensee to conduct a public eating and drinking place as defined in the Public Eating and Drinking Place Law.

**Public eating or drinking place**—

(i) A place within this Commonwealth where food or drink is served to or provided for the public, with or without charge.

(ii) This provisions does apply to dining cars operated by a railroad company in interstate commerce or a bed and breakfast homestead or inn.

**Public water system**—A system which provides water to the public for human consumption, and which has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

(i) The term includes collection, treatment, storage and distribution facilities under control of the operator of the system and used in connection with the system.

(ii) The term also includes a system which provides water for bottling or bulk hauling for human consumption.

**Ratite**—An animal belonging to the same family as ostriches, emus and rheas.

**Ready-to-eat food**—

(i) Food in a form that is edible without washing, cooking or additional preparation by the food facility or the consumer, and that is reasonably expected to be consumed in that form.

(ii) The term includes:

(A) Unpackaged potentially hazardous food that is cooked to the temperature and time required for the specific food under § 46.361 (relating to cooking raw animal foods).

(B) Raw, washed, cut fruits and vegetables.

(C) Whole, raw fruits and vegetables that are presented for consumption without the need for further washing, such as at a buffet.

(D) Other food presented for consumption for which further washing or cooking is not required and from which rinds, peels, husks or shells are removed.

**Reduced oxygen packaging**—

(i) The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding 21% oxygen atmosphere.

(ii) A process as specified in subparagraph (i) that involves a food for which *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form.

(iii) The term includes vacuum packaging, modified atmosphere packaging and controlled atmosphere packaging.

**Refuse**—Solid waste not carried by water through the sewage system.

**Reg. Penna. Dept. Agr.**—An abbreviation connoting that a food bearing that abbreviation on its package label has been processed by a food facility that is "registered with the Pennsylvania Department of Agriculture" in accordance with section 14(a) of the act (31 P. S. § 20.14(a)).

**Restricted use pesticide**—A pesticide classified for restricted use under section 3(d) of the Federal Insecticide, Fungicide and Rodenticide Act of 1947 (7 U.S.C.A. § 136(d)), or a pesticide designated by the Secretary for restricted use under section 7(b)(6) of the Pennsylvania Pesticide Control Act of 1973 (3 P. S. § 111.27(b)(6)).

**Safe material**—One or more of the following:

(i) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food.

(ii) An additive that is used as specified in section 409 or section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301 and 376).

(iii) A material that is not an additive and that is used in conformity with applicable regulations of the FDA.

**Sanitization**—The application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

**Sealed**—Free of cracks or other openings that allow the entry or passage of moisture.

**Service animal**—An animal such as a guide dog, signal dog or other animal individually trained to provide assistance to an individual with a disability.

**Secretary**—The Secretary of the Department or an authorized representative, employee or agent of the Department.

**Servicing area**—An operating base location to which a mobile food facility or transportation vehicle returns

regularly for things such as discharging liquid or solid wastes, refilling water tanks and ice bins and boarding food.

**Sewage**—A substance, which contains waste products or excrements or other discharges from the bodies of human beings or animals and any noxious or deleterious substance being harmful or inimical to the public health, or to animal or aquatic life, or to the use of water for domestic water supply or for recreation.

**Shellfish control authority**—A State, Federal, foreign, tribal or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.

**Shellfish permit**—A permit issued by the Department in accordance with this chapter and the National Shellfish Sanitation Program, that authorizes a person to operate a food establishment for shellfish.

**Shellfish permit holder**—The entity that meets the following conditions:

- (i) Is legally responsible for the operation of the food facility such as the owner, owner's agent or other person.
- (ii) Possesses a valid shellfish permit to operate a shellfish food facility.

**Shellstock**—Raw, in-shell molluscan shellfish.

**Shucked shellfish**—Molluscan shellfish that have one or both shells removed.

**Single-service articles**—Tableware, carry-out utensils and other items such as bags, containers, place mats, stirrers, straws, toothpicks and wrappers that are designed and constructed for one time; one person consumer use after which they are intended for discard.

**Single-use articles**—

- (i) Utensils and bulk food containers designed and constructed to be used once and discarded.

(ii) The term includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles and number 10 cans which do not meet the materials, durability, strength and cleanability specifications in §§ 46.521(a), 46.541(a) and 46.542(a) and (b) (relating to materials in multiuse utensils and food contact surfaces; durability and strength; and cleanability of multiuse food-contact surfaces and CIP equipment) for multiuse utensils.

(iii) The term does not include formed aluminum containers, used in conjunction with pan liners that may be reused to cook nonpotentially hazardous baked goods.

**Slacking**—The process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of  $-23^{\circ}\text{C}$  ( $-10^{\circ}\text{F}$ ) to  $-4^{\circ}\text{C}$  ( $25^{\circ}\text{F}$ ) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach.

**Smooth**—One or more of the following:

- (i) A food-contact surface having a surface free of pits and inclusions with cleanability equal to or exceeding that of (100 grit) number-3 stainless steel.
- (ii) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale.

(iii) A floor, wall or ceiling having an even or level surface with no roughness or projections that renders it difficult to clean.

**Substance**—A substance intended for use in producing, manufacturing, packaging, processing, preparing, treating, transporting or holding food and any source of radiation intended for any use.

**Sulfiting agent**—A substance which imparts a residual of sulfur dioxide.

**Table-mounted equipment**—Equipment that is not portable and is designed to be mounted off the floor on a table, counter or shelf.

**Tableware**—Eating, drinking and serving utensils for table use such as plates, flatware (including forks, knives, and spoons) and hollowware (including bowls, cups, serving dishes and tumblers).

**Temperature measuring device**—A thermometer, thermocouple, thermistor or other device that indicates the temperature of food, air or water.

**Temporary food facility**—A food facility that operates for a period of no more than 14 days a year utilizing a permanent facility or in conjunction with a single event or celebration.

**USDA**—The United States Department of Agriculture.

**Utensil**—A food-contact implement or container used in the storage, preparation, transportation, dispensing, sale or service of food. The term includes the following:

- (i) Kitchenware or tableware that is multiuse, single-service or single-use.
- (ii) Gloves used in contact with food.
- (iii) Food temperature measuring devices.
- (iv) Probe-type price or identification tags used in contact with food.

**Vacuum packaging**—A type of reduced oxygen packaging in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package, such as sous vide.

**Variance**—A written document issued by the Department that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the Department, a health hazard or nuisance will not result from the modification or waiver.

**Vending machine**—A self-service device that, upon insertion of a coin, paper currency, token, card or key, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

**Vending machine location**—The room, enclosure, space or area where one or more vending machines are installed and operated. The term includes the storage areas and areas on the premises that are used to service and maintain the vending machines.

**Warewashing**—The cleaning and sanitizing of food-contact surfaces of equipment and utensils.

**Water activity or  $a_w$** —A measure of the free moisture in a food, obtained by dividing the water vapor pressure of the substance by the vapor pressure of pure water at the same temperature. Water activity is typically indicated by the symbol  $a_w$ .

**Water for human consumption**—The term includes water that is used for drinking, bathing and showering, cooking, dishwashing or maintaining oral hygiene.



**Whole-muscle, intact beef**—Whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

## **Subchapter B. MANAGEMENT AND PERSONNEL SUPERVISION**

- Sec.  
46.101. Designation of person in charge.  
46.102. Duties of the person in charge.

### **EMPLOYEE HEALTH**

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## **SUPERVISION**

### **§ 46.101. Designation of person in charge.**

The food facility 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 food facility during all hours of operation.

### **§ 46.102. Duties of the person in charge.**

The person in charge shall perform the following duties:

- (1) Ensure that food facility operations are not conducted in a private home where the food facility has not been approved by the Department, or in a room used as living or sleeping quarters as specified in § 46.922(k) (relating to functionality of various physical facilities of a food facility).
- (2) Ensure that persons unnecessary to the food facility operation are not allowed in the food preparation, food storage or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food, clean equipment, utensils, linens and unwrapped single-service and single-use articles are protected from contamination.
- (3) Ensure that employees and other persons (such as delivery and maintenance persons and pesticide applicators) entering the food preparation, food storage and warewashing areas comply with this chapter.
- (4) Routinely monitor employee handwashing to ensure that employees effectively clean their hands.
- (5) Routinely monitor employee observations and periodically evaluate foods upon receipt to ensure that employees visibly observe foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated and accurately presented.
- (6) Conduct daily oversight of the employees' routine monitoring of cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated in accordance with §§ 46.561 and 46.691(b) (relating to accuracy of temperature measuring devices for food; and to utensils and temperature and pressure measuring devices: repair and calibration), to ensure the

employees are properly cooking potentially hazardous food, and are being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats.

(7) Conduct daily oversight of the employees' routine monitoring of food temperatures during cooling, to ensure that employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours.

(8) Ensure that consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed, in accordance with § 46.423 (relating to consumer advisory required with respect to animal foods that are raw, undercooked or not otherwise processed to eliminate pathogens), that the food is not cooked sufficiently to ensure its safety.

(9) Routinely monitor solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing, to ensure that employees properly sanitize cleaned multiuse equipment and utensils before they are reused.

(10) Ensure that consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets, in accordance with § 46.306 (relating to using clean tableware for second portions and refills).

(11) Ensure that employees prevent cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils. These utensils may include deli tissue, spatulas, tongs, single-use gloves or dispensing equipment.

(12) Ensure that employees are properly trained in food safety as it relates to their assigned duties.

### **EMPLOYEE HEALTH**

#### **§ 46.111. Duty to report disease or medical condition.**

(a) *Responsibility of a food facility operator to require reporting.* A food facility operator shall require a food employee and a food employee applicant to whom a conditional offer of employment is made to report to the person in charge, information about their health and activities as they relate to diseases described in § 46.112 (relating to diseases or medical conditions that must be reported) or diseases that are transmissible through food.

(b) *Responsibility of a person in charge to report information to Department.* The person in charge shall notify the Department that a food employee is diagnosed with an illness due to *Salmonella typhi*, *Shigella* spp., *Escherichia coli* O157:H7 or hepatitis A virus.

(c) *Responsibilities of a food employee or food employee applicant.* A food employee or a person who applies for a job as a food employee shall report to the person in charge the information specified in this section in a manner that allows the person in charge to prevent the likelihood of foodborne disease transmission. This information includes the date of onset of jaundice or the date of onset of any illness or condition specified in § 46.112.

#### **§ 46.112. Diseases or medical conditions that must be reported.**

A food employee or food employee applicant shall report the following diseases or medical conditions to the person in charge:

- (1) A diagnosis of an illness due to any of the following:
  - (i) *Salmonella typhi*.

(ii) *Shigella* spp.

(iii) *Escherichia coli* O157:H7.

(iv) Hepatitis A virus.

(2) A past illness from any of the infectious agents listed in paragraph (1).

(3) A symptom caused by illness, infection or other source, where that symptom is associated with an acute gastrointestinal illness such as any of the following:

(i) Diarrhea.

(ii) Fever.

(iii) Vomiting.

(iv) Jaundice.

(v) Sore throat with fever.

(4) A lesion containing pus such as a boil or infected wound that is open or draining and is any of the following:

(i) On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover.

(ii) On exposed portions of the arms, unless the lesion is protected by an impermeable cover.

(iii) On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage.

(5) Is suspected of causing a confirmed disease outbreak caused by *S. typhi*, *Shigella* spp., *E. coli* O157:H7 or hepatitis A virus, including an outbreak at an event such as a family meal, church supper or festival because the food employee or applicant prepared food implicated in the outbreak.

(6) Is suspected of being exposed to a confirmed disease outbreak caused by *S. typhi*, *Shigella* spp., *E. coli* O157:H7, or hepatitis A virus, including an outbreak at an event such as a family meal, church supper or festival because the food employee or applicant did either of the following:

(i) Consumed food implicated in the outbreak.

(ii) Consumed food at the event prepared by a person who is infected or ill with the infectious agent that caused the outbreak or who is suspected of being a shedder of the infectious agent.

(7) Lives in the same household as a person who is diagnosed with a disease caused by *S. typhi*, *Shigella* spp., *E. coli* O157:H7 or hepatitis A virus.

(8) Lives in the same household as a person who attends or works in a setting where there is a confirmed disease outbreak caused by *S. typhi*, *Shigella* spp., *E. coli* O157:H7 or hepatitis A virus.

#### § 46.113. Duty to impose exclusions and restrictions.

(a) *General exclusions and restrictions.* A person in charge shall impose the following exclusions and restrictions:

(1) Exclude a food employee from a food facility if the food employee is diagnosed with an infectious agent specified in § 46.112(1) (relating to diseases or medical conditions that must be reported).

(2) Restrict a food employee from working with exposed food; clean equipment, utensils, linens and unwrapped single-service and single-use articles, in a food facility if the food employee is either of the following:

(i) Experiencing a symptom specified in § 46.112(3) and (4).

(ii) Not experiencing a symptom of acute gastroenteritis specified in § 46.112(3), but has a stool that yields a specimen culture that is positive for *Salmonella typhi*, *Shigella* spp. or *Escherichia coli* O157:H7.

(b) *Special exclusions with respect to a food employee who is jaundiced.* If a food employee is jaundiced, the person in charge shall exclude the food employee as a food handler until 7 days after the onset of jaundice. If a food employee is jaundiced more than 7 days after onset, the person in charge shall restrict the food employee from working with exposed food and clean equipment, utensils, linens and unwrapped single service and single use articles in a food facility.

(c) *Special exclusions with respect to a food facility serving a highly susceptible population.* If the population served by the food facility is a highly susceptible population, a person in charge shall impose any exclusions or restrictions required under subsection (a) and also exclude a food employee from the food facility if the food employee is any of the following:

(1) Experiencing a symptom of acute gastrointestinal illness specified in § 46.112(3) and meets any of the high-risk conditions specified in § 46.112(5), (6), (7) or (8).

(2) Is not experiencing a symptom of acute gastroenteritis specified in § 46.112(3), but has a stool that yields a specimen culture that is positive for *S. typhi*, *Shigella* spp. or *E. coli* O157:H7.

(3) Had a past illness from *S. typhi* within the last 3 months.

(4) Had a past illness from *Shigella* spp. or *E. coli* O157:H7 within the last month.

(5) Jaundiced, regardless of the time of onset.

#### § 46.114. Duty to comply with exclusions and restrictions.

A food employee or a person who applies for a job as a food employee shall comply with exclusions and restrictions that are imposed by the person in charge under authority of § 46.113 (relating to duty to impose exclusions and restrictions).

#### § 46.115. Removing exclusions and restrictions.

(a) *Disease or medical condition described in § 46.112(1).* A person in charge may remove an exclusion imposed as a result of a disease or medical condition described in § 46.112(1) (relating to diseases or medical conditions that must be reported) if the excluded person provides the person in charge written medical documentation specifying that the excluded person may work in an unrestricted capacity in a food facility, including a facility that serves a highly susceptible population, because the person is free of the infectious agent of concern. This documentation shall be from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician assistant.

(b) *Disease or medical condition with respect to which restrictions are imposed under § 46.113(a)(2)(i).* A person in charge may remove a restriction imposed under authority of § 46.113(a)(2)(i) (relating to duty to impose exclusions and restrictions) as a result of a disease or medical condition if any of the following are accurate:

(1) The person is free of the symptoms specified in § 46.112(3) and (4), and no foodborne illness occurs that may have been caused by the restricted person.

(2) The person is suspected of causing foodborne illness, but both of the following are true:

(i) The person is free of the symptoms specified in § 46.112(3) and (4).

(ii) The person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician assistant, stating that the restricted person is free of the infectious agent that is suspected of causing the person's symptoms or causing foodborne illness.

(3) The restricted person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician assistant stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome or ulcerative colitis.

(c) *Disease or medical condition with respect to which restrictions are imposed under authority of § 46.113(a)(2)(ii).* A person in charge may remove a restriction imposed as a result of a disease or medical condition imposed under authority of § 46.113(a)(2)(ii) if the restricted person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician assistant that indicates the restricted person's stools are free from *Salmonella typhi*, *Shigella* spp. or *Escherichia coli* O157:H7—whichever is the infectious agent of concern.

(d) *Disease or medical condition with respect to which exclusions or restrictions are imposed under authority of § 46.113(b).* A person in charge may remove an exclusion or restriction imposed as a result of a disease or medical condition described in § 46.113(b) if the excluded or restricted person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician's assistant that specifies that the person is free of hepatitis A virus.

(e) *Disease or medical condition with respect to which exclusions are imposed under authority of § 46.113(c).* A person in charge may remove an exclusion imposed with respect to a food facility serving a highly susceptible population as a result of a disease or medical condition described in § 46.113(c) if the restricted person provides written medical documentation from a physician licensed to practice medicine, a licensed nurse practitioner or a licensed physician's assistant that states, as applicable, that the person is:

- (1) Free of the infectious agent of concern.
- (2) Free of jaundice, if hepatitis A virus is the infectious agent of concern.
- (3) Experiencing symptoms resulting from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome or ulcerative colitis.

#### PERSONAL CLEANLINESS

##### § 46.131. Cleanliness of hands and exposed portions of arms.

(a) *Responsibility of food employees.* Food employees shall keep their hands and exposed portions of their arms clean.

(b) *Cleaning procedure.*

- (1) *General procedure.* Except as specified in paragraph (2), food employees shall clean their hands and exposed portions of their arms with a cleaning compound in a lavatory that is equipped as specified in § 46.822(b) relating to design, construction and installation of

plumbing systems) by vigorously rubbing together the surfaces of their lathered hands and arms for at least 20 seconds and thoroughly rinsing with clean water. Employees shall pay particular attention to the areas underneath the fingernails and between the fingers.

(2) *Alternative procedure.* An automatic handwashing facility may be used by food employees to clean their hands if the facility is approved and capable of removing the types of soils encountered in the food operations involved.

##### § 46.132. Duty of food employees to wash.

Food employees shall clean their hands and exposed portions of their arms as specified in § 46.131 (relating to cleanliness of hands and exposed portions of arms) as follows:

(1) Immediately before engaging in food preparation activities such as working with exposed food, working with clean equipment and utensils, and working with unwrapped single-service and single-use articles.

(2) After touching bare human body parts other than clean hands and clean, exposed portions of arms.

(3) After using the toilet room.

(4) After caring for or handling service animals or aquatic animals as specified in § 46.153(b) (relating to animals).

(5) Except as specified in § 46.151(a)(2) (relating to food contamination prevention), after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking.

(6) After handling soiled equipment or utensils.

(7) During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks.

(8) When switching between working with raw food and working with ready-to-eat food.

(9) After engaging in other activities that contaminate the hands.

##### § 46.133. Required washing locations.

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

##### § 46.134. Hand sanitizers.

(a) *Requirements.* A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall:

(1) Comply with one or more of the following:

(i) Be an approved drug that is listed in the most current FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* as an approved drug based on safety and effectiveness.

(ii) Have active antimicrobial ingredients that are listed in one or more of the following:

(A) The most current FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash.

(B) The most current USDA *List of Proprietary Substances and Nonfood Compounds*, Miscellaneous Publication No. 1419 or its successor.

(2) Comply with one or more of the following:

(i) Have components that are exempted from the requirement of being listed in Federal food additive regulations as specified in 21 CFR 170.39 (relating to threshold of regulation for substances used in food-contact articles) or its successor.

(ii) Comply with, and be listed in, one or more of the following:

(A) 21 CFR 178 (relating to indirect food additives; adjuvants, production aids, and sanitizers) as regulated for use as a food additive with conditions of safe use).

(B) 21 CFR 182 (relating to substances generally recognized as safe), 21 CFR 184 (relating to direct food substances affirmed as generally recognized as safe) or 21 CFR 186 (relating to indirect food substances affirmed as generally recognized as safe for use in contact with food).

(iii) Be limited to situations when use is followed by a thorough hand rinsing in clean water before hand contact with food, or when hand contact with food is avoided by the use of gloves, or where there is no direct contact with food by bare hands.

(3) Be applied only to hands that are cleaned as specified in § 46.131(b) (relating to cleanliness of hands and exposed portions of arms).

(b) *Chemical hand sanitizing solution.* A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to at least 100 mg/L (ppm) chlorine.

#### § 46.135. Cleanliness of fingernails.

(a) *General.* Food employees shall keep their fingernails trimmed, filed and maintained so the edges and surfaces are cleanable and not rough.

(b) *Fingernail polish and artificial fingernails.* Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial fingernails when working with exposed food.

#### § 46.136. Jewelry.

Food employees may not wear jewelry on their arms and hands while preparing food. This prohibition does not apply to a plain ring such as a wedding band.

#### § 46.137. Cleanliness of outer clothing.

Food employees shall wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, single-service articles and single-use articles.

### HYGIENIC PRACTICES

#### § 46.151. Food contamination prevention.

(a) *Eating, drinking or using tobacco.*

(1) *General prohibition.* An employee may not eat, drink or use any form of tobacco unless the use occurs in designated areas where the contamination of exposed food; clean equipment, utensils and linens; unwrapped single-service and single-use articles; or other items needing protection can not result. The sole exception to this prohibition is in paragraph (2).

(2) *Exception for closed beverage containers.* A food employee may drink from a closed beverage container if the container is handled to prevent contamination of the following:

(i) The employee's hands.

(ii) The container.

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

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

#### § 46.152. Hair restraints.

(a) *General requirement.* Employees shall wear hair restraints such as hats, hair coverings or nets, beard restraints and clothing that covers body hair, that are effectively designed and worn to keep their hair from contacting exposed food; clean equipment, utensils and linens; and unwrapped single-service and single-use articles.

(b) *Exception.* This section does not apply to food employees who present a minimal risk of contaminating exposed food, clean equipment, utensils, linens and unwrapped single-service and single-use articles. These food employees may include employees such as counter staff who only serve beverages and wrapped or packaged foods, hostesses and wait staff.

#### § 46.153. Animals.

(a) *Circumstances under which handling of animals is prohibited.* Food employees may not care for or handle animals that may be present such as patrol dogs, service animals or pets that are allowed as specified in § 46.982 (relating to limitations on animals).

(b) *Circumstances under which handling of animals is permissible.* Employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified in §§ 46.131(b) and 46.132 (relating to cleanliness of hands and exposed portions of arms; and duty of food employees to wash).

### Subchapter C. FOOD

#### CHARACTERISTICS

Sec.

46.201. Food shall be safe, unadulterated and honestly presented.

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**PREVENTING CONTAMINATION BY EMPLOYEES**

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- 46.461. Additional safeguards for a food facility that serves a highly susceptible population.

**CHARACTERISTICS**

- 46.201. Food shall be safe, unadulterated and honestly presented.

Food shall be safe, unadulterated and—in accordance with § 46.421(b) (relating to accurate representation)—honestly presented.

**FOOD SOURCES**

**§ 46.211. Food sources.**

Food shall be obtained from sources that comply with the act, the Public Eating and Drinking Place Law and this chapter.

**§ 46.212. Food prepared in a private home.**

Food prepared in a private home, not approved by the Department, may not be used or offered for human consumption in a food facility.

**§ 46.213. Packaged food.**

Packaged food shall be labeled as specified in the Food Act, this chapter, 21 CFR 101 (relating to food labeling), 9 CFR 317 (relating to labeling, marking devices, and containers) and 9 CFR 381, Subpart N (relating to labeling and containers).

**§ 46.214. Whole-muscle, intact beef.**

Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in § 46.361(c) (relating to cooking raw animal foods) shall be one of the following:

(1) Obtained from a food establishment that packages the steaks and labels them to indicate that they meet the definition of whole-muscle, intact beef.

(2) Individually cut in a food facility, and all of the following:

(i) Cut from whole-muscle intact beef that is labeled by a food establishment to indicate that the beef meets the definition of "whole-muscle intact beef."

(ii) Prepared so they remain intact.

(iii) If packaged for undercooking in a food facility, labeled to indicate that they meet the definition of "whole-muscle, intact beef."

**§ 46.215. Packaged meat and poultry that is not a ready-to-eat food.**

Meat and poultry that is not a ready-to-eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in the act, including 9 CFR 317.2(i) (relating to labels: definitions; required features) and 9 CFR 381.125(b) (relating to special handling label requirements).

**§ 46.216. Food in a hermetically sealed container.**

Food in a hermetically sealed container shall be obtained from a food establishment that is regulated by the Department or other food regulatory agency that has jurisdiction over the plant.

**§ 46.217. Milk and milk products.**

Milk and milk products shall be obtained from sources that comply with the Milk Sanitation Law.

**§ 46.218. Fish.**

(a) *Sources.* Fish that are received for sale or service shall be one of the following:

(1) Commercially and legally caught or harvested.

(2) Approved for sale or service.

(b) *Nonmolluscan fish for raw consumption.* Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified in § 46.361(d)(1) (relating to cooking of raw animal foods) may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified in

§ 46.364(a) and (b) (relating to parasite destruction in fish other than molluscan shellfish by freezing); or frozen on the premises as specified in § 46.364(a) and (b) and records are retained as specified in § 46.364(c).

**§ 46.219. Molluscan shellfish.**

(a) *Sources.* Molluscan shellfish shall be obtained from sources according to the act and this chapter, and the requirements specified in the United States Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(b) *Molluscan shellfish received or intended for sale in interstate commerce.* Molluscan shellfish received or intended for sale in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

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

**§ 46.220. Wild mushrooms.**

(a) *General source requirement.* Mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert. The exceptions to this requirement are in subsection (b).

(b) *Exceptions.* Subsection (a) does not apply to the following:

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

(2) Wild mushroom species if they are in packaged form and are the product of a food establishment that is regulated by the Department or other food regulatory agency that has jurisdiction over the food establishment.

**§ 46.221. Game animals.**

(a) *Game animals commercially raised for food.* If game animals commercially raised for food are received for sale or service they shall be at least one of the following:

(1) Raised, slaughtered and processed under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo or bison) that are "inspected and approved" in accordance with the Voluntary Exotic Animal Program established in 9 CFR 352 (relating to exotic animals; voluntary inspection) or rabbits that are "inspected and certified" in accordance with the Rabbit Inspection Program established in 9 CFR 354 (relating to voluntary inspection of rabbits and edible products thereof).

(2) Under a routine inspection program conducted by the Department or other regulatory agency that has animal health jurisdiction, and raised, slaughtered and processed according to both of the following:

(i) Laws governing meat and poultry, as determined by the Department or other regulatory agency that has animal health jurisdiction.

(ii) Requirements which are developed by the Department or other regulatory agency that has animal health jurisdiction, with consideration of factors such as the need for antemortem and postmortem examination by a licensed veterinarian or veterinarian's designee.

(b) *Wild game animals that are live-caught.* Wild game animals that are live-caught may be received for sale or service if the following apply:

(1) The animal is under a routine inspection program conducted by the Department or other regulatory agency that has animal health jurisdiction.

(2) The animal is slaughtered and processed according to the following:

(i) Laws governing meat and poultry, as determined by the Department or other regulatory agency that has animal health jurisdiction.

(ii) Requirements which are developed by the Department or other regulatory agency that has animal health jurisdiction, with consideration of factors such as the need for antemortem and postmortem examination by a licensed veterinarian or veterinarian's designee.

(c) *Field-dressed wild game animals.* Field-dressed wild game animals may be received for sale or service under a routine inspection program that ensures that the following occur:

(1) The animals receive a postmortem examination by a licensed veterinarian or veterinarian's designee.

(2) The animals are field-dressed and transported according to requirements specified by the Department or other regulatory agency that has animal health jurisdiction.

(3) The animals are processed according to laws governing meat and poultry as determined by the Department or other regulatory agency that has animal health jurisdiction.

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

**§ 46.222. Ice.**

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

**SPECIFICATIONS FOR RECEIVING, ORIGINAL CONTAINERS AND RECORDS**

**§ 46.241. Receiving temperature of food.**

(a) *Refrigerated potentially hazardous food.* Except as specified in §§ 46.243(b) and 46.244(b) (relating to receiving shell eggs; and receiving eggs and milk products), refrigerated potentially hazardous food shall be at an internal temperature of 5°C (41°F) or below when received.

(b) *Cooked potentially hazardous food.* Potentially hazardous food that is cooked to a temperature and for a time specified in §§ 46.361—46.363 (relating to cooking raw animal foods; microwave cooking; and plant food cooking for hot holding) and received hot shall be at an internal temperature of 60°C (140°F) or above.

(c) *Frozen food.* A food that is labeled frozen and shipped frozen by a food establishment shall be received frozen.

(d) *Visible evidence of improper temperature.* Upon receipt, potentially hazardous food shall be free of evidence of previous temperature abuse.

**§ 46.242. Additives.**

Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170—180 (relating to food additives), generally recognized as



safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181—186 (relating to food substances generally recognized as safe), substances that exceed amounts specified in 9 CFR 318.7 (Reserved), or pesticide residues that exceed provisions specified in 40 CFR 185 (Reserved).

**§ 46.243. Receiving shell eggs.**

(a) *General.* Shell eggs shall be received clean and sound and may not exceed the restricted egg tolerances for PA Consumer Grade B as specified in Chapter 87 (relating to standards for grading and marketing eggs).

(b) *Temperature.* Shell eggs shall be received by a food facility in refrigerated equipment that maintains an ambient temperature of 7°C (45°F) or less, or as otherwise specified in the Egg Refrigeration Law (31 P.S. §§ 300.1—300.9).

(c) *Labeling.* Shell eggs received by a food facility shall be labeled as specified in Chapter 87 and include safe handling instructions as specified in 21 CFR 101.17(h) (relating to food labeling).

**§ 46.244. Receiving eggs and milk products.**

(a) *Liquid, frozen and dry eggs and egg products.* Liquid, frozen and dry eggs and egg products shall be obtained pasteurized.

(b) *Milk and milk products.* Milk and milk products shall be obtained pasteurized and received at a temperature of 7°C (45°F) or less, or as otherwise specified in the Milk Sanitation Law.

(c) *Frozen milk products.* Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in the Milk Sanitation Law.

(d) *Cheese.* Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are specified and published in the CFR. An example of acceptable alternative standards for curing certain cheese varieties is in 21 CFR 133 (relating to cheeses and related cheese products).

**§ 46.245. Package integrity of food upon receipt.**

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

**§ 46.246. Receiving shucked shellfish: packaging and identification.**

(a) *Label requirement.* Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the following:

(1) The name, address and certification number of the shucker-packer or repacker of the molluscan shellfish.

(2) For packages with a capacity of less than 1.87 L (1/2 gallon): the "sell by" date.

(3) For packages with a capacity of 1.87 L (1/2 gallon) or more: the date shucked.

(b) *No label or inadequate label.* A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified in subsection (a) shall be subject to a detention, in accordance with section 6 of the act (31 P.S. § 20.6).

**§ 46.247. Shellstock identification.**

(a) *Harvester's and dealer's source identification tags or labels.* Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed

by the harvester and each dealer that depurates, ships or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(1) *Contents of harvester's tag or label.* A harvester's tag or label shall list the following information, in the following order:

(i) The harvester's identification number as described in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that is assigned by the Department or other shellfish control authority having jurisdiction.

(ii) The date of harvesting.

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

(iv) The type and quantity of shellfish.

(v) The following statement in bold, capitalized type:

This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days.

(2) *Contents of dealer's tag or label.* A dealer's tag or label shall list the following information, in the following order:

(i) The dealer's name and address, and the certification number assigned by the Department or other shellfish control authority having jurisdiction.

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

(iii) The same information as specified for a harvester's tag under paragraph (1)(ii)—(iv).

(iv) The following statement in bold, capitalized type:

This tag is required to be attached until container is empty and thereafter kept on file for 90 days.

(b) *Missing or incomplete tag or label.* A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified in subsection (a) shall be subject to a detention, in accordance with section 6 of the act (31 P.S. § 20.6).

(c) *Harvester's tag or label may include dealer information.* If a place is provided on the harvester's tag or label for a dealer's name, address and certification number, the dealer's information shall be listed first, notwithstanding subsection (a)(1).

(d) *Exception to requirement of separate dealer's tag or label.* If the harvester's tag or label is designed to accommodate each dealer's identification as specified in subsection (a)(2)(i) and (ii), individual dealer tags or labels need not be provided.

**§ 46.248. Shellstock: condition upon receipt.**

Shellstock shall be reasonably free of mud, dead shellfish and shellfish with broken shells when received by a food facility. Dead shellfish or shellstock with badly broken shells shall be discarded.

**§ 46.249. Molluscan shellfish: original container.**

(a) *General requirement.* Molluscan shellfish may not be removed from the container in which they are received

other than immediately before sale or preparation for service. The two exceptions to this requirement are set forth in subsections (b) and (c).

(b) *Exception: shellstock.* Shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if both of the following occur:

(1) The source of the shellstock on display is identified as specified in § 46.247 (relating to shellstock identification) and recorded as specified in § 46.250 (relating to shellstock: maintaining identification)

(2) The shellstock are protected from contamination.

(c) *Exception: shucked shellfish.* Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if both of the following apply:

(1) The labeling information for the shellfish on display as specified in § 46.246 (relating to receiving shucked shellfish: packaging and identification) is retained and correlated to the date when, or dates during which, the shellfish are sold or served.

(2) The shellfish are protected from contamination.

#### § 46.250. Shellstock: maintaining identification.

(a) *General requirement.* Shellstock tags shall remain attached to the container in which the shellstock are received until the container is empty. The exception to this requirement is set forth in subsection (b)(2).

(b) *Records of identification.* The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90-calendar days from the date the container is emptied by the following methods:

(1) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the shellstock are sold or served.

(2) Where shellstock are removed from their tagged or labeled container, using either of the following methods:

(i) Using only one tagged or labeled container at a time.

(ii) Using more than one tagged or labeled container at a time and obtaining a variance from the Department as specified in § 46.1103(a) (relating to variances) based on a HACCP plan that:

(A) Is submitted by the permit holder and approved as specified in § 46.1103(b).

(B) Preserves source identification by using a recordkeeping system as specified in paragraph (1).

(C) Ensures that shellstock from one tagged or labeled container are not commingled with shellstock from another container before being ordered by the consumer.

#### PREVENTING CONTAMINATION BY EMPLOYEES

##### § 46.261. Preventing contamination from food employees' hands.

(a) *Hand washing required.* Food employees shall wash their hands as specified in § 46.131 (relating to cleanliness of hands and exposed portions of arms).

(b) *Hand contact with ready-to-eat food.* Except when washing fruits and vegetables as specified in § 46.285

(relating to washing raw fruits and vegetables) or when otherwise approved, food employees may not contact exposed, ready-to-eat food with their bare hands, unless hands have been washed as specified in § 46.131(b) and shall use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves or dispensing equipment whenever possible.

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

##### § 46.262. Preventing contamination when tasting.

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

#### PREVENTING FOOD AND INGREDIENT CONTAMINATION

##### § 46.281. Preventing contamination of packaged and unpackaged food: separation, packaging and segregation.

(a) *Required protective measures.* Food shall be protected from cross contamination by the following procedures, as applicable:

(1) Separating raw animal foods during storage, preparation, holding and display from:

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

(ii) Cooked ready-to-eat food.

(2) Separating types of raw animal foods (such as beef, fish, lamb, pork and poultry) from each other during storage, preparation, holding and display, except when these raw animal foods are combined as ingredients, by doing the following:

(i) Using separate equipment for each type or arranging each type of food in equipment so that cross contamination of one type with another is prevented.

(ii) Preparing each type of food at different times or in separate areas.

(3) Cleaning equipment and utensils as specified in § 46.712(a) (relating to frequency of cleaning equipment food-contact surfaces and utensils) and sanitizing as specified in § 46.731(c) (relating to sanitization: requirement, frequency and methods).

(4) Storing the food in packages, covered containers or wrappings. The exception to this requirement is in subsection (b).

(5) Cleaning hermetically sealed containers of food of visible soil before opening.

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

(7) Storing damaged, spoiled or recalled food being held in the food facility as specified in § 46.964 (relating to distressed merchandise: segregated).

(8) Separating fruits and vegetables from ready-to-eat food before the fruits and vegetables are washed as specified in § 46.285 (relating to washing raw fruits and vegetables).

(b) *Exception to the requirement of storing foods in packages, covered containers or wrappings.* Subsection (a)(4) does not apply to the following:



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

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

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

(4) Food being cooled as specified in § 46.384(d)(2) (relating to potentially hazardous food: cooling).

(5) Shellstock.

**§ 46.282. Identification of content on food storage containers.**

Working containers holding food or food ingredients (such as cooking oils, flour, herbs, potato flakes, salt, spices and sugar) that are removed from their original packages for use in the food facility shall be identified with the common name of the food they contain. However, containers holding food that can be readily and unmistakably recognized (such as dry pasta) need not be identified.

**§ 46.283. Substituting pasteurized eggs for raw shell eggs in certain recipes.**

Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods such as Caesar salad, hollandaise or béarnaise sauce, mayonnaise, eggnog, ice cream and egg-fortified beverages that are not either of the following:

(1) Cooked as specified in § 46.361(a)(1) or (2) (relating to cooking raw animal foods).

(2) Included in § 46.361(d).

**§ 46.284. Protection from unapproved additives.**

(a) *Unapproved additives or unsafe levels of approved additives.* Food or food ingredients shall be protected from contamination that may result from the addition of unsafe or unapproved food or color additives, and from unsafe or unapproved levels of approved food and color additives, as described in § 46.242 (relating to additives).

(b) *Sulfiting agents.* A food employee may not do the following:

(1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1, as that term is defined in 21 CFR 101.54(c) (relating to nutrient content claims for "good source," "high," "more," and "high potency").

(2) Serve or sell a food specified in paragraph (1), other than grapes, that is treated with sulfiting agents before receipt by the food facility.

**§ 46.285. Washing raw fruits and vegetables.**

(a) *General.* Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served or offered for human consumption in ready-to-eat form.

(b) *Exception.* Whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.

(c) *Chemical washing.* Fruits and vegetables may be washed by using chemicals as specified in § 46.1024(b) (relating to chemicals: use criteria).

**§ 46.286. Preventing contamination from ice used as a coolant.**

(a) *Ice used as exterior coolant is prohibited as ingredient.* Ice may not be used as food after it has been used as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment.

(b) *Storage or display of food in contact with water or ice.*

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

(2) *General prohibition.* Unpackaged foods other than those described in paragraphs (3) and (4) may not be stored in direct contact with undrained ice.

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

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

**PREVENTING CONTAMINATION FROM EQUIPMENT, UTENSILS AND LINENS**

**§ 46.301. Preventing contamination from food contact with equipment and utensils.**

Food shall only contact surfaces of equipment and utensils that are cleaned as specified in §§ 46.711—46.719 (relating to cleaning of equipment) and sanitized as specified in § 46.731 (relating to sanitization: requirement, frequency and methods).

**§ 46.302. In-use utensils and between-use storage.**

(a) *General.* During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored in the food with their handles above the top of the food and the container, unless the food is non-potentially hazardous and within containers or equipment that can be closed, such as bins of sugar, flour or cinnamon—in which case the food preparation and dispensing utensils shall be stored with their handles above the top of the food within the containers.

(b) *Storage on cleaned and sanitized tables or equipment.* During pauses in food preparation or dispensing, food preparation and dispensing utensils may be stored on a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the table or equipment are cleaned and sanitized at a frequency specified in §§ 46.712 and 46.731 (relating to frequency of cleaning equipment food-contact surfaces and utensils; and sanitization: requirement, frequency and methods).

(c) *Storage in running water.* During pauses in food preparation or dispensing, food preparation and dispensing utensils may be stored in running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes.

(d) *Storage in clean, protected locations.* During pauses in food preparation or dispensing, food preparation and dispensing utensils may be stored in a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not potentially hazardous.

(e) *Storage in a container of water.* During pauses in food preparation or dispensing, food preparation and dispensing utensils may be stored in a container of water if the water is maintained at a temperature of at least 60°C (140°F) and the container is cleaned at frequency specified in § 46.712(d)(7) (relating to frequency of cleaning equipment food-contact surfaces and utensils).

**§ 46.303. Linens and napkins: use limitations.**

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

**§ 46.304. Wiping cloths: use limitations.**

(a) *Cloths used for wiping food spills.* Cloths that are used for wiping food spills shall be used for no other purpose.

(b) *Wet and dry wiping cloths.* Cloths used for wiping food spills shall be one of the following.

(1) Dry and used for wiping food spills from tableware and carry-out containers.

(2) Wet and cleaned as specified in § 46.751(b)(4) (relating to requirement and frequency of laundering) stored in a chemical sanitizer at a concentration specified in § 46.674(a) (relating to warewashing equipment: mechanical or manual) and used for wiping spills from food-contact and nonfood-contact surfaces of equipment.

(c) *Wiping cloths used with raw animal foods.* Dry or wet cloths that are used with raw animal foods shall be kept separate from cloths used for other purposes, and wet cloths used with raw animal foods shall be kept in a separate sanitizing solution.

(d) *General cleanliness.* Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths shall be free of food debris and visible soil.

**§ 46.305. Gloves: use limitations.**

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

(b) *Slash-resistant gloves: general.* Except as specified in subsection (c), slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified in §§ 46.361–46.365 (relating to destruction of organisms of public health concern), such as frozen food or a primal cut of meat.

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

(d) *Cloth gloves.* Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required in §§ 46.361–46.365, such as frozen food or a primal cut of meat.

**§ 46.306. Using clean tableware for second portions and refills.**

(a) *General.* A food employee may not use tableware, including single-service articles, soiled by the consumer, to provide second portions or refills. However, a food employee may refill a consumer's drinking cup or con-

tainer without contact between the pouring utensil and the lip-contact area of the drinking cup or container.

(b) *Use of soiled tableware by self-service consumers to obtain food from display or serving equipment prohibited.* Self-service consumers may not be allowed to use soiled tableware (including single-service articles) to obtain additional food from the display and serving equipment. The sole exception to this prohibition is described in subsection (c).

(c) *Use of soiled drinking cups by self-service consumer to obtain drinks.* Drinking cups and containers may be reused by self-service consumers if refilling is a contamination-free process as specified in § 46.583(1), (2) and (4) (relating to dispensing equipment: protection of equipment and food).

**§ 46.307. Refilling returnables.**

(a) *Refilling with potentially hazardous food prohibited.* A take-home food container returned to a food facility may not be refilled at a food facility with a potentially hazardous food.

(b) *Refilling with a cleaned container.* Except as specified in subsection (c), a take-home food container refilled with food that is not potentially hazardous shall be cleaned as specified in § 46.719(b) (relating to washing returnable containers for refilling).

(c) *Refilling certain containers by a contamination-free process.* Personal take-out beverage containers, such as thermally insulated bottles, non-spill coffee cups and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified in § 46.583(1), (2) and (3) (relating to dispensing equipment: protection of equipment and food).

**PREVENTING CONTAMINATION FROM THE PREMISES**

**§ 46.321. Food storage.**

(a) *General storage requirements.* Except as specified in subsections (b) and (c), food shall be protected from contamination by storing as follows:

- (1) In a clean, dry location.
- (2) Where it is not exposed to splash, dust or other contamination.
- (3) At least 15 cm (6 inches) above the floor.

(b) *Exception for food stored on case lot handling equipment.* Food in packages and working containers may be stored less than 15 cm (6 inches) above the floor on case lot handling equipment as specified in § 46.595 (relating to case lot handling equipment: moveability).

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

(d) *Food storage: prohibited areas.* Food may not be stored in any of the following locations:

- (1) A locker room.
- (2) A toilet room.
- (3) A dressing room.
- (4) A garbage room.
- (5) A mechanical room.
- (6) Under a sewer line that is not shielded to intercept potential drips.

(7) Under a leaking water line (including a leaking automatic fire sprinkler head), or under a line on which water has condensed.

(8) Under an open stairwell.

(9) Under any source of contamination.

**§ 46.322. Vended potentially hazardous food: original container.**

Potentially hazardous food dispensed through a vending machine shall be in the package in which it was placed at the food facility at which it was prepared.

**§ 46.323. Food preparation.**

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

**PREVENTING CONTAMINATION BY CONSUMERS**

**§ 46.341. Food display.**

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line or salad bar food guards; display cases; or other effective means.

**§ 46.342. Protection of condiments.**

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

(b) *Condiments at a vending machine location.* Condiments at a vending machine location shall be in individual packages or provided in dispensers that are filled at an approved location, such as the food facility that provides food to the vending machine location, or a properly equipped food facility that is located on the site of the vending machine location.

**§ 46.343. Consumer self-service operations.**

(a) *Raw, unpackaged animal foods.* Raw, unpackaged animal food (such as beef, lamb, pork, poultry and fish) may not be offered for consumer self-service. This subsection does not apply to consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish; or ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue; or raw, frozen, shell-on shrimp or lobster.

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

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

**§ 46.344. Returned food and reservice of food.**

(a) *General prohibition of reuse of returned or unused food.* Except as specified in subsection (b), after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption.

(b) *Exception for certain foods and packages.* Except as specified in § 46.461(c) (relating to additional safeguards for a food facility that serves a highly susceptible popula-

tion), a container of food that is not potentially hazardous may be transferred from one consumer to another if either of the following occurs:

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

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

**§ 46.345. Miscellaneous sources of contamination.**

Food shall be protected from contamination that may result from a factor or source not specified in §§ 46.261, 46.262, 46.281—46.286, 46.301—46.307, 46.321—46.323 and 46.341—46.344.

**DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN**

**§ 46.361. Cooking raw animal foods.**

(a) *General cooking requirement.* Except as specified in subsections (b)—(d), raw animal foods (such as eggs, fish, meat, poultry and foods containing these raw animal foods) shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods, based on the food that is being cooked:

(1) 63°C (145°F) or above for 15 seconds for either of the following:

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

(ii) Except as specified in paragraphs (2) and (3), and subsection (b), fish, meat and pork, including game animals commercially raised for food as specified in § 46.221(a) (relating to game animals).

(2) 68°C (155°F) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified in § 46.221(a); and raw eggs that are not broken and prepared in response to a consumer's order and for immediate service:

Minimum Temperature	Minimum Time
63°C (145°F)	3 Minutes
66°C (150°F)	1 Minute
70°C (158°F)	Less than 1 second (instantaneous)

(3) 74°C (165°F) or above for 15 seconds for poultry, wild game animals as specified in § 46.221(b) and (c), stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites or stuffing containing fish, meat, poultry or ratites.

(b) *Certain roasts.* Whole beef roasts, corned beef roasts, pork roasts and cured pork roasts such as ham, shall be cooked as follows:

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

## PROPOSED RULEMAKING

Oven Type	Oven Temperature for Roast Weighing less than 4.5 kg (10 lbs.)	Oven Temperature for Roast Weighing 4.5 kg (10 lbs.) or more
Still Dry	177°C (350°F) or more	121°C (250°F) or more
Convection	163°C (325°F) or more	121°C (250°F) or more
High Humidity Cooking	121°C (350°F) or more	121°C (250°F) or more

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

Minimum Temperature	Minimum Time
54°C (130°F)	121 Minutes
56°C (132°F)	77 Minutes
57°C (134°F)	47 Minutes
58°C (136°F)	32 Minutes
59°C (138°F)	19 Minutes
60°C (140°F)	12 Minutes
61°C (142°F)	8 Minutes
62°C (144°F)	5 Minutes
63°C (145°F)	3 Minutes

(c) *Raw or undercooked whole-muscle, intact beef steak.* A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if the following apply:

(1) The food facility serves a population that is not a highly susceptible population.

(2) The steak is labeled to indicate that it meets the definition of "whole-muscle, intact beef" as specified in § 46.214 (relating to whole-muscle, intact beef).

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

(d) *Other raw animal foods.* A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or undercooked meat other than whole-muscle, intact beef steaks as specified in subsection (c), may be served or offered for sale in a ready-to-eat form if either of the following occurs:

(1) The food facility serves a population that is not a highly susceptible population, and the consumer is informed as specified in § 46.423 (relating to consumer advisory required with respect to animal foods that are raw, undercooked or not otherwise processed to eliminate pathogens) that to ensure its safety, the food should be cooked as specified in subsections (a) or (b).

(2) The Department grants a variance from subsection (a) or (b) as specified in § 46.1103(a) (relating to variances), based on a HACCP plan that is all of the following:

(i) Submitted by the license holder and approved as specified in § 46.1103(b) (relating to variances).

(ii) Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food.

(iii) Verifies that equipment and procedures for food preparation and training of food employees at the food facility meet the conditions of the variance.

#### § 46.362. Microwave cooking.

Raw animal foods cooked in a microwave oven meet all of the following conditions:

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

(2) Covered to retain surface moisture.

(3) Heated to a temperature of at least 74°C (165°F) in all parts of the food.

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

#### § 46.363. Plant food cooking for hot holding.

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of 60°C (140°F).

#### § 46.364. Parasite destruction in fish other than molluscan shellfish by freezing.

(a) *General temperature requirement.* Except as specified in subsection (b), before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked or marinated-partially cooked fish other than molluscan shellfish shall be frozen throughout to a temperature of one of the following:

(1) -20°C (-4°F) or below for 168 hours (7 days) in a freezer.

(2) -35°C (-31°F) or below for 15 hours in a blast freezer.

(b) *Exception for certain tuna species.* If the fish are tuna of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern), the fish may be served or sold in a raw, raw-marinated or partially cooked ready-to-eat form without freezing as specified in subsection (a).

#### (c) Records: creation and retention.

(1) Except as specified in subsection (b) and paragraph (2), if raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the food facility for 90-calendar days beyond the time of service or sale of the fish.

(2) If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified in subsection (a) may substitute for the records specified in paragraph (1).

#### § 46.365. Reheating food.

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

#### (b) Reheating for hot holding.

(1) Potentially hazardous food that is cooked, cooled and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least 74°C (165°F) for 15 seconds. Reheating for hot holding shall be done rapidly and the time the food is between the temperature specified in § 46.385(a)(2) or (3) (relating to

potentially hazardous food: hot and cold holding) and 74°C (165°F) may not exceed 2 hours. Exceptions to these requirements are specified in paragraphs (2), (3) and (4).

(2) Except as specified in paragraph (3), reheating of potentially hazardous food in a microwave oven for hot holding shall be performed in accordance with § 46.362 (relating to microwave cooking).

(3) Ready-to-eat food taken from a commercially processed, hermetically sealed container or from an intact package from a food establishment that is inspected by the Department or other food regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least 60°C (140°F) for hot holding.

(4) Remaining unsliced portions of roasts of beef that are cooked as specified in § 46.361(b) (relating to cooking raw animal foods) may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified in § 46.361(b).

#### TEMPERATURE AND TIME CONTROL FOR LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

##### § 46.381. Stored frozen food.

Stored frozen foods shall be maintained frozen.

##### § 46.382. Potentially hazardous food: slacking.

Frozen potentially hazardous food that is slacked to moderate the temperature shall be held at one of the following:

(1) Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding).

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

##### § 46.383. Potentially hazardous food: thawing.

Except as specified in paragraph (4), potentially hazardous food shall be thawed by one of the procedures that follow:

(1) Under refrigeration that maintains the food temperature at 5°C (41°F) or less, or at 7°C (45°F) or less as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding).

(2) Completely submerged under running water at a water temperature of 21°C (70°F) or below; with sufficient water velocity to agitate and float off loose particles in an overflow, for one of the following:

(i) A period of time that does not allow thawed portions of ready-to-eat food to rise above 5°C (41°F), or 7°C (45°F) as specified in § 46.385(a)(3).

(ii) A period of time that does not allow thawed portions of a raw animal food requiring cooking as specified in § 46.361(a) or (b) (relating to cooking raw animal foods) to be above 5°C (41°F), or 7°C (45°F) as specified in § 46.385(a)(3) for more than 4 hours including both of the following:

(A) The time the food is exposed to the running water and the time needed for preparation for cooking.

(B) The time it takes under refrigeration to lower the food temperature to 5°C (41°F), or 7°C (45°F) as specified in § 46.385(a)(3).

(3) As part of a cooking process if the food that is frozen is one of the following:

(i) Cooked as specified in § 46.361(a) or (b) or § 46.362 (relating to microwave cooking).

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

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

##### § 46.384. Potentially hazardous food: cooling.

(a) *Cooling cooked potentially hazardous food.* Cooked potentially hazardous food shall be cooled as follows:

(1) Within 2 hours, from 60°C (140°F) to 21°C (70°F).

(2) Within 4 hours, from 21°C (70°F) to 5°C (41°F) or less, or to 7°C (45°F) as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding).

(b) *Cooling potentially hazardous food prepared from ingredients at ambient temperature.* Potentially hazardous food shall be cooled within 4 hours to 5°C (41°F) or less, or to 7°C (45°F) as specified in § 46.385(a)(3) if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.

(c) *Cooling methods.* Cooling shall be accomplished in accordance with the time and temperature criteria specified in subsection (a) by using one or more of the following methods, based on the type of food being cooled:

(1) Placing the food in shallow pans.

(2) Separating the food into smaller or thinner portions.

(3) Using rapid cooling equipment.

(4) Stirring the food in a container placed in an ice water bath.

(5) Using containers that facilitate heat transfer.

(6) Adding ice as an ingredient.

(7) Other effective methods.

(d) *Food containers in which food is cooled.* When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be both of the following:

(1) Arranged in the equipment to provide maximum heat transfer through the container walls.

(2) Loosely covered, or uncovered if protected from overhead contamination as specified in § 46.321(a)(2) (relating to food storage), during the cooling period to facilitate heat transfer from the surface of the food.

##### § 46.385. Potentially hazardous food: hot and cold holding.

(a) Except during preparation, cooking, or cooling, or when time is used as the public health control as specified in subsection (b), potentially hazardous food shall be maintained at one of the following temperatures, as applicable:

(1) At 60°C (140°F) or above, except that roasts cooked to a temperature and for a time specified in § 46.361(b) (relating to cooking raw animal foods) or reheated as specified in § 46.365(b)(5) (relating to reheating food) may be held at a temperature of 54°C (130°F).

(2) At 5°C (41°F) or less, except as specified in paragraphs (3)—(5), or § 46.584(b) (relating to vending machines).

(3) At 7°C (45°F) or between 7°C (45°F) and 5°C (41°F) in existing refrigeration equipment that is not capable of maintaining the food at 5°C (41°F) or less if either of the following is accurate:

(i) The equipment is in place and in use in the food facility; and by \_\_\_\_\_ (Editor's Note: The blank refers to a date 5 years from the effective date of this proposal.), the equipment is upgraded or replaced so that it shall maintain food at a temperature of 5°C (41°F) or less.

(ii) A food facility operator can demonstrate to the Department that a hardship would result from meeting the requirements of this paragraph and a variance is applied for and granted by the Department. The variance will not relieve the applicant from meeting the food safety objectives of this chapter.

(4) At 7°C (45°F) or less for shell eggs, or as otherwise specified in the Egg Refrigeration Law (31 P. S. §§ 300.1—300.9).

(5) At 7°C (45°F) or less, or as otherwise specified in the Milk Sanitation Law.

(b) *Time as a public health control.*

(1) Except as specified in paragraph (2), if time—rather than temperature—is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption, all of the following shall be done:

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

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

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

(iv) Written procedures shall be maintained in the food facility and made available to the Department upon request, that ensure compliance with this subsection and § 46.384(a)—(b) (relating to potentially hazardous food: cooling) for food that is prepared, cooked and refrigerated before time is used as a public health control.

(2) In a food facility that serves a highly susceptible population, time only—rather than temperature—may not be used as the public health control for raw eggs.

#### SPECIALIZED PROCESSING METHODS

##### § 46.401. Variance requirement for specialized processing methods.

A food facility shall obtain a variance from the Department as specified in § 46.1103(a) and (b) (relating to variances) before using any specialized processing method not currently recognized by the Department as a safe method for processing food.

##### § 46.402. Reduced oxygen packaging.

(a) *General requirement.* A food facility that packages food using a reduced oxygen packaging method—where *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form of the food—shall

ensure that there are at least two barriers in place to control the growth and toxin formation of *Clostridium botulinum*. This requirement does not apply to a food facility that has obtained a variance under § 46.401 (relating to variance requirement for specialized processing methods).

(b) *HACCP plan requirement.* A food facility that packages food using a reduced oxygen packaging method—where *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form of the food—shall have a HACCP plan that contains the information specified in § 46.1122(b)(4) (relating to HACCP plans) and that does all of the following:

(1) Identifies the food to be packaged.

(2) Limits the food packaged to a food that does not support the growth of *Clostridium botulinum* because it complies with one of the following:

(i) Has an  $a_w$  of 0.91 or less.

(ii) Has a pH of 4.6 or less.

(iii) Is a meat or poultry product cured at a food establishment regulated by USDA using substances specified in 9 CFR 318.7 (relating to approval of substances for use in the preparation of products) and 9 CFR 381.147 (relating to restrictions on the use of substances in poultry products), and is received in an intact package.

(iv) Is a food with a high level of competing organisms such as raw meat or raw poultry.

(3) Specifies methods for maintaining food at 5°C (41°F) or below.

(4) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to do the following:

(i) Maintain the food at 5°C (41°F) or below.

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

(5) Limits the shelf life to no more than 14-calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first.

(6) Includes operational procedures that do all of the following:

(i) Prohibit contacting food with bare hands.

(ii) Identify a designated area and the method by which the following occur:

(A) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination.

(B) Access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation.

(iii) Cleaning and sanitization procedures for food contact surfaces are delineated.

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

(i) Concepts required for a safe operation.



(ii) Equipment and facilities.

(iii) Procedures specified in paragraph (6) and § 46.1122(b)(4).

(c) *Special restriction with respect to certain fish.* Except for fish that is frozen before, during, and after packaging, a food facility may not package fish using a reduced oxygen packaging method.

#### FOOD IDENTITY, PRESENTATION AND ON-PREMISES LABELING

##### § 46.421. Accurate representation.

(a) *Standards of identity.* Packaged food shall comply with standard of identity requirements in the following:

(1) The act.

(2) Definitions in 21 CFR 131—169 (relating to Food and Drug Administration, Department of Health and Human Services) and 9 CFR 319 (relating to definitions and standards of identity or composition).

(3) 21 CFR 130 (relating to food standards: general).

(4) 9 CFR 319 Subpart A (relating to definitions and standards of identity or composition).

(b) *Food shall be honestly presented.*

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

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

##### § 46.422. Labeling.

(a) *Labels required on packaged foods.* Food packaged in a food facility shall be labeled as specified in the act, 21 CFR 101 (relating to food labeling), 9 CFR 317 (relating to labeling, marking devices, and containers) and 9 CFR 381 Subpart N (relating to poultry products inspection regulations: labeling and containers).

(b) *Label information on packaged foods.* Label information on packaged foods shall include the following:

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

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

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

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

(5) Except as exempted in section 403(q)(3)—(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 343(q)(3)—(5)), nutritional labeling as specified in 21 CFR 101 (relating to food labeling) and 9 CFR 317 Subpart B (relating to nutrition labeling).

(c) *Labeling information on bulk foods available for consumer self-dispensing or on unpackaged foods portioned to consumer specifications.* Bulk food that is available for consumer self-dispensing or unpackaged foods portioned to consumer specifications shall be prominently labeled with one of the following in plain view of the consumer:

(1) The manufacturer's or processor's label that was provided with the food.

(2) A card, sign or other method of notification that includes the information specified in subsection (b)(1), (2) and (5).

(d) *Labeling information on certain bakery products.* Bakery products need not be labeled if they are sold directly to the consumer and the following are accurate:

(1) The food is either manufactured or prepared on the premises of the food facility or at another food facility that is owned by the same person and is regulated by the Department or other food regulatory agency that has jurisdiction.

(2) The information specified in subsection (b)(1), (2) and (5) is available at the place of sale.

(3) A health, nutrient content or other claim is not made.

(e) *Other forms of information.*

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

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

##### § 46.423. Consumer advisory required with respect to animal foods that are raw, undercooked or not otherwise processed to eliminate pathogens.

Except as specified in §§ 46.361(c) and (d)(3) and 46.461 (relating to cooking raw animal foods; and additional safeguards for a food facility that serves a highly susceptible population), if an animal food such as beef, eggs, fish, lamb, milk, ~~pork~~ poultry or shellfish that is raw, undercooked or not otherwise processed to eliminate pathogens is offered in a ready-to-eat form as a deli, menu, vended or other item; or as a raw ingredient in another ready-to-eat food, the food facility shall inform consumers by brochures, deli case or menu advisories, label statements, table tents, placards or other effective written means of the significantly increased risk associated with certain highly susceptible populations eating these foods in raw or undercooked form.

#### CONTAMINATED FOOD

##### § 46.441. Discarding, or reconditioning unsafe, adulterated or contaminated food.

The following foods shall be discarded:

(1) A food that is unsafe, adulterated or not honestly presented as specified in § 46.201 (relating to food shall be safe, unadulterated and honestly presented), unless the food is reconditioned according to a procedure approved by the Department.

(2) Food that is not from an approved source as specified in §§ 46.211—46.221.

(3) Ready-to-eat food that may have been contaminated by an employee that has been restricted or excluded as specified in § 46.113 (relating to duty to impose exclusions and restrictions).

(4) Food that is contaminated by food employees, consumers or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means.

#### SPECIAL REQUIREMENTS FOR HIGHLY SUSCEPTIBLE POPULATIONS

##### § 46.461. Additional safeguards for a food facility that serves a highly susceptible population.

(a) *Prepackaged juice bearing a warning label prohibited.* In a food facility that serves a highly susceptible population, prepackaged juice or a prepackaged beverage containing juice, that bears a warning label as specified

in 21 CFR 101.17(g) (relating to labeling warning and notice statements), may not be served or offered for sale.

(b) *Pasteurized eggs required in certain foods.* In a food facility that serves a highly susceptible population, pasteurized shell eggs or pasteurized liquid, frozen, or dry eggs or egg products shall be substituted for raw shell eggs in the preparation of the following:

(1) Foods such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, egg nog, ice cream and egg-fortified beverages.

(2) Except as specified in subsection (e), recipes in which more than one egg is broken and the eggs are combined.

(c) *Food in unopened original packages.* In a food facility that serves a highly susceptible population, food in an unopened original package may not be re-served.

(d) *Prohibited ready-to-eat foods.* In a food facility that serves a highly susceptible population, the following foods may not be served or offered for sale in a ready-to-eat form:

(1) Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish and steak tartare.

(2) A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw shell eggs, and meringue.

(3) Raw seed sprouts.

(e) *Limited exception allowing use of raw eggs.* In a food facility that serves a highly susceptible population, subsection (b)(2) does not apply in any of the following circumstances:

(1) The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified in § 46.361(a)(1) (relating to cooking raw animal foods), and served immediately, such as an omelet, soufflé or scrambled eggs.

(2) The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin or bread.

(3) The preparation of the food is conducted under a HACCP plan that accomplishes the following:

(i) Identifies the food to be prepared.

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

(iii) Includes specifications and practices that ensure the following:

(A) *Salmonella Enteritidis* growth is controlled before and after cooking.

(B) *Salmonella Enteritidis* is destroyed by cooking the eggs according to the temperature and time specified in § 46.361(a)(2).

(iv) Contains the information specified in § 46.1122(b)(4) (relating to HACCP plans) including procedures that accomplish the following:

(A) Control cross contamination of ready-to-eat food with raw eggs.

(B) Delineate cleaning and sanitization procedures for food-contact surfaces.

(v) Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

## Subchapter D. EQUIPMENT, UTENSILS AND LINENS

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**GENERAL STANDARD**

**§ 46.501. Acceptability of food equipment certified or classified for sanitation by an ANSI-accredited certification program.**

Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program shall be deemed to comply with the applicable provisions of §§ 46.521—46.523, 46.541—46.544, 46.561—46.563 and 46.581—46.595.

**MATERIALS FOR USE IN CONSTRUCTION AND REPAIR**

**§ 46.521. Materials in multiuse utensils and food contact surfaces.**

(a) *Required characteristics.* Materials that are used in the construction of utensils and food-contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors or tastes to food. Under normal use conditions these materials shall be all of the following:

- (1) Safe.
- (2) Durable, corrosion-resistant and nonabsorbent.
- (3) Sufficient in weight and thickness to withstand repeated warewashing.
- (4) Finished to have a smooth, easily cleanable surface.
- (5) Resistant to pitting, chipping, crazing, scratching, scoring, distortion and decomposition.

(b) *Cast iron: use limitation.* Except as specified in paragraphs (1) and (2), cast iron may not be used for utensils or food-contact surfaces of equipment.

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

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

Utensil Category	Description	Maximum Lead in Mg/L (ppm)
Hot Beverage Mugs	Coffee Mugs	0.5
Large Hollowware	Bowls $\geq$ 1.1 L (1.16 Qt.)	1.0

Utensil Category	Description	Maximum Lead in Mg/L (ppm)
Small Hollowware	Bowls < 1.1 L (1.16 Qt.)	2.0
Flat Utensils	Plates, Saucers	3.0

(d) *Copper: use limitation.*

(1) Except as specified in paragraph (2), copper and copper alloys (such as brass) may not be used in contact with a food that has a pH below 6 (such as vinegar, fruit juice or wine) or for a fitting or tubing installed between a backflow prevention device and a carbonator.

(2) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

(e) *Galvanized metal: use limitation.* Galvanized metal may not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.

(f) *Sponges: use limitation.* Sponges may not be used in contact with cleaned and sanitized or in-use food-contact surfaces.

(g) *Lead in pewter alloys: use limitation.* Pewter alloys containing lead in excess of 0.05% may not be used as a food-contact surface.

(h) *Lead in solder and flux; use limitation.* Solder and flux containing lead in excess of 0.2% may not be used as a food-contact surface.

(i) *Wood: use limitation.* Except as specified in paragraphs (1)—(3), wood and wood wicker may not be used as a food-contact surface.

(1) Hard maple or an equivalently hard, close-grained wood may be used for the following:

(i) Cutting boards; cutting blocks; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls and chopsticks.

(ii) Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 110°C (230°F) or above.

(2) Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables or nuts are used.

(3) If the nature of the food requires removal of rinds, peels, husks or shells before consumption, the whole, uncut, raw food may be kept in the following:

(i) Untreated wood containers.

(ii) Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 (relating to preservatives for wood).

(j) *Nonstick coatings, use limitation.* Multiuse kitchenware (such as frying pans, griddles, sauce pans, cookie sheets and waffle bakers) that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching utensils and cleaning aids.

**§ 46.522. Materials for surfaces that are nonfood-contact surfaces.**

Surfaces of equipment that are nonfood-contact surfaces, but are exposed to splash, spillage or other food

soiling or that require frequent cleaning shall be constructed of a corrosion-resistant, nonabsorbent and smooth material.

**§ 46.523. Single-service and single-use articles: required characteristics.**

Materials that are used to make single-service and single-use articles shall be safe and clean, and may not allow the migration of deleterious substances, or impart colors, odors or tastes to food.

**DESIGN AND CONSTRUCTION**

**§ 46.541. Durability and strength.**

(a) *Equipment and utensils.* Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

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

**§ 46.542. Cleanability of multiuse food-contact surfaces and CIP equipment.**

(a) *Multiuse food-contact surfaces.* Multiuse food-contact surfaces shall be all of the following:

- (1) Smooth.
- (2) Free of breaks, open seams, cracks, chips, inclusions, pits and similar imperfections.
- (3) Free of sharp internal angles, corners and crevices.
- (4) Finished to have smooth welds and joints.
- (5) Except as specified in subsection (b), accessible for cleaning and inspection by one of the following methods:
  - (i) Without being disassembled.
  - (ii) By disassembling without the use of tools.
  - (iii) By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel (such as screwdrivers, pliers, open-end wrenches and Allen wrenches).

(b) *Exception.* Subsection (a)(5) does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes.

(c) *CIP equipment.* CIP equipment shall meet the characteristics specified in subsection (a) and shall be designed and constructed so that the following are accurate:

- (1) Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces.
- (2) The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions.
- (3) If the CIP equipment is not designed for disassembly during cleaning, it is designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

**§ 46.543. "V" threads: use limitation.**

Except for hot oil cooking or filtering equipment, "V" type threads may not be used on food-contact surfaces.

**§ 46.544. Cleanability of hot oil filtering equipment, can openers, nonfood-contact surfaces, kick plates and ventilation hood systems.**

(a) *Hot oil filtering equipment.* Hot oil filtering equipment shall meet the characteristics specified in § 46.542

(relating to cleanability of multiuse food-contact surfaces and CIP equipment), as applicable, and shall be readily accessible for filter replacement and cleaning of the filter.

(b) *Can openers.* Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

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

(d) *Kick plates, removable.* Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being both of the following:

- (1) Removable by one of the methods specified in § 46.542(a)(5) or capable of being rotated open.
- (2) Removable or capable of being rotated open without unlocking equipment doors.

(e) *Ventilation hood systems, filters.* Filters or other grease extracting equipment, if not designed to be cleaned in place, shall be designed to be readily removable for cleaning and replacement.

**ACCURACY**

**§ 46.561. Accuracy of temperature measuring devices for food.**

(a) *Accuracy range for Celsius-scaled or Celsius/Fahrenheit-scaled devices.* Food temperature measuring devices that are scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to  $\pm 1^{\circ}\text{C}$  in the intended range of use.

(b) *Accuracy for Fahrenheit-scaled devices.* Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to  $\pm 2^{\circ}\text{F}$  in the intended range of use.

**§ 46.562. Accuracy of temperature measuring devices for ambient air and water.**

(a) *Accuracy range for Celsius-scaled or Celsius/Fahrenheit-scaled devices.* Ambient air and water temperature measuring devices that are scaled in Celsius or dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to  $\pm 1.5^{\circ}\text{C}$  in the intended range of use.

(b) *Accuracy for Fahrenheit-scaled devices.* Ambient air and water temperature measuring devices that are scaled only in Fahrenheit shall be accurate to  $\pm 3^{\circ}\text{F}$  in the intended range of use.

**§ 46.563. Accuracy of pressure measuring devices on mechanical warewashing equipment.**

Pressure measuring devices that display the pressure in the water supply line for the fresh hot water sanitizing rinse on mechanical warewashing equipment shall have increments of 7 kilopascals (1 pounds per square inch) or smaller, and shall be accurate to  $\pm 14$  kilopascals ( $\pm 2$  pounds per square inch) in the 100–170 kilopascals (15–25 pounds per square inch) range.

**FUNCTIONALITY**

**§ 46.581. Ventilation hood systems, drip prevention**

Exhaust ventilation hood systems in food preparation and warewashing areas (including components such as hoods, fans, guards and ducting) shall be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.

**§ 46.582. Equipment openings, closures and deflectors.**

(a) *Overlap and slope of covers.* A cover or lid for equipment shall overlap the opening and be sloped to drain.

(b) *Flange requirement.* An opening located within the top of a unit of equipment that is designed for use with a cover or lid shall be flanged upward at least 5 millimeters (2/10 of an inch).

(c) *Watertight joint.* Except as specified in subsection (d), fixed piping, temperature measuring devices, rotary shafts and other parts extending into equipment shall be provided with a watertight joint at the point where the item enters the equipment.

(d) *Alternative to watertight joint.* If a watertight joint is not provided, the piping, temperature measuring devices, rotary shafts and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips and dust from openings into the food. The openings shall be flanged as specified in subsection (b).

**§ 46.583. Dispensing equipment: protection of equipment and food.**

In equipment that dispenses or vends liquid food or ice in unpackaged form, the following shall occur:

(1) The delivery tube, chute orifice and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food.

(2) The delivery tube, chute and orifice shall be protected from manual contact such as by being recessed.

(3) The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents and other contamination by a self-closing door if the equipment is either of the following:

(i) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents and other contaminants that are present in the environment.

(ii) Available for self-service during hours when it is not under the full-time supervision of a food employee.

(4) The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

**§ 46.584. Vending machines.**

(a) *Vending stage closure.* The dispensing compartment of a vending machine—including a machine that is designed to vend prepackaged snack food that is not potentially hazardous (such as chips, party mixes and pretzels)—shall be equipped with a self-closing door or cover if the machine is either of the following:

(1) Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents and other contaminants that are present in the environment.

(2) Available for self-service during hours when it is not under the full supervision of a food employee.

(b) *Automatic shutoff.*

(1) A machine vending potentially hazardous food shall have an automatic control that prevents the machine from vending food under either of the following circumstances:

(i) If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that can not maintain food temperatures as specified in Subchapter C (relating to food).

(ii) If a condition specified in subparagraph (i) occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified in Subchapter C.

(2) When the automatic shutoff within a refrigerated vending machine vending potentially hazardous food is activated, the ambient temperature may not exceed 5°C (41°F) or 7°C (45°F) as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding) for more than 30 minutes immediately after the machine is filled, serviced or restocked.

(3) When the automatic shutoff within a hot holding vending machine vending potentially hazardous food is activated, the ambient temperature may not be less than 60°C (140°F) for more than 120 minutes immediately after the machine is filled, serviced or restocked.

(c) *Can openers.* Cutting or piercing parts of can openers on vending machines shall be protected from manual contact, dust, insects, rodents and other contamination.

(d) *Vending machines that dispense liquids in paper containers.* Vending machines designed to store beverages that are packaged in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(e) *Vending machines that dispense liquid food in bulk.* Vending machines that dispense liquid food in bulk shall be both of the following:

(1) Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow or other internal wastes.

(2) Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(f) *Requirements for a liquid shutoff device.* Shutoff devices described in subsection (e)(2) shall prevent water or liquid food from continuously running if there is a failure of a flow control device in the water or liquid food system or waste accumulation that could lead to overflow of the waste receptacle.

(g) *Doors and openings.*

(1) Vending machine doors and access opening covers to food and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than 1.5 millimeters or 1/16 inch by one or more of the following:

(i) Being covered with louvers, screens or materials that provide an equivalent opening of not greater than 1.5 millimeters or 1/16 inch. Screening of 12 or more

mesh to 2.5 centimeters (12 mesh to 1 inch) meets this requirement.

(ii) Being effectively gasketed.

(iii) Having interface surfaces that are at least 13 millimeters or 1/2 inch wide.

(iv) Jambes or surfaces used to form an L-shaped entry path to the interface.

(2) Vending machine service connection openings through an exterior wall of the machine, shall be closed by sealants, clamps, or grommets so that the openings are no larger than 1.5 millimeters or 1/16 inch.

**§ 46.585. Bearings and gear boxes: leakproof.**

Equipment containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant can not leak, drip or be forced into food or onto food-contact surfaces.

**§ 46.586. Beverage tubing: separation.**

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

**§ 46.587. Ice units: separation of drains.**

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

**§ 46.588. Condenser unit: separation.**

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

**§ 46.589. Molluscan shellfish tanks.**

(a) *General.* Except as specified in subsection (b), molluscan shellfish life support system display tanks may not be used to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only.

(b) *Exception.* Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with the following:

(1) A variance granted by the Department in accordance with the procedure described in § 46.1103(a) (relating to variances).

(2) A HACCP plan that is submitted by the food facility operator and approved as specified in § 46.1103(b), ensuring the following:

(i) Water used with fish other than molluscan shellfish does not flow into the molluscan tank.

(ii) The safety and quality of the shellfish as they were received are not compromised by the use of the tank.

(iii) The identity of the source of the shellstock is retained as specified in § 46.250 (relating to shellstock: maintaining identification).

**§ 46.590. Temperature measuring devices.**

(a) *Location of device in storage unit.* In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature in the warmest part of a

mechanically refrigerated unit and in the coolest part of a hot food storage unit.

(b) *General device requirement.* Except as specified in subsection (c), cold or hot holding equipment used for potentially hazardous food shall be designed to include—and shall be equipped with—at least one integral or permanently affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.

(c) *Exception to device requirement.* Subsection (b) does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers and salad bars.

(d) *Easily readable.* Temperature measuring devices shall be designed to be easily readable.

(e) *Devices on warewashing machines.* Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record or digital readout in increments no greater than 1°C or 2°F in the intended range of use.

**§ 46.591. Warewashing machines.**

(a) *Data plate summarizing operating specifications.* A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operating specifications, including the following:

(1) Temperatures required for washing, rinsing and sanitizing.

(2) Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse.

(3) Conveyor speed for conveyor machines or cycle time for stationary rack machines.

(b) *Internal baffles.* Warewashing machine wash and rinse tanks shall be equipped with baffles, curtains or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.

(c) *Temperature measuring devices.* A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature in the following locations or instances:

(1) In each wash and rinse tank.

(2) As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.

(d) *Sanitizer level indicator.* A warewashing machine that uses a chemical for sanitization and that is installed after the \_\_\_\_\_ (Editor's Note: The blank refers to the effective date of adoption of the proposal.) effective date of this chapter, shall be equipped with a device that indicates audibly or visually when more chemical sanitizer needs to be added.

(e) *Flow pressure device.* Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine. If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse

control valve, the device shall be mounted in a 6.4 millimeter or 1/4 inch Iron Pipe Size (IPS) valve. This subsection does not apply to a machine that uses only a pumped or recirculated sanitizing rinse.

**§ 46.592. Manual warewashing machines.**

If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall comply with the following:

(1) Be designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F).

(2) Be provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

**§ 46.593. Warewashing sinks and drainboards: self-draining.**

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

**§ 46.594. Equipment compartments: drainage.**

Equipment compartments that are subject to accumulation of moisture due to conditions such as condensation, food or beverage drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

**§ 46.595. Case lot handling equipment: moveability.**

Equipment, such as dollies, pallets, racks and skids used to store and transport large quantities of packaged foods received from a supplier in a cased or over-wrapped lot, shall be designed to be moved by hand or by conveniently available equipment such as hand trucks and forklifts.

**NUMBERS AND CAPACITIES OF EQUIPMENT**

**§ 46.611. Cooling, heating and holding capacities.**

Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity to provide food temperatures as specified in Subchapter C (relating to food).

**§ 46.612. Manual warewashing: sink compartment requirements.**

(a) *General: three compartments required.* Except as specified in subsection (c), a sink with at least three compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.

(b) *Large equipment and utensils.* Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in subsection (c) shall be used.

(c) *Exception for approved alternative equipment.* Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved by the Department. Alternative manual warewashing equipment may include any of the following:

- (1) High-pressure detergent sprayers.
- (2) Low- or line-pressure spray detergent foamers.
- (3) Other task-specific cleaning equipment.
- (4) Brushes or other implements.
- (5) Two-compartment sinks as specified in subsection (d).

(6) Receptacles that substitute for the compartments of a multicompartment sink.

(d) *Use of two compartment sink.* A two-compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process. A two-compartment sink may be used when all of the following are accurate:

(1) The food facility operator has obtained approval from the Department to use the two-compartment sink.

(2) The nature of warewashing is limited to batch operations for cleaning kitchenware (such as between cutting one type of raw meat and another or cleanup at the end of a shift) and the following are accurate:

(i) The number of items to be cleaned is limited.

(ii) The cleaning and sanitizing solutions are made up immediately before use and drained immediately after use.

(iii) Either a detergent-sanitizer is used to sanitize and is applied as specified in § 46.676(e) (relating to manual warewashing equipment), or a hot water sanitization immersion step is used as specified in § 46.718(3) (relating to rinsing procedures).

**§ 46.613. Drainboards.**

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.

**§ 46.614. Ventilation hood systems: adequacy.**

Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

**§ 46.615. Clothes washers and dryers.**

A mechanical clothes washer and dryer shall be provided and used at a food facility if work clothes or linens are laundered on the premises. This section does not apply if on-premises laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified in § 46.772 (relating to wiping cloths: air-drying locations).

**NUMBERS AND CAPACITIES OF UTENSILS, TEMPERATURE MEASURING DEVICES AND TESTING DEVICES**

**§ 46.631. Consumer self-service utensils.**

A food-dispensing utensil shall be available for each container displayed at a consumer self-service unit (such as a buffet or salad bar).

**§ 46.632. Food temperature measuring devices.**

Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified in Subchapter C (relating to food).

**§ 46.633. Temperature measuring devices for manual warewashing.**

In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

**§ 46.634. Sanitizing solution testing devices.**

A test kit or other device that accurately measures the concentration in mg/L or ppm, of sanitizing solutions shall be provided.

**LOCATION AND INSTALLATION OF EQUIPMENT****§ 46.651. Location of equipment, clothes washers and dryers and storage cabinets to prevent contamination.**

(a) *Prohibited locations.* Except as specified in subsection (b), equipment, a cabinet used for the storage of food, or a cabinet that is used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be located in the following:

- (1) Locker rooms.
- (2) Toilet rooms.
- (3) Garbage rooms.
- (4) Mechanical rooms.
- (5) Under sewer lines that are not shielded to intercept potential drips.
- (6) Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed.
- (7) Under open stairwells.
- (8) Under other sources of contamination.

(b) *Exception.* A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.

(c) *Mechanical clothes washer or dryer.* If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no exposed food; clean equipment, utensils and linens; and unwrapped single-service and single-use articles.

**§ 46.652. Installation of fixed equipment, fixed table-mounted equipment and fixed floor-mounted equipment.**

(a) *Fixed equipment: spacing or sealing.* Equipment that is fixed because it is not easily movable shall be installed so that it is both of the following:

- (1) Spaced to allow access for cleaning along the sides, behind and above the equipment.
- (2) Spaced from adjoining equipment, walls and ceilings a distance of not more than 1 millimeter or 1/32 inch or—if the equipment is exposed to spillage or seepage—sealed to adjoining equipment or walls.

(b) *Fixed table-mounted equipment.* Table-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being one of the following:

- (1) Sealed to the table.
- (2) Elevated on legs that provide at least one of the following:
  - (i) 10 centimeters (4 inches) clearance between the table and the equipment.
  - (ii) 7.5 centimeters (3 inches) clearance between the table and the equipment if the horizontal distance of the table top under the equipment is no more than 50 centimeters (20 inches) from the point of access for cleaning.

(iii) 5 centimeters (2 inches) clearance between the table and the equipment if the horizontal distance of the table top under the equipment is no more than 7.5 centimeters (3 inches) from the point of access for cleaning.

**(c) Fixed floor-mounted equipment.**

(1) Except as specified in paragraph (2) or (3), floor-mounted equipment that is not easily movable shall be sealed to the floor or elevated on legs that provide at least a 15 centimeters (6 inches) clearance between the floor and the equipment.

(2) If no part of the floor under the floor-mounted equipment is more than 15 centimeters (6 inches) from the point of cleaning access, the clearance space may be only 10 centimeters (4 inches).

(3) This section does not apply to display shelving units, display refrigeration units and display freezer units located in the consumer shopping areas of a retail food store, if the floor under the units is maintained clean.

**MAINTENANCE AND OPERATION OF EQUIPMENT****§ 46.671. Equipment: good repair and proper adjustment.**

(a) *General.* Equipment shall be maintained in a state of repair and condition that meets the requirements specified in §§ 46.501, 46.521–46.523, 46.541–46.544, 46.561–46.563 and 46.581–46.595.

(b) *Equipment components.* Equipment components such as doors, seals, hinges, fasteners and kick plates shall be kept intact, tight and adjusted in accordance with manufacturer's specifications.

(c) *Cutting or piercing parts of can openers.* Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

**§ 46.672. Cutting surfaces.**

Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded if they are not capable of being resurfaced.

**§ 46.673. Microwave ovens.**

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 (relating to microwave ovens).

**§ 46.674. Warewashing equipment: mechanical or manual.**

(a) *Cleaning frequency.* A warewashing machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, or raw foods, or laundering wiping cloths; and drainboards or other equipment used to substitute for drainboards as specified in § 46.613 (relating to drainboards) shall be cleaned as follows:

- (1) Before use.
- (2) Throughout the day at a frequency necessary to prevent recontamination of equipment and utensils and to ensure that the equipment performs its intended function.



(3) If used, at least every 24 hours.

(b) *Cleaning agents.* When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in § 46.612(c) (relating to manual warewashing: sink compartment requirements), shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner or other cleaning agent according to the cleaning agent manufacturer's label instructions.

(c) *Clean solutions.* The wash, rinse and sanitize solutions shall be maintained clean.

Minimum Concentration	Minimum Temperature for Solution with pH of 10 or less	Minimum Temperature for Solution with pH of 8 or less
25 mg/L (ppm)	49°C (120°F)	49°C (120°F)
50 mg/L (ppm)	38°C (100°F)	24°C (75°F)
100 mg/L (ppm)	13°C (55°F)	13°C (55°F)

(2) An iodine solution shall have the following:

(i) A minimum temperature of 24°C (75°F).

(ii) A pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective.

(iii) A concentration between 12.5 mg/L (ppm) and 25 mg/L (ppm).

(3) A quaternary ammonium compound solution shall:

(i) Have a minimum temperature of 24°C (75°F).

(ii) Have a concentration as specified in § 46.713 (relating to chemicals: use criteria) and as indicated by the manufacturer's use directions included in the labeling.

(iii) Be used only in water with 500 mg/L (ppm) hardness or less or in water having a hardness no greater than specified by the manufacturer's label.

(4) If another solution of a chemical specified in paragraphs (1)–(3) is used, the food facility operator shall demonstrate to the Department that the solution achieves sanitization and the use of the solution may be approved by the Department.

(5) If a chemical sanitizer other than chlorine, iodine or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer use directions included in the labeling.

(e) *Determining chemical sanitizer concentration.* Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.

#### § 46.675. Mechanical warewashing equipment.

(a) *Manufacturers' operating instructions.*

(1) A warewashing machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.

(2) A warewashing machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

(b) *Wash solution temperature where hot water is used to sanitize.* The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than the following temperature, as applicable:

(d) *Chemical sanitization: temperature, pH, concentration and hardness.* A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at exposure times specified in § 46.731(c)(3) (relating to sanitization: requirement, frequency and methods) shall be listed in 21 CFR 178.1010 (relating to sanitizing solutions), shall be used in accordance with the EPA-approved manufacturer's label use instructions, and shall be used as follows:

(1) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart:

(1) For a stationary rack, single temperature machine, 74°C (165°F).

(2) For a stationary rack, dual temperature machine, 66°C (150°F).

(3) For a single tank, conveyor, dual temperature machine, 71°C (160°F).

(4) For a multitank, conveyor, multitemperature machine, 66°C (150°F).

(c) *Wash solution temperature where chemicals are used to sanitize.* The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than 49°C (120°F).

(d) *Sanitizing rinse temperature where hot water is used to sanitize.*

(1) Except as specified in paragraph (2), in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than 90°C (194°F), or less than the following, as applicable:

(i) For a stationary rack, single temperature machine: 74°C (165°F).

(ii) For all other machines: 82°C (180°F).

(2) The maximum temperature specified in paragraph (1) does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment such as meat saws.

(e) *Sanitization pressure.* The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine may not be less than 100 kilopascals (15 pounds per square inch) or more than 170 kilopascals (25 pounds per square inch) as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve.

#### § 46.676. Manual warewashing equipment.

(a) *Warewashing sinks: use limitation.* A warewashing sink may not be used for handwashing.

(b) *Sanitizing warewashing sink after other uses.* If a warewashing sink is used to wash wiping cloths, wash produce or thaw food, the sink shall be cleaned as specified in § 46.674(a) (relating to warewashing equip-

ment: mechanical or manual) before and after each time it is used to wash wiping cloths, wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified in § 46.731 (relating to sanitization: requirement, frequency and methods) before and after using the sink to wash produce or thaw food.

(c) *Wash solution temperature.* The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 43°C (110°F) or the temperature specified on the cleaning agent manufacturer's label instructions.

(d) *Hot water sanitization temperatures.* If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 77°C (171°F) or above.

(e) *Chemical sanitization using detergent-sanitizers.* If a detergent-sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step shall be the same detergent-sanitizer that is used in the washing step.

#### MAINTENANCE AND OPERATION OF UTENSILS AND TEMPERATURE AND PRESSURE MEASURING DEVICES

##### § 46.691. Utensils and temperature and pressure measuring devices: repair and calibration.

(a) *General requirement of good repair and calibration.* Utensils shall be maintained in a state of repair or condition that complies with the requirements specified in §§ 46.501—46.521, 46.523, 46.541—46.544, 46.561—46.563, 46.581—46.595 or shall be discarded.

(b) *Food temperature measuring devices.* Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

(c) *Ambient air temperature, water pressure and water temperature measuring devices.* Ambient air temperature, water pressure and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use.

##### § 46.692. Single-service and single-use articles.

(a) *Required use.* A food facility without facilities specified in §§ 46.711—46.719 (relating to cleaning of equipment and utensils) for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers.

(b) *Use limitation.*

(1) Single-service and single-use articles may not be reused.

(2) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than 1 inch protruding from the chilled dispensing head.

##### § 46.693. Mollusk and crustacean shells used as serving containers.

Mollusk and crustacean shells may not be used more than once as serving containers.

#### CLEANING OF EQUIPMENT AND UTENSILS

##### § 46.711. Objective of cleaning equipment and utensils.

(a) *General cleanliness requirement.* Equipment food-contact surfaces and utensils shall be clean to sight and touch.

(b) *Grease and soil accumulations.* The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulation.

(c) *Nonfood contact surfaces.* Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue and other debris.

##### § 46.712. Frequency of cleaning equipment food contact surfaces and utensils.

(a) *General requirements.* Equipment food-contact surfaces and utensils shall be cleaned as follows:

(1) Except as specified in subsection (b), before each use with a different type of raw animal food such as beef, fish, lamb, pork or poultry.

(2) Each time there is a change from working with raw foods to working with ready-to-eat foods.

(3) Between uses with raw fruits and vegetables and with potentially hazardous food.

(4) Before using or storing a food temperature measuring device.

(5) At any time during the operation when contamination may have occurred.

(b) *Exception.* Subsection (a)(1) does not apply if the food-contact surface or utensil is in contact with succession of different raw animal foods each requiring higher cooking temperature as specified in § 46.36 (relating to cooking raw animal foods) than the previous food (such as preparing raw fish followed by cutting raw poultry on the same cutting board).

(c) *Maximum cleaning interval for equipment food contact surfaces and utensils in contact with potentially hazardous food.* Except as specified in subsection (d), used with potentially hazardous food, equipment food contact surfaces and utensils shall be cleaned throughout the day at least every 4 hours.

(d) *Exceptions.* Surfaces of utensils and equipment contacting potentially hazardous food may be cleaned less frequently than every 4 hours under any of the following circumstances:

(1) In storage, containers of potentially hazardous food and their contents are maintained at temperatures specified in Subchapter C (relating to food characteristics) and the containers are cleaned when they are empty.

(2) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the chart in subparagraph (i) and both of the following occur:

(i) The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature:

Temperature	Cleaning Frequency
5.0°C (41°F) or less	24 hours
> 5.0°C and ≤ 7.2°C (> 41°F and ≤ 45°F)	20 hours
> 7.2°C and ≤ 10°C (> 45°F and ≤ 50°F)	16 hours
> 10°C and ≤ 12.8°C (> 50°F and ≤ 55°F)	10 hours

(ii) The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food facility.



(3) Containers in serving situations such as salad bars, delis and cafeteria lines hold ready-to-eat potentially hazardous food that is maintained at the temperatures specified in Subchapter C, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours.

(4) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified in Subchapter C.

(5) Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues.

(6) The cleaning schedule is approved by the Department based on consideration of the following:

- (i) Characteristics of the equipment and its use.
- (ii) The type of food involved.
- (iii) The amount of food residue accumulation.

(iv) The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease.

(7) In-use utensils are intermittently stored in a container of water in which the water is maintained at 60°C (140°F) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.

(e) *Maximum cleaning interval for equipment food-contact surfaces and utensils in contact with food that is not potentially hazardous.* Except when dry cleaning methods are used as specified in § 46.715(a) (relating to methods of cleaning) surfaces of utensils and equipment contacting food that is not potentially hazardous shall be cleaned as follows:

(1) At any time when contamination may have occurred.

(2) At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops or ladles.

(3) Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers.

(4) In equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders and water vending equipment as follows:

- (i) At a frequency specified by the manufacturer.
- (ii) Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

**§ 46.713. Frequency of cleaning cooking and baking equipment.**

(a) *Food contact surfaces.* The food-contact surfaces of cooking and baking equipment shall be cleaned at least every 24 hours. This requirement does not apply to hot oil cooking and filtering equipment if it is cleaned as specified in § 46.712(d)(6) (relating to frequency of cleaning equipment food-contact surfaces and utensils).

(b) *Microwave ovens.* The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

**§ 46.714. Frequency of cleaning nonfood-contact surfaces.**

Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

**§ 46.715. Methods of cleaning.**

(a) *Dry cleaning.*

(1) If used, dry cleaning methods such as brushing, scraping and vacuuming shall contact only surfaces that are soiled with dry food residues that are not potentially hazardous.

(2) Cleaning equipment used in dry cleaning food-contact surfaces may not be used for any other purpose.

(b) *Precleaning.*

(1) Food debris on equipment and utensils shall be scrapped over a waste disposal unit scupper, or garbage receptacle or may be removed in a warewashing machine with a prewash cycle.

(2) If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked or scrubbed with abrasives.

(c) *Wet cleaning.*

(1) Equipment food-contact surfaces and utensils shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary, such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.

(2) The washing procedures selected shall be based on the type and purpose of the equipment or utensil, and on the type of soil to be removed.

**§ 46.716. Washing: loading of soiled items into warewashing machines.**

Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that exposes the items to the unobstructed spray from all cycles, and allows the items to drain.

**§ 46.717. Washing procedures for alternative warewashing equipment.**

If washing in sink compartments or a warewashing machine is impractical (such as when the equipment is fixed or the utensils are too large) washing shall be done by using alternative manual warewashing equipment as specified in § 46.612(c) (relating to manual warewashing: sink compartment requirements) in accordance with the following procedures:

(1) Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts.

(2) Equipment components and utensils shall be scrapped or rough cleaned to remove food particle accumulation.

(3) Equipment and utensils shall be washed as specified in § 46.715(c)(1) (relating to methods of cleaning).

**§ 46.718. Rinsing procedures.**

Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one of the following procedures:

(1) Use of a distinct, separate water rinse after washing and before sanitizing if using any of the following:

(i) A three-compartment sink.

(ii) Alternative manual warewashing equipment equivalent to a three-compartment sink as specified in § 46.612(c) (relating to manual warewashing: sink compartment requirements).

(iii) A three-step washing, rinsing and sanitizing procedure in a warewashing system for CIP equipment.

(2) Use of a detergent-sanitizer as specified in § 46.676(f) (relating to manual warewashing equipment) if using either of the following:

(i) Alternative warewashing equipment as specified in § 46.612(c) that is approved for use with a detergent-sanitizer.

(ii) A warewashing system for CIP equipment.

(3) Use of a nondistinct water rinse that is integrated in the hot water sanitization immersion step of a two-compartment sink operation.

(4) If using a warewashing machine that does not recycle the sanitizing solution as specified in paragraph (5), or alternative manual warewashing equipment (such as sprayers), use of a nondistinct water rinse that is the following:

(i) Integrated in the application of the sanitizing solution.

(ii) Wasted immediately after each application.

(5) If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the sanitizing solution.

**§ 46.719. Washing returnable containers for refilling.**

(a) *General requirement.* Except as specified in subsections (b) and (c), returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food establishment.

(b) *Exception.* A food-specific container for beverages may be refilled at a food facility if all of the following are accurate:

(1) Only a beverage that is not a potentially hazardous food is used as specified in § 46.307(a) (relating to refilling returnables).

(2) The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food facility.

(3) Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system.

(4) The consumer-owned container returned to the food facility for refilling is refilled for sale or service only to the same consumer.

(5) The container is refilled by either of the following:

(i) An employee of the food facility.

(ii) The owner of the container if the beverage system includes a contamination-free transfer process that cannot be bypassed by the container owner.

(c) *Exception.* Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

**SANITIZATION OF EQUIPMENT AND UTENSILS****§ 46.731. Sanitization: requirement, frequency and methods.**

(a) *Requirement.* Equipment food-contact surfaces and utensils shall be sanitized in accordance with this section.

(b) *Frequency.* Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning.

(c) *Methods: hot water and chemical.* After being cleaned, equipment food-contact surfaces and utensils shall be sanitized by the following methods, based upon the type of operation:

(1) In hot water manual operations: by immersion for at least 30 seconds and as specified in § 46.676(d) (relating to manual warewashing equipment).

(2) In hot water mechanical operations: by being cycled through equipment that is set up as specified in § 46.675(a), (d) and (e) (relating to mechanical warewashing equipment) and achieving a utensil surface temperature of 71°C (160°F) as measured by an irreversible registering temperature indicator.

(3) In chemical manual or mechanical operations: including the application of sanitizing chemicals by immersion, manual swabbing, brushing or pressure spraying methods, using a solution as specified in § 46.674(d) (relating to warewashing equipment: mechanical or manual) for the following exposure time, as applicable:

(i) Except as specified in subparagraph (ii), an exposure time of at least 10 seconds for a chlorine solution specified in § 46.674(d)(1).

(ii) An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L (ppm) that has a pH of 10 or less and a temperature of at least 38°C (100°F) or a pH of 8 or less and a temperature of at least 24°C (75°F).

(iii) An exposure time of at least 30 seconds for other chemical sanitizing solutions.

(iv) An exposure time used in relationship with a combination of temperature, concentration and pH that, when evaluated for efficacy, yields sanitization.

**LAUNDERING****§ 46.751. Requirement and frequency of laundering.**

(a) *Requirement.* Clean linens shall be free from food residues and other soiling matter.

(b) *Frequency of laundering.*

(1) Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky or visibly soiled.

(2) Cloth gloves used as specified in § 46.305(d) (relating to gloves: use limitations) shall be laundered before being used with a different type of raw animal food such as beef, lamb, pork and fish.

(3) Linens and napkins that are used as specified in § 46.303 (relating to linens and napkins: use limitations) and cloth napkins shall be laundered between each use.

(4) Wet wiping cloths shall be laundered daily.

(5) Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

**§ 46.752. Methods of laundering.**

(a) *Storage of soiled linens.* Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single-service and single-use articles.

(b) *Mechanical washing.* All linens shall be mechanically washed, except in food facilities where only wiping cloths are laundered as specified in § 46.615(b) (relating to clothes washers and dryers), the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a warewashing or food preparation sink that is cleaned as specified in § 46.674(a) (relating to warewashing equipment: mechanical or manual).

**§ 46.753. Use of laundry facilities.**

(a) *General requirement.* Except as specified in subsection (b), laundry facilities on the premises of a food facility shall be used only for the washing and drying of items used in the operation of the facility.

(b) *Exception.* Separate laundry facilities located on the premises for the purpose of general laundering (such as for institutions providing boarding and lodging) may also be used for laundering food facility items.

**PROTECTION OF CLEAN ITEMS**

**§ 46.771. Drying clean equipment and utensils.**

(a) *Air-drying or adequate draining required.* After cleaning and sanitizing, equipment and utensils shall be air-dried or used after adequate draining as specified in paragraph (a) of 21 CFR 78.1010 (relating to sanitizing solutions) before contact with food.

(b) *Cloth drying.* After cleaning and sanitizing, equipment and utensils may not be cloth-dried, except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

**§ 46.772. Wiping cloths: air-drying locations.**

(a) *General.* Except as provided in subsection (b), wiping cloths laundered in a food facility that does not have a mechanical clothes dryer as specified in § 46.615(b) (relating to clothes washers and dryers) shall be air-dried in a location and in a manner that prevents contamination of food, equipment, utensils, linens, and single-service and single-use articles and the wiping cloths.

(b) *Exception.* This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified in § 46.674(d) (relating to warewashing equipment: mechanical or manual).

**§ 46.773. Lubricating and reassembling clean food contact surfaces and equipment.**

(a) *Food-contact surfaces.* Lubricants shall be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces.

(b) *Equipment.* Equipment shall be reassembled so that food-contact surfaces are not contaminated.

**§ 46.774. Storing clean items.**

(a) *General requirement for equipment, utensils, linens, and single-service and single-use articles.* Except as specified in subsection (d), cleaned equipment and utensils,

laundered linens, and single-service and single-use articles shall be stored as follows:

(1) In a clean, dry location.

(2) Where they are not exposed to splash, dust or other contamination.

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

(b) *Additional storage requirements for equipment and utensils.* Clean equipment and utensils shall be stored as specified in subsection (a) and shall be stored covered or inverted, and in a self-draining position that allows air drying.

(c) *Additional storage requirements for single-service and single-use articles.* Single-service and single-use articles shall be stored as specified in subsection (a) and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(d) *Items in closed packages.* Items that are kept in closed packages may be stored less than 15 cm (6 inches) above the floor on dollies, pallets, racks and skids that are designed as specified in § 46.595 (relating to case lot handling equipment: moveability).

(e) *Prohibited storage locations.* Except as specified in subsection (f), cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be stored in any of the following locations:

(1) A locker rooms.

(2) A toilet room.

(3) A garbage room.

(4) A mechanical room.

(5) Under a sewer line that is not shielded to intercept potential drips.

(6) Under a leaking water line—including a leaking automatic fire sprinkler head—or under a line on which water has condensed.

(7) Under an open stairwell.

(8) Under another source of contamination.

(f) *Limited exception for a locker room.* Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

**§ 46.775. Handling clean items.**

(a) *Kitchenware and tableware.*

(1) Single-service and single-use articles and cleaned and sanitized utensils shall be handled, displayed and dispensed so that contamination of food- and lip-contact surfaces is prevented.

(2) Knives, forks and spoons that are not prewrapped shall be presented so that only the handles are touched by employees and by consumers if consumer self-service is provided.

(3) Except as specified in paragraph (2), single-service articles that are intended for food- or lip-contact shall be furnished for consumer self-service with the original individual wrapper intact or from an approved dispenser.

(b) *Preset tableware.* If tableware is preset, it shall be protected from contamination by being wrapped, covered or inverted. Exposed, unused settings shall be either removed when a consumer is seated, or cleaned and sanitized before further use if the settings are not removed when a consumer is seated.

(c) *Soiled and clean tableware.* Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated.

#### Subchapter E. WATER, PLUMBING AND WASTE

##### WATER

###### Sec.

- 46.801. Sources of drinking water.
- 46.802. Drinking water system flushing and disinfection.
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##### MOBILE WATER TANK AND MOBILE FOOD FACILITY WATER TANK

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##### REFUSE, RECYCLABLES AND RETURNABLES

- 46.881. Storage areas and receptacles for refuse, recyclables and returnables: materials, design, construction and installation.
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- 46.885. Removal of refuse, recyclable and returnables.
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##### WATER

#### § 46.801. Sources of drinking water.

Drinking water shall be obtained from an approved source that is either of the following:

- (1) A public water system.
- (2) A nonpublic water system that is constructed, maintained and operated in accordance with 25 Pa. Code Chapter 109 (relating to safe drinking water). For the purpose of approval of a nonpublic water system that serves a food facility, a nonpublic water system shall be required to conform to the construction, maintenance and operation requirements established for a transient noncommunity water system as defined in 25 Pa. Code Chapter 109.

#### § 46.802. Drinking water system flushing and disinfection.

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

#### § 46.803. Bottled drinking water.

Bottled drinking water used or sold in a food facility shall be obtained from approved sources in accordance with 25 Pa. Code Chapter 109 (relating to safe drinking water).

#### § 46.804. Quality of water.

(a) *Standards for drinking water.* Except as specified in subsection (b), water obtained from either a public water system or a nonpublic water system for use in a food facility shall meet the quality standards for public drinking water established in 25 Pa. Code Chapter 109 (relating to safe drinking water).

##### (b) *Nondrinking water.*

(1) A nondrinking water supply shall be used only if approved by the Department.

(2) Nondrinking water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, fire protection and irrigation.

(c) *Sampling of water from nonpublic water systems.* Except when used as nondrinking water as specified in subsection (b), water from a nonpublic water system shall be sampled and tested for contamination at the same frequency and for the same contaminants as established in 25 Pa. Code Chapter 109 for a transient noncommunity public water system that serves 25 people daily. All analytical work must be performed in accordance with 25 Pa. Code Chapter 109.

(d) *Sample report for nonpublic water system to be retained at food facility.* If a food facility receives all of its drinking water from a nonpublic water system, the results from all required self-monitoring samples collected during the previous 12 months or, if less frequent than annual monitoring is approved by the Department for the facility, the most recent sample report for the nonpublic water system shall be retained on file in the food facility. Food facilities that use a Department of Environmental Protection approved self-contained public water system shall maintain test result records in accordance with 25 Pa. Code Chapter 109.

#### § 46.805. Quantity and availability of water: capacity and pressure.

##### (a) *Capacity.*

(1) The water source and system shall be of sufficient capacity to meet the peak water demands of the food facility.

(2) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the food facility.

(b) *Pressure.* Water under pressure shall be provided to all fixtures, equipment and nonfood equipment that are required to use water except that water supplied as specified in § 46.806(b)(1) and (2) (relating to distribution, delivery and retention of water) to a temporary food facility or in response to a temporary interruption of a water supply need not be under pressure.

#### § 46.806. Distribution, delivery and retention of water.

(a) *Delivery system.* Water shall be received from the source through the use of one or more of the following:

(1) A properly constructed and maintained service connection or lateral from a public water system that is

approved by the Department of Environmental Protection in accordance with 25 Pa. Code Chapter 109 (relating to safe drinking water).

(2) One or more of the following that shall be constructed, maintained and operated in accordance with 25 Pa. Code Chapter 109:

(i) Nonpublic water main, water pumps, pipes, hoses, connections and other appurtenances.

(ii) Water transport vehicles.

(iii) Water containers.

(b) *Alternative water supply.* Water meeting the applicable requirements in §§ 46.801—46.805 and subsection (a) shall be made available for a mobile facility, for a temporary food facility without a permanent water supply, and for a food facility with a temporary interruption of its water supply through one or more of the following sources:

(1) A supply of containers of commercially bottled drinking water.

(2) One or more closed portable water containers.

(3) An enclosed vehicular water tank.

(4) An on-premises water storage tank.

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

#### PLUMBING SYSTEM

##### § 46.821. Approved materials to be used in plumbing systems.

(a) *Approved materials required.* A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to the Pennsylvania Construction Code Act.

(b) *Safe materials for water filters.* A water filter shall be made of safe materials.

##### § 46.822. Design, construction and installation of plumbing systems.

(a) *Approved system and cleanable fixtures.*

(1) A plumbing system shall be designed, constructed and installed according to the Pennsylvania Construction Code Act.

(2) A plumbing fixture such as a handwashing facility, toilet for urinal shall be easily cleanable.

(b) *Handwashing facility: installation.*

(1) A handwashing lavatory shall be equipped to provide water at a temperature of at least 32°C (90°F) through a mixing valve or combination faucet.

(2) A steam mixing valve may not be used at a handwashing lavatory.

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

(4) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions.

(c) *Air gap requirement for backflow prevention.* An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than 25 mm (1 inch).

(d) *Design standard for backflow prevention device.* A backflow or backsiphonage prevention device installed on

a water supply system shall meet American Society of Sanitary Engineering (A.S.S.E.) standards for construction, installation, maintenance, inspection and testing for that specific application and type of device.

(e) *Design of conditioning device.* A water filter, screen and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

##### § 46.823. Numbers and capacities of plumbing facilities.

(a) *Handwashing facilities.*

(1) Except as specified in paragraphs (2) and (3), at least one handwashing lavatory—and a number of handwashing lavatories necessary for their convenient use by employees in areas specified in § 46.824(a) (relating to location and placement of plumbing facilities) shall be provided.

(2) If approved by the Department and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing lavatories in a food facility that has at least one handwashing lavatory.

(3) If approved by the Department, when food exposure is limited and handwashing lavatories are not conveniently available, such as in some mobile or temporary food facilities or at some vending machine locations, employees may use chemically treated towelettes for handwashing.

(b) *Toilets and urinals.* At least one toilet and not fewer than the toilets (and urinals, if used) required by the Department or the Department of Labor and Industry shall be provided.

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

(d) *Backflow prevention device: when required.* A plumbing system shall be installed to preclude backflow of a solid, liquid or gas contaminant into the water supply system at each point of use at the food facility, including on a hose bib if a hose is attached, or on a hose bib if a hose is not attached and backflow prevention is required by 25 Pa. Code Chapter 109 (relating to safe drinking water), by doing either of the following:

(1) Providing an air gap as specified in § 46.822(c) (relating to design, construction and installation of plumbing systems).

(2) Installing an approved backflow prevention device as specified in § 46.822(d).

##### § 46.824. Location and placement of plumbing facilities.

(a) *Handwashing facilities.* A handwashing facility shall be located as follows:

(1) In food preparation, food dispensing and warewashing areas to allow convenient use by employees.

(2) In, or immediately adjacent to, toilet rooms.

(b) *Location of backflow prevention device.* A backflow prevention device shall be located so that it may be serviced and maintained.

(c) *Location of conditioning device.* A water filter, screen and other water-conditioning device installed on

water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

**§ 46.825. Operation and maintenance of plumbing facilities.**

**(a) Using a handwashing facility.**

(1) A handwashing facility shall be maintained so that it is accessible at all times for employee use.

(2) A handwashing facility may not be used for purposes other than handwashing.

(3) An automatic handwashing facility shall be used in accordance with manufacturer's instructions.

**(b) Cross connection prohibited.**

(1) Except for firefighting, a person may not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.

(2) The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.

(c) *Scheduling inspection and service for a water system device.* A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge.

(d) *Cleaning the water reservoir of water devices such as fogging devices.*

(1) A reservoir that is used to supply water to a device such as a produce fogger shall be both of the following:

(i) Maintained in accordance with manufacturer's specifications.

(ii) Cleaned in accordance with manufacturer's specifications or according to the procedures specified in paragraph (2), whichever is more stringent.

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

(i) Draining and complete disassembly of the water and aerosol contact parts.

(ii) Brush-cleaning the reservoir, aerosol tubing and discharge nozzles with a suitable detergent solution.

(iii) Flushing the complete system with water to remove the detergent solution and particulate accumulation.

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

(e) *System maintained in good repair.* A plumbing system shall be repaired according to the Pennsylvania Construction Code Act, and shall be maintained in good repair.

**MOBILE WATER TANK AND MOBILE FOOD FACILITY WATER TANK**

**§ 46.841. Materials used in construction of mobile water tanks and mobile food facility water tanks.**

Materials that are used in the construction of a mobile water tank, mobile food facility water tank and appurtenances shall be the following:

(1) Safe.

(2) Durable, corrosion-resistant and nonabsorbent.

**§ 46.842. Design and construction of mobile water tanks and mobile food facility water tanks.**

(a) *Requirement: enclosed system sloped to drain.* A mobile water tank shall be the following:

(1) Enclosed from the filling inlet to the discharge outlet.

(2) Sloped to an outlet that allows complete drainage of the tank.

(b) *Requirement: inspection and cleaning port protected and secured.* If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and both of the following:

(1) Flanged upward at least 13 mm (1/2 inch).

(2) Equipped with a port cover assembly that is both of the following:

(i) Provided with a gasket and a device for securing the cover in place.

(ii) Flanged to overlap the opening and sloped to drain.

(c) *"V" type threads: use limitation.* A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

(d) *Requirement: tank vent protected.* If provided, a water tank vent shall terminate in a downward direction and shall be covered with the following, as applicable:

(1) 16 mesh to 25.4 mm (16 mesh to 1 inch) screen or equivalent when the vent is in a protected area.

(2) A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

(e) *Requirement: inlet and outlet sloped to drain.* A water tank and its inlet and outlet shall be sloped to drain, and a water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil or grease.

(f) *Hose: construction and identification.* A hose used for conveying drinking water from a water tank shall be all of the following:

(1) Safe.

(2) Durable, corrosion-resistant and nonabsorbent.

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

(4) Finished with a smooth interior surface.

(5) Clearly and durably identified as to its use if not permanently attached.

**§ 46.843. Numbers and capacities of mobile water tanks and mobile food facility water tanks.**

(a) *Filter requirement where compressed air pressurize the water tank system.* A filter that does not pass oil or vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is used to pressurize the water tank system.

(b) *Protective cover or device.* A cap and keeper chain, closed cabinet, closed storage tube or other approved protective cover or device shall be provided for a water inlet, outlet and hose.

(c) *Mobile food facility tank inlet.* A mobile food facility's water tank inlet shall be both of the following:

(1) 19.1 mm (3/4 inch) in inner diameter or less.



(2) Provided with a hose connection of a size or type that will prevent its use for any other service.

**§ 46.844. Operation and maintenance of mobile water tanks and mobile food facility water tanks.**

(a) *System flushing and disinfection.* A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification and periods of nonuse.

(b) *Preventing backflow while using a pump and hoses.* A person shall operate a water tank, pump and hoses so that backflow and other contamination of the water supply are prevented.

(c) *Protecting inlet, outlet and hose fitting.* If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified in § 46.843(b) (relating to numbers and capacities of mobile water tanks and mobile food facility water tanks).

(d) *Tank, pump and hoses, dedication.* A water tank, pump and hoses used for conveying drinking water shall be used for no other purpose, except that water tanks, pumps and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

**SEWAGE, OTHER LIQUID WASTE AND RAINWATER**

**§ 46.861. Capacity and drainage of a sewage holding tank in a mobile food facility.**

A sewage holding tank in a mobile food facility shall be both of the following:

(1) Sized 15 % larger in capacity than the water supply tank.

(2) Sloped to a drain that is 25 mm (1 inch) in inner diameter or greater, equipped with a shut-off valve.

**§ 46.862. Retention, drainage and delivery of sewage, other liquid waste and rainwater.**

(a) *Facility drainage system.* Food facility drainage systems, including grease traps, that convey sewage shall be designed and installed as specified in § 46.822(a) (relating to design, construction and installation of plumbing systems).

(b) *Backflow prevention.*

(1) Except as specified in paragraphs (2) and (3), a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment or utensils are placed.

(2) If allowed under the Pennsylvania Construction Code Act, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 1.5 m (5 feet) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

(3) If allowed under the Pennsylvania Construction Code Act, a warewashing or culinary sink may have a direct connection.

(c) *Grease trap.* If used, a grease trap shall be located to be easily accessible for cleaning.

(d) *Conveying sewage.* Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses and

connections that are constructed, maintained and operated according to the Pennsylvania Construction Code Act.

(e) *Removing mobile food facility wastes.* Sewage and other liquid wastes shall be removed from a mobile food facility at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created.

(f) *Flushing a waste retention tank.* A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

**§ 46.863. Disposal of sewage and nonsewage.**

(a) *Disposal of sewage.* Sewage shall be disposed through an approved facility that is either of the following:

(1) A public sewage treatment plant.

(2) An individual sewage disposal system that is sized, constructed, maintained, and operated according to the Pennsylvania Construction Code Act.

(b) *Other liquid wastes and rainwater.* Condensate drainage and other nonsewage liquids and rainwater shall be drained from point of discharge to disposal according to the Pennsylvania Construction Code Act.

**REFUSE, RECYCLABLES AND RETURNABLES**

**§ 46.881. Storage areas and receptacles for refuse, recyclables and returnables: materials, design, construction and installation.**

(a) *Indoor storage area.* If located within the food facility, a storage area for refuse, recyclables and returnables shall meet the requirements specified in §§ 46.901, 46.921 and 46.922(e) and (f) (relating to indoor areas of food facilities: surface characteristics; cleanability of floors, walls and ceilings; and functionality of various physical features of a food facility).

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

(c) *Outdoor enclosure.* If used, an outdoor enclosure for refuse, recyclables and returnables shall be constructed of durable and cleanable materials.

(d) *Receptacles.* Receptacles and waste handling units for refuse, recyclables and returnables and for use with materials containing food residue shall be durable, cleanable, insect- and rodent-resistant, leakproof and nonabsorbent. Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the food facility, or within closed outside receptacles.

(e) *Receptacles in vending machines.* A refuse receptacle may not be located within a vending machine, except that a receptacle for beverage bottle crown closures may be located within a vending machine.

(f) *Outside receptacles.*

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

(2) Receptacles and waste handling units for refuse and recyclables such as an onsite compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective

cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

**§ 46.882. Storage areas and receptacles for refuse, recyclables and returnables: numbers and capacities.**

(a) *Storage areas, rooms and receptacles: capacity and availability.*

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

(2) A receptacle shall be provided in each area of the food facility or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.

(3) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

(b) *Toilet room receptacle for sanitary napkins.* A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

(c) *Cleaning implements and supplies.* Suitable cleaning implements and supplies (such as high-pressure pumps, hot water, steam and detergent) shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables and returnables, except that approved off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.

**46.883. Location of storage areas, redeeming machines, receptacles and waste handling units.**

(a) *General requirement.* An area designated for refuse, recyclables, returnables, and—except as specified in subsection (b)—a redeeming machine for recyclables or returnables shall be located so that it is separate from food, equipment, utensils, linens, and single-service and single-use articles and a public health hazard or nuisance is not created.

(b) *Redeeming machine.* A redeeming machine may be located in the packaged food storage area or consumer area of a food facility if food, equipment, utensils, linens, and single-service and single-use articles are not subject to contamination from the machines and a public health hazard or nuisance is not created.

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

**46.884. Operation and maintenance of storage areas, redeeming machines, receptacles and waste handling units.**

(a) *Storing refuse, recyclables and returnables.* Refuse, recyclables and returnables shall be stored in receptacles and waste handling units so that they are inaccessible to insects and rodents.

(b) *Keeping areas, enclosures and receptacles in good air.* Storage areas, enclosures and receptacles for refuse, recyclables and returnables shall be maintained in good repair.

(c) *Outside storage prohibitions.*

(1) Except as specified in paragraph (2), refuse receptacles not meeting the requirements specified in 46.881(d) (relating to storage areas and receptacles for

refuse, recyclables and returnables: materials, design, construction and installation) (such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue) may not be stored outside.

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

(d) *Covering receptacles.* Receptacles and waste handling units for refuse, recyclables and returnables shall be kept covered as follows:

(1) Inside the food facility if the receptacles and units are filled or contain food residue and are not in continuous use.

(2) With tight-fitting lids or doors if kept outside the food facility.

(e) *Using drain plugs.* Drains in receptacles and waste handling units for refuse, recyclables and returnables shall have drain plugs in place.

(f) *Maintaining refuse areas and enclosures.* A storage area and enclosure for refuse, recyclables or returnables shall be maintained free of unnecessary items, as specified in § 46.981(n) (relating to premises, structures, attachments and fixtures: methods), and clean.

(g) *Cleaning receptacles.*

(1) Receptacles and waste handling units for refuse, recyclables and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of as specified in § 46.862(e) (relating to retention, drainage and delivery of sewage, other liquid waste and rainwater).

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

**§ 46.885. Removal of refuse, recyclable and returnables.**

(a) *Frequency.* Refuse, recyclables and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

(b) *Receptacles or vehicles.* Refuse, recyclables and returnables shall be removed from the premises by way of either of the following:

(1) Portable receptacles adequately constructed and maintained to contain the refuse, recyclables or returnables placed therein.

(2) A transport vehicle adequately constructed and maintained to contain the refuse, recyclables or returnables transported therein.

**§ 46.886. Facilities for disposal and recycling of refuse, recyclables and returnables.**

Solid waste not disposed of through the sewage system, such as through grinders and pulpers shall be recycled or disposed of in an approved public or private community recycling or refuse facility; or solid waste shall be dis-



used of in an individual refuse facility such as a fully-operated landfill or incinerator.

## Subchapter F. PHYSICAL FACILITIES

### MATERIALS FOR CONSTRUCTION AND REPAIR

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- .902. Outdoor areas of food facilities: surface characteristics.

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### MATERIALS FOR CONSTRUCTION AND REPAIR

#### 46.901. Indoor areas of food facilities: surface characteristics.

(a) *General requirement.* Except as specified in subsection (b), materials for indoor floor, wall and ceiling surfaces of a food facility under conditions of normal use shall be all of the following:

- (1) Smooth, durable and easily cleanable for areas where food facility operations are conducted.
- (2) Closely woven and easily cleanable carpet for carpeted areas.
- (3) Nonabsorbent for areas subject to moisture such as food preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, mobile food facility servicing areas, and areas subject to flushing or spray cleaning methods.

(b) *Exception for a temporary food facility.*

- (1) If graded to drain, a floor in a temporary food facility may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other suitable approved materials that are effectively treated to control dust and mud.
- (2) Walls and ceilings in a temporary food facility shall be constructed of a material that protects the interior from the weather and windblown dust and debris.

#### 46.902. Outdoor areas of food facilities: surface characteristics.

(a) *Walking and driving areas.* The outdoor walking and driving areas of a food facility shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(b) *Exterior surfaces.* Exterior surfaces of food facility buildings and mobile food facilities shall be of weather-resistant materials and shall comply with the Pennsylvania Construction Code Act.

(c) *Certain outdoor storage areas.* Outdoor storage areas of a food facility used for storing refuse, recyclables or returnables shall be of materials specified in § 46.525(b) and (c) (relating to storage areas and receptacles for refuse, recyclables and returnables: materials, design, construction and installation).

### DESIGN, CONSTRUCTION AND INSTALLATION

#### § 46.921. Cleanability of floors, walls and ceilings.

(a) *General requirement.* Except as specified in subsection (d), the floors, floor coverings, walls, wall coverings and ceilings of a food facility shall be designed, constructed and installed so they are smooth and easily cleanable, except that antislip floor coverings or applications may be used for safety reasons.

(b) *Utility lines.*

(1) Utility service lines and pipes in a food facility may not be unnecessarily exposed.

(2) Exposed utility service lines and pipes in a food facility shall be installed so they do not obstruct or prevent cleaning of the floors, walls or ceilings.

(3) Exposed horizontal utility service lines and pipes in a food facility may not be installed on the floor.

(c) *Floor and wall junctures: coved, and enclosed or sealed.*

(1) In food facilities in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1 mm (1/32 inch).

(2) The floors in food facilities in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and sealed.

(d) *Floor carpeting: restrictions and installation.*

(1) A floor covering such as carpeting or similar material may not be installed as a floor covering in food preparation areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing lavatories, toilets and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing or spray cleaning methods.

(2) If carpeting is installed as a floor covering in areas other than those specified in paragraph (1), it shall be both of the following:

(i) Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method.

(ii) Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

(e) *Floor covering: mats and duckboards.* Mats and duckboards in a food facility shall be designed to be removable and easily cleanable.

(f) *Wall and ceiling coverings and coatings.*

(1) Wall and ceiling covering materials in a food facility shall be attached so that they are easily cleanable.

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

(g) *Attachments to walls and ceilings.* Attachments to walls and ceilings (such as light fixtures, mechanical

room ventilation system components, vent covers, wall mounted fans, decorative items and other attachments) in a food facility shall be easily cleanable, except that in a consumer area of a food facility, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.

(h) *Studs, joists and rafters in walls and ceilings.* Studs, joists and rafters in a food facility may not be exposed in areas subject to moisture. This requirement does not apply to temporary food facilities.

**§ 46.922. Functionality of various physical facilities of a food facility.**

(a) *Light bulbs: protective shielding.*

(1) Except as specified in paragraph (2), light bulbs in use in a food facility shall be shielded, coated or otherwise shatter-resistant in areas where there is exposed food; clean equipment, utensils and linens; or unwrapped single-service and single-use articles.

(2) Shielded, coated or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages, if both of the following are accurate:

(i) The integrity of the packages can not be affected by broken glass falling onto them.

(ii) The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

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

(b) *Heating, ventilating and air conditioning system vents.* Heating, ventilating and air conditioning systems in a food facility shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment or utensils.

(c) *Design and installation of insect control devices.*

(1) Insect control devices that are used in a food facility to electrocute or stun flying insects shall be designed to retain the insect within the device.

(2) Insect control devices shall be installed so that they meet the following requirements:

(i) The devices are not located over a food preparation area.

(ii) Dead insects and insect fragments are prevented from being impelled onto or falling on exposed food; clean equipment, utensils and linens; and unwrapped single-service and single-use articles.

(d) *Toilet rooms shall be enclosed.* A toilet room located on the premises of a food facility shall be completely enclosed and provided with a tight-fitting and self-closing door. This requirement does not apply to a toilet room that is located outside a food facility and does not open directly into the food facility (such as a toilet room that is provided by the management of a shopping mall).

(e) *Outer openings shall be protected.*

(1) Except as specified in paragraphs (2)–(5), outer openings of a food facility shall be protected against the entry of insects and rodents by use of the following:

(i) Filling or closing holes and other gaps along floors, walls and ceilings.

(ii) Having closed, tight-fitting windows.

(iii) Having solid, self-closing, tight-fitting doors.

(2) Paragraph (1) does not apply if a food facility opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.

(3) Exterior doors used as exits need not be self-closing if they are all of the following:

(i) Solid and tight-fitting;

(ii) Designated for use only when an emergency exists;

(iii) Restricted so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.

(4) Except as specified in paragraphs (2) and (5), if the windows or doors of a food facility, or of a larger structure within which a food facility is located, are kept open for ventilation or other purposes or a temporary food facility is not provided with windows and doors as specified in paragraph (1), the openings shall be protected against the entry of insects and rodents by one or more of the following:

(i) 16 mesh to 25.4mm (16 mesh to 1 inch) screening;

(ii) Properly designed and installed air curtains.

(iii) Other effective means.

(5) Paragraph (4) does not apply if flying insects and other pests are absent due to the location of the facility or the weather or other limiting condition.

(f) *Exterior walls and roofs: protective barrier.* Perimeter walls and roofs of a food facility shall effectively protect the facility from the weather and the entry of insects, rodents and other animals.

(g) *Outdoor food vending areas, overhead protection.* If located outside, a machine used to vend food shall be provided with overhead protection except that machine vending canned beverages need not meet this requirement.

(h) *Outdoor servicing areas: overhead protection.* Servicing areas of a food facility shall be provided with overhead protection. However, if the area is used only for the loading of water or the discharge of sewage and other liquid waste, through the use of a closed system of hoses, the area need not be provided with overhead protection.

(i) *Outdoor walking and driving surfaces: graded to drain.* Exterior walking and driving surfaces of a food facility shall be graded to drain.

(j) *Outdoor refuse areas: curbed and graded to drain.* Outdoor refuse areas shall be constructed in accordance with the Pennsylvania Construction Code Act and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the refuse and from cleaning the area and waste receptacles.

(k) *Living or sleeping quarters, use prohibition.* A room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters, may not be used for conducting food facility operations.

(l) *Living or sleeping quarters: separation.* Living or sleeping quarters located on the premises of a food facility, such as those provided for lodging registration clerks, resident managers shall be separated from rooms and

areas used for food facility operations by complete partitioning and solid self-closing doors.

### NUMBERS AND CAPACITIES

#### § 46.941. Handwashing facilities: numbers and capacities.

(a) *Minimum number.* Handwashing facilities shall be provided in a food facility as specified in § 46.823(a) (relating to numbers and capacities of plumbing facilities).

(b) *Availability of handwashing cleanser.* Each handwashing lavatory or group of two adjacent lavatories shall be provided with a supply of hand cleaning liquid, powder or bar soap.

(c) *Availability of hand drying.* Each handwashing lavatory or group of adjacent lavatories shall be provided with one or more of the following:

- (1) Individual, disposable towels.
- (2) A continuous towel system that supplies the user with a clean towel.
- (3) A heated-air hand drying device.

(d) *Restrictions on use of handwashing aids and devices.* A sink used for food preparation or utensil washing, or a utility sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and devices required for a handwashing lavatory as specified in subsections (b) and (c) and § 46.882(a)(3) (relating to storage areas and receptacles for refuse, recyclables and returnables: numbers and capacities).

(e) *Handwashing signage.* A sign or poster that notifies food employees to wash their hands shall be provided at all handwashing lavatories used by food employees and shall be clearly visible to food employees.

(f) *Disposable towels, waste receptacle.* A handwashing lavatory or group of adjacent lavatories that is provided with disposable towels shall be provided with a waste receptacle as specified in § 46.882(a)(3).

#### § 46.942. Toilets and urinals: numbers and capacities.

(a) *Minimum number.* Toilets and urinals shall be provided in a food facility as specified in § 46.823(b) (relating to numbers and capacities of plumbing facilities).

(b) *Availability of toilet tissue.* A supply of toilet tissue shall be available at each toilet.

#### § 46.943. Lighting: intensity.

The light intensity in a food facility shall be all of the following:

(i) At least 110 lux (10 foot candles) at a distance of 75 cm (30 inches) above the floor, in walk-in refrigeration and dry food storage areas and in other areas and during periods of cleaning.

(ii) At least 220 lux (20 foot candles) at each of the following locations:

(1) A surface where food is provided for consumer self-service such as buffets and salad bars or where fresh produce or packaged foods are sold or offered for consumption.

(2) Inside equipment such as reach-in and under-counter refrigerators.

(iii) At a distance of 75 cm (30 inches) above the floor in areas used for handwashing, warewashing, and equipment and utensil storage, and in toilet rooms.

(3) At least 540 lux (50 foot candles) at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders or saws where employee safety is a factor.

#### § 46.944. Mechanical ventilation as needed.

If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke and fumes in a food facility, mechanical ventilation of sufficient capacity shall be provided.

#### § 46.945. Requirement and designation of dressing areas and storage areas.

(a) *Designation.* Dressing rooms or dressing areas shall be designated in a food facility if employees routinely change their clothes in that facility.

(b) *Storage of employees' clothing and possessions.* Lockers or other suitable facilities shall be provided for the orderly storage of employees' clothing and other possessions.

#### § 46.946. Utility sinks.

A utility sink or curbed cleaning facility shall be provided as specified in § 46.823(c) (relating to numbers and capacities of plumbing facilities).

### LOCATION AND PLACEMENT

#### § 46.961. Handwashing facilities: located for convenience.

Handwashing facilities in a food facility shall be conveniently located as specified in § 46.824(a) (relating to location and placement of plumbing facilities).

#### § 46.962. Toilet rooms: located for convenience.

Toilet rooms in a food facility shall be conveniently located and accessible to employees during all hours of operation.

#### § 46.963. Employee accommodations: located to prevent contamination.

(a) *Designated eating, drinking and smoking areas.* Areas designated for employees to eat, drink and use tobacco shall be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.

(b) *Lockers and other facilities.* Lockers or other suitable facilities shall be located in a designated room or area where contamination of food, equipment, utensils, linens, and single-service and single-use articles cannot occur.

#### § 46.964. Distressed merchandise: segregated.

Products that are held by the food facility operator for credit, redemption or return to the distributor; such as damaged, spoiled or recalled products, shall be segregated and held in designated areas that are separate from food, equipment, utensils, linens, and single-service and single-use articles.

#### § 46.965. Refuse, recyclables and returnables: receptacles, waste handling units and designated storage areas.

Units, receptacles, and areas designated for storage of refuse and recyclable and returnable containers shall be located as specified in § 46.883 (relating to location of storage areas, redeeming machines, receptacles and waste handling units)

## MAINTENANCE AND OPERATION

**§ 46.981. Premises, structures, attachments and fixtures: methods.**

(a) *General requirement.* The physical facilities of a food facility shall be maintained in good repair.

(b) *Cleaning: frequency and restrictions.*

(1) The physical facilities of a food facility shall be cleaned as often as necessary to keep them clean.

(2) Cleaning shall be done during periods when the least amount of food is exposed such as after closing. This requirement does not apply to cleaning that is necessary due to a spill or other accident.

(c) *Cleaning floors by dustless methods.*

(1) Except as specified in paragraph (2), only dustless methods of cleaning shall be used (such as wet cleaning, vacuum cleaning, mopping with treated dust mops or sweeping using a broom and dust-arresting compounds).

(2) Spills or drippage on floors that occur between normal floor cleaning times shall be cleaned as follows:

(i) Without the use of dust-arresting compounds.

(ii) In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.

(d) *Cleaning ventilation systems without causing contamination, health hazard or nuisance.*

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

(2) If vented to the outside, ventilation systems may not create a public health hazard or nuisance or unlawful discharge.

(e) *Preventing contamination by cleaning maintenance tools.* Food preparation sinks, handwashing lavatories and warewashing equipment may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials or the disposal of mop water and similar liquid wastes.

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

(g) *Absorbent materials on floors: use limitation.* Except as specified in subsection (c)(2), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth or similar materials may not be used on floors.

(h) *Maintaining and using handwashing facilities.* Handwashing facilities shall be kept clean, and maintained and used as specified in § 46.825(a) (relating to operation and maintenance of plumbing facilities).

(i) *Closing toilet room doors.* Toilet room doors as specified in § 46.922(d) (relating to functionality of various physical facilities at a food facility) shall be kept closed except during cleaning and maintenance operations.

(j) *Using dressing rooms and lockers.* Dressing rooms shall be used by employees if the employees regularly change their clothes in the facility. Lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.

(k) *Controlling pests.* The presence of insects, rodents and other pests shall be controlled to minimize their presence on the premises by all of the following:

(1) Routinely inspecting incoming shipments of food and supplies.

(2) Routinely inspecting the premises for evidence of pests.

(3) Using methods, if pests are found, such as trapping devices or other means of pest control as specified in § 46.1026(b) and (c) (relating to pesticides).

(4) Eliminating harborage conditions.

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

(m) *Storing maintenance tools.* Maintenance tools (such as brooms, mops, vacuum cleaners and similar items) shall be stored so that they do not contaminate food equipment, utensils, linens, and single-service and single-use articles, and in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

(n) *Removing unnecessary items and litter from the premises.* The premises of a food facility shall be free of items that are unnecessary to the operation or maintenance of the facility, such as equipment that is nonfunctional or no longer used, and litter.

**§ 46.982. Limitations on animals.**

(a) *General.* Live animals may not be allowed on the premises of a food facility, unless under an exception specified in subsection (b).

(b) *Exceptions.*

(1) Live animals may be allowed in any of the following situations if the contamination of food; clean equipment; utensils and linens; and unwrapped single-service and single-use articles can not result:

(i) Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems.

(ii) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas.

(iii) Service animals that are controlled by the disabled employee or person, in areas that are not used for food preparation and that are usually open for customers (such as dining and sales areas), if a health or safety hazard will not result from the presence or activities of the service animal.

(iv) Pets in the common dining areas of group residences at times other than during meals if all of the following are accurate:

(A) Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas.

(B) Condiments, equipment and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present.

(C) Dining areas including tables, countertops and similar surfaces are effectively cleaned before the next meal service.

(v) Caged animals or animals that are similarly restricted, in areas that are not used for food preparation, storage, sales, display or dining, such as in a variety store that sells pets or a tourist park that displays animals.

(2) Live or dead fish bait may be stored if contamination of food, clean equipment, utensils and linens; and unwrapped single-service and single-use articles cannot result.

### Subchapter G. POISONOUS OR TOXIC MATERIALS

#### LABELING AND IDENTIFICATION

Sec.

46.1001. Poisonous or toxic substances: original containers to display identifying information.

46.1002. Poisonous or toxic substances: working containers labeled with common name.

#### OPERATIONAL SUPPLIES AND APPLICATIONS

46.1021. Poisonous or toxic substances: storage.

46.1022. Poisonous or toxic substances: limitations on presence and use.

46.1023. Prohibition of use of poisonous or toxic material containers to store food.

46.1024. Chemicals: use criteria.

46.1025. Lubricants that have incidental contact with food: criteria.

46.1026. Pesticides.

46.1027. Medicines.

46.1028. First aid supplies: storage.

46.1029. Other personal care items: storage.

#### STOCK AND RETAIL SALE

46.1041. Storage and display: separation of poisonous or toxic materials from food.

#### LABELING AND IDENTIFICATION

§ 46.1001. Poisonous or toxic substances: original containers to display identifying information.

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

§ 46.1002. Poisonous or toxic substances: working containers labeled with common name.

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

#### OPERATIONAL SUPPLIES AND APPLICATIONS

§ 46.1021. Poisonous or toxic substances: storage.

Poisonous or toxic materials shall be stored so they can not contaminate food, equipment, utensils, linens, and single-service and single-use articles by taking both of the following measures:

(1) Separating the poisonous or toxic materials by spacing or partitioning.

(2) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This paragraph does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles.

§ 46.1022. Poisonous or toxic substances: limitations on presence and use.

(a) *Restriction.* Only those poisonous or toxic materials that are required for the operation and maintenance of a food facility, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a food facility. This section does not apply to packaged poisonous or toxic materials that are for retail sale.

(b) *Conditions of use.* Poisonous or toxic materials shall be used in a lawful manner according to the following:

(1) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food facility.

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

(3) Additional conditions that may be established by the Department.

(c) *Conditions of application.* Poisonous or toxic materials shall be applied so that the following are accurate:

(1) A hazard to employees or other persons is not constituted.

(2) Contamination (including toxic residues due to drip, drain, fog, splash or spray on food, equipment, utensils, linens, and single-service and single-use articles) is prevented, and for a restricted-use pesticide, this is achieved by doing all of the following:

(i) Removing the items.

(ii) Covering the items with impermeable covers, or taking other appropriate preventive actions.

(iii) Cleaning and sanitizing equipment and utensils after the application.

(d) *Applicator.* A restricted use pesticide shall be applied only by an applicator certified in accordance with the Pennsylvania Pesticide Control Act of 1973 (3 P.S. §§ 111.21—111.61) or a person under the direct supervision of a certified applicator.

§ 46.1023. Prohibition of use of poisonous or toxic material containers to store food.

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

§ 46.1024. Chemicals: use criteria.

(a) *Sanitizers.* Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010 (relating to sanitizing solutions).

(b) *Chemicals for washing fruits and vegetables.* Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 (relating to chemicals used in washing or to assist in the lye peeling of fruits and vegetables).

(c) *Boiler water additives.* Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310 (relating to boiler water additives).

(d) *Drying agents.*

(1) Drying agents used in conjunction with sanitization shall contain only components that are listed as one or more of the following:

(i) Generally recognized as safe for use in food as specified in 21 CFR 182 (relating to substances generally recognized as safe), or 21 CFR 184 (relating to direct food substances affirmed as generally recognized as safe).

(ii) Generally recognized as safe for the intended use as specified in 21 CFR 186 (relating to indirect food substances affirmed as generally recognized as safe).

(iii) Approved for use as a drying agent under a prior sanction specified in 21 CFR 181 (relating to prior-sanctioned food ingredients).

(iv) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175—178 (relating to indirect food additives).

(v) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 (relating to threshold of regulation for substances used in food-contact articles).

(2) When sanitization is with chemicals, the approval required in paragraph (1)(iii) or (v), or the regulation as an indirect food additive required in paragraph (1)(iv), shall be specifically for use with chemical sanitizing solutions.

**§ 46.1025. Lubricants that have incidental contact with food: criteria.**

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

**§ 46.1026. Pesticides.**

(a) *Restricted use pesticides: criteria.* Restricted use pesticides specified in § 46.1022(d) (relating to poisonous or toxic substances: limitations on presence and use) shall meet the requirements of a restricted use pesticide as specified in § 128.2 (relating to definitions). This section requires restricted use pesticides be one of the following:

(1) Classified for restricted use under section 3(d) of the Federal Insecticide, Fungicide and Rodenticide Act of 1947 (7 U.S.C.A. § 136(d)).

(2) A pesticide designated by the Secretary for restricted use under section 7(b)(6) of the Pennsylvania Pesticide Control Act of 1973 (3 P.S. § 111.27(b)(6)).

(b) *Rodent bait stations.* Rodent bait shall be contained in a covered, tamper-resistant bait station.

(c) *Tracking powders: pesticides and nontoxics.* A tracking powder pesticide may not be used in a food facility. A nontoxic tracking powder (such as talcum or flour) may be used in a food facility if it will not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

**§ 46.1027. Medicines.**

(a) *Restriction and storage.*

(1) Only those medicines that are necessary for the health of employees shall be allowed in a food facility. This section does not apply to medicines that are stored or displayed for retail sale.

(2) Medicines that are in a food facility for the employees' use shall be labeled as specified in § 46.1001 (relating to poisonous or toxic substances: original containers to display identifying information) and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.

(b) *Refrigerated medicines: storage.* Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be in compliance with the following:

(1) Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines.

(2) Located so they are inaccessible to children.

**§ 46.1028. First aid supplies: storage.**

First aid supplies that are in a food facility for the employees' use shall be both of the following:

(1) Labeled as specified in § 46.1001 (relating to poisonous or toxic substances: original containers to display identifying information).

(2) Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and linens, and single-service and single-use articles.

**§ 46.1029. Other personal care items: storage.**

Except as specified in § 46.1027(b) and 46.1028 (relating to medicines; and first aid supplies: storage), employees shall store their personal care items in facilities specified in § 46.945(b) (relating to requirement a designation of dressing areas and storage areas).

**STOCK AND RETAIL SALE**

**§ 46.1041. Storage and display: separation of poisonous or toxic materials from food.**

Poisonous or toxic materials shall be stored and displayed for retail sale so they can not contaminate food, equipment, utensils, linens, and single-service and single-use articles by one or both of the following:

(1) Separating the poisonous or toxic materials by spacing or partitioning.

(2) Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.

**Subchapter H. ADMINISTRATIVE PROCEDURES**

**CHAPTER APPLICABILITY**

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**CHAPTER APPLICABILITY**

**§ 46.1101. Application for intended purpose: public health protection.**

The Department will apply this chapter to promote its underlying purpose—as specified in § 46.1 (relating to purpose)—of safeguarding public health and ensuring that food is safe, unadulterated and honestly presented when offered to the consumer.

**§ 46.1102. Access to food facilities.**

After the Secretary presents credentials, the person in charge shall allow the Secretary to determine if the food facility is in compliance with this chapter by allowing access to the facility, allowing inspection, and providing information and records specified in this chapter and to which the Secretary is entitled under the Public Eating and Drinking Place Law, the act and any other relevant statutory or regulatory authority, during the food facility hours of operation and other reasonable times.

**§ 46.1103. Variances.**

(a) *Modifications and waivers.* The Department may grant a variance by modifying or waiving the requirements of this chapter if—in the opinion of the Department—



ment—a health hazard will not result from the variance. If a variance is granted, the Department will retain the information specified in subsection (b) in its records for the food facility.

(b) *Documentation of proposed variance and justification.* Before a variance from a requirement of this chapter is approved, the information that shall be provided by the person requesting the variance and retained in the Department's file on the food facility includes the following:

(1) A statement of the proposed variance of the chapter requirement citing relevant chapter section numbers.

(2) An analysis of the rationale for how the potential public health hazards addressed by the relevant chapter sections will be alternatively addressed by the proposal.

(3) A HACCP plan—if required as specified in § 46.1122(a)(1) (relating to HACCP plans)—that includes the information specified in § 46.1122(b) as it is relevant to the variance requested.

(c) *Conformance with approved procedures.* If the Department grants a variance as specified in subsection (a), or a HACCP plan is otherwise required as specified in § 46.1122(a), the food facility operator shall do the following:

(1) Comply with the HACCP plans and procedures that are submitted as specified in § 46.1122(b) and approved as a basis for the modification or waiver.

(2) Maintain and provide to the Department, upon request, records specified in § 46.1122(b)(4) and (5) that demonstrate that the following are routinely employed:

- (i) Procedures for monitoring critical control points.
- (ii) Monitoring of the critical control points.
- (iii) Verification of the effectiveness of an operation or process.

(iv) Necessary corrective actions if there is failure at a critical control point.

#### PLAN SUBMISSION AND APPROVAL

##### § 46.1121. Facility and operating plans.

(a) *When plans are required.* A food facility licensing applicant or food facility operator required by the Public Eating and Drinking Place Law to have plans and specifications reviewed by the Department will submit these properly prepared plans and specifications (as described in subsection (b)) to the Department for review and approval before any of the following:

- (1) The construction of a food facility.
- (2) The conversion of an existing structure for use as a food facility.
- (3) The remodeling of a food facility or a change of type of food facility or food operation if the Department determines that plans and specifications are necessary to ensure compliance with this chapter.

(b) *Contents of the plans and specifications.* The plans and specifications for a food facility, including a food facility specified in § 46.1122(a) (relating to HACCP plans), shall include (as required by the Department based on the type of operation, type of food preparation and foods prepared) the following information to demonstrate conformance with this chapter:

- (1) Intended menu.
- (2) Anticipated volume of food to be stored, prepared, and sold or served.

(3) Proposed layout, mechanical schematics, construction materials and finish schedules.

(4) Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities and installation specifications.

(5) Other information that may be required by the Department for the proper review of the proposed construction, conversion or modification of a food facility.

##### § 46.1122. HACCP plans.

(a) *When an HACCP plan is required.*

(1) Before engaging in an activity that requires an HACCP plan, a food facility applicant or food facility operator shall submit to the Department for approval a properly prepared HACCP plan as specified in subsection (b) and the relevant provisions of this chapter if any of the following occurs:

(i) Submission of an HACCP plan is required according to applicable Federal or State laws.

(ii) A variance is required as specified in §§ 46.250(b)(2)(ii), 46.345(d)(3), 46.401 or 46.589(b).

(iii) The Department determines that a food preparation or processing method requires a variance based on a plan submittal specified in § 46.1121(b) (relating to facility and operating plans), an inspectional finding, or a variance request.

(2) A food facility applicant or food facility operator shall have a properly prepared HACCP plan as specified in § 46.402 (relating to reduced oxygen packaging).

(b) *Contents of an HACCP plan.* For a food facility that is required in subsection (a) to have an HACCP plan, the plan and specifications shall indicate the following:

(1) A categorization of the types of potentially hazardous foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the Department.

(2) A flow diagram by specific food or category type identifying critical control points and providing information on the following:

(i) Ingredients, materials and equipment used in the preparation of that food.

(ii) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

(3) Food employee and supervisory training plan that addresses the food safety issues of concern.

(4) A statement of standard operating procedures for the plan under consideration including clearly identifying the following:

- (i) Each critical control point.
- (ii) The critical limits for each critical control point.
- (iii) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge.

(iv) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points.

(v) Action to be taken by the person in charge if the critical limits for each critical control point are not met.

(vi) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed.

(5) Additional scientific data or other information, as required by the Department, supporting the determination that food safety is not compromised by the proposal.

**§ 46.1123. Confidentiality of trade secrets.**

The Department will treat as confidential information that meets the criteria specified in law for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified in §§ 46.1121(b) and 46.1122(b) (relating to facility and operating plans; and HACCP plans).

**§ 46.1124. Preoperational inspection of construction.**

The Department will conduct one or more preoperational inspections to verify that the food facility is constructed and equipped in accordance with the approved plans and approved modifications of those plans, and variances granted under § 46.1103 (relating to variances). The Department will also verify the food facility is otherwise in compliance with this chapter and the Public Eating and Drinking Place Law.

**REQUIREMENTS FOR OPERATION**

**§ 46.1141. Requirement: permit, license or registration.**

A person may not operate a food facility without a valid permit, license or registration issued by the Department.

**§ 46.1142. Application procedure for appropriate permit, license or registration.**

Prior to the opening of a food facility, the operator shall contact the Department to obtain the appropriate application form for the required permit, license or registration. The Department will supply the applicant the appropriate form, based upon the type of food facility involved.

**§ 46.1143. Issuance.**

(a) *New, converted or remodeled food facilities.*

(1) For food facilities that are required to submit plans as specified in § 46.1121(a) (relating to facility and operating plans), the Department will issue a license or permit to the applicant after the following occur:

(i) The required plans, specifications, and information are reviewed and approved.

(ii) A preoperational inspection, as described in 46.1124 (relating to preoperational inspection of construction) shows that the facility is built or remodeled in accordance with the approved plans and specifications and that the facility is in compliance with this chapter.

(iii) A properly completed application is submitted.

(iv) The required fee is submitted.

(2) For food facilities that are not required to submit plans as specified in § 46.1121(a), the Department will issue a registration to the applicant after the following occur:

(i) A properly completed application is submitted.

(ii) The required fee is submitted.

(b) *License or permit renewal.* The food facility operator of an existing facility shall submit an application, the required fee, and be in compliance with this chapter prior to issuance by the Department of a renewed license or permit.

(c) *Registration renewal.* The food facility operator of an existing facility shall submit an application and the required fee prior to issuance by the Department of a renewed registration.

(d) *Change of ownership.* Licenses, registrations and permits are nontransferable. New owners shall apply to the Department in accordance with § 46.1142 (relating to application procedure for appropriate permit, license or registration).

**§ 46.1144. Conditions of retention: responsibilities of the food facility operator.**

To retain a license, registration or permit issued by the Department under this chapter, a food facility operator shall do the following:

(1) Post the license, registration or permit in a location in the food facility that is conspicuous to consumers and the Department.

(2) Comply with this chapter—including the conditions of a granted variance as specified in § 46.1103(c) (relating to variances)—and approved plans as specified in § 46.1121(b) (relating to facility and operating plans).

(3) If a food facility is required in § 46.1122(a) (relating to HACCP plans) to operate under a HACCP plan, comply with the plan as specified in § 46.1103(c) (relating to variances).

(4) Immediately contact the Department to report an illness of an employee as specified in § 46.111(b) (relating to duty to report disease or medical condition).

(5) Immediately discontinue operations and notify the Department if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger public health. A food facility operator need not discontinue operations in an area of a facility that is unaffected by the imminent health hazard.

(6) Not resume operations discontinued in accordance with paragraph (5) or otherwise according to the Public Eating and Drinking Place Law or the act until approval is obtained from the Department.

(7) Allow representatives of the Secretary access to the food facility as specified in § 46.1102 (relating to access to food facilities).

(8) Except as specified in paragraph (9), replace existing facilities and equipment with facilities and equipment that comply with this chapter if either of the following occurs:

(i) The Department directs the replacement because the facilities and equipment constitute a public health hazard or no longer comply with the criteria upon which the facilities and equipment were accepted.

(ii) The facilities and equipment are replaced in the normal course of operation.

(9) Upgrade or replace refrigeration equipment as specified in § 46.385(a)(3) (relating to potentially hazardous food: hot and cold holding) by \_\_\_\_\_ (Editor's Note: The blank refers to a date 5 years after the effective date of adoption of this proposal.), if the circumstances specified in paragraph (8)(i) and (ii) do not occur first, and unless a variance has been approved as specified in § 46.1103.



(10) Comply with directives of the Department including time frames for corrective actions specified in inspection reports, notices, orders, warnings and other directives issued by the Department in regard to the operator's food facility or in response to community emergencies.

(11) Accept notices issued and served by the Department according to the Public Eating and Drinking Place Law or the act.

*(Editor's Note: The Department proposes to delete Chapter 47, Pa. Code pages 47-1 and 47-2, serial pages (217561) to (217562).)*

**CHAPTER 47. (Reserved)**

§§ 47.1—47.3. (Reserved).

*(Editor's Note: The Department proposes to delete Chapter 49, Pa. Code pages 49-1—49-26, serial pages (217563) to (217580), (237815) to (237816) and (217583) to (217588).)*

**CHAPTER 49. (Reserved)**

**Subchapter A. (Reserved)**

§§ 49.1—49.6. (Reserved).

**Subchapter B. (Reserved)**

§§ 49.11—49.20. (Reserved).

**Subchapter C. (Reserved)**

§§ 49.31—49.36. (Reserved).

**Subchapter D. (Reserved)**

§§ 49.41—49.47. (Reserved).

**Subchapter E. (Reserved)**

§§ 49.51—49.56. (Reserved).

**Subchapter F. (Reserved)**

§ 49.61. (Reserved).

§ 49.62. (Reserved).

**Subpart B. LIQUID FOODS**

*(Editor's Note: The Department proposes to delete Chapter 53, Pa. Code pages 53-1—53-5, serial pages (217591) to (217595).)*

**CHAPTER 53. (Reserved)**

§§ 53.1—53.7. (Reserved).

§§ 53.11—53.19. (Reserved).

§ 53.21. (Reserved).

§ 53.22. (Reserved).

*(Editor's Note: The Department proposes to delete Chapter 55, Pa. Code pages 55-1 and 55-2, serial pages (260909) to (260910).)*

**CHAPTER 55. (Reserved)**

§§ 55.1—55.5. (Reserved).

*(Editor's Note: The Department proposes to delete Chapter 61, Pa. Code pages 61-1—61-13, serial pages (217705) to (217717).)*

**CHAPTER 61. (Reserved)**

**Subchapter A. (Reserved)**

§§ 61.1—61.7. (Reserved).

§§ 61.11—61.13. (Reserved).

§ 61.21. (Reserved).

§ 61.22. (Reserved).

§§ 61.31—61.34. (Reserved).

§§ 61.41—61.43. (Reserved).

**Subchapter B. (Reserved)**

§§ 61.51—61.53. (Reserved).

§§ 61.61—61.65. (Reserved).

§ 61.71. (Reserved).

§ 61.72. (Reserved).

*(Editor's Note: The Department proposes to delete Chapter 63, Pa. Code pages 63-1 and 63-2, serial pages (217719) to (217720).)*

**CHAPTER 63. (Reserved)**

§§ 63.1—63.4. (Reserved).

**Subchapter C. MISCELLANEOUS PROVISIONS**

*(Editor's Note: The Department proposes to delete Chapter 78, Pa. Code pages 78-1—78-33, serial pages (217741) to (217754), (237817) to (237818) and (217757) to (217773).)*

**CHAPTER 78. (Reserved)**

**Subchapter A. (Reserved)**

§§ 78.1—78.3. (Reserved).

**Subchapter B. (Reserved)**

§§ 78.11—78.14. (Reserved).

§§ 78.21—78.24. (Reserved).

§ 78.31. (Reserved).

§ 78.32. (Reserved).

§§ 78.41—78.43. (Reserved).

§§ 78.51—78.53. (Reserved).

§§ 78.61—78.65. (Reserved).

§§ 78.71—78.78. (Reserved).

§§ 78.91—78.97. (Reserved).

§ 78.101. (Reserved).

*(Editor's Note: The Department proposes to delete Chapter 79, Pa. Code page 79-1, serial page (217775).)*

**CHAPTER 79. (Reserved)**

§ 79.1. (Reserved).

*(Editor's Note: The Department proposed to delete Chapter 80, Pa. Code pages 80-1—80-10, serial pages (217777) to (217786).)*

## PROPOSED RULEMAKING

## CHAPTER 80. (Reserved)

80.1. (Reserved).

§ 80.11—80.13. (Reserved).

§ 80.21—80.23. (Reserved).

80.31. (Reserved).

80.32. (Reserved).

§ 80.41—80.48. (Reserved).

80.51. (Reserved).

80.52. (Reserved).

§ 80.61—80.63. (Reserved).

80.71. (Reserved).

80.72. (Reserved).

§§ 80.81—80.84. (Reserved).

(Editor's Note: The Department proposes to delete Chapter 81, Pa. Code pages 81-1 and 81-2, serial pages (217787) to (217788).)

## CHAPTER 81. (Reserved).

§ 81.1. (Reserved).

§ 81.11. (Reserved).

§ 81.12. (Reserved).

§ 81.21. (Reserved).

[Pa.B. Doc. No. 02-297. Filed for public inspection February 22, 2002, 9:00 a.m.]



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September 17, 2003

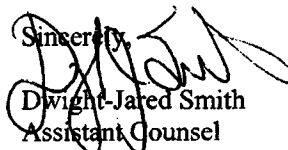
Independent Regulatory Review Commission  
333 Market Street, 14<sup>TH</sup> Floor  
Harrisburg, PA 17120

**RE: FINAL-FORM REGULATION**  
**Department of Agriculture**  
**Bureau of Food Safety and Laboratory Services**  
**I.D. No. 2-137**  
**7 Pa. Code Chapter 46 – The Food Code**  
**Proposed Rulemaking: 32 Pa. Bulletin 1046 (February 23, 2002)**  
**Approved by Office of General Counsel: September 15, 2003**

Dear Sir or Madam:

Please find enclosed a copy of the above-referenced final-form regulation. This material includes copies of the Preamble and Annex "A". Copies of the Notice of Proposed Rulemaking and Regulatory Analysis Form are also enclosed. I respectfully request the Independent Regulatory Review Commission review and approve the above-referenced final-form regulation in accordance with the requirements and procedures of the Regulatory Review Act.

This Department's responses to the comments received from the public, the Legislature and the Independent Regulatory Review Commission with respect to the proposed regulation are set forth in the Preamble to the final-form regulation. Copies of this final-form regulation have been delivered to the appropriate Legislative Committees (the House and Senate Agricultural and Rural Affairs Committees), and have been mailed or delivered to each commentator on this date. In response to the requirement (at 71 P.S. § 745.5a(b) and 1 Pa. Code § 307.2(c)(7)) that this Department provide the names and addresses of commentators who requested additional information on the final-form regulation, the Department hereby relates that no commentators have made this request. The Department will provide you with any assistance you may require to facilitate a thorough review of this final-form regulation. Thank you for your attention to this matter.

Sincerely,  
  
Dwight-Jared Smith  
Assistant Counsel

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

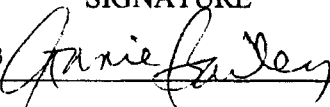



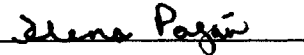
I.D. NUMBER: 2-137  
SUBJECT: Food Code  
AGENCY: DEPARTMENT OF AGRICULTURE

**TYPE OF REGULATION**

Proposed Regulation  
X Final Regulation  
Final Regulation with Notice of Proposed Rulemaking Omitted  
120-day Emergency Certification of the Attorney General  
120-day Emergency Certification of the Governor  
Delivery of Tolled Regulation  
a. With Revisions b. Without Revisions

RECEIVED  
2003 SEP 17 PM 3:04  
INDEPENDENT REGULATORY REVIEW COMMISSION

**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
9/17/03		HERSHEY HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
9/17/03		DALEY
9/17/03		WAUGH SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
9/17/03		O'PAKE
9/17/03		INDEPENDENT REGULATORY REVIEW COMMISSION
_____	_____	ATTORNEY GENERAL (for Final Omitted only)
_____	_____	LEGISLATIVE REFERENCE BUREAU (for Proposed only)

September 15, 2003