

<h1>Regulatory Analysis Form</h1>		<p>This space for use by IRRC</p>
<p>(1) Agency</p> <p>Department of Agriculture</p>		<p>IRRC Number: 2255</p>
<p>(2) I.D. Number (Governor's Office Use)</p> <p>2-137</p>		
<p>(3) Short Title</p> <p>The Food Code</p>		
<p>(4) PA Code Cite</p> <p>7 Pa. Code Chapter 46</p>	<p>(5) Agency Contacts &amp; Telephone Numbers</p> <p>Primary Contact: Sheri Dove: (717) 772-8353</p> <p>Secondary Contact: Lenchen Radle: (717) 772-3234</p>	
<p>(6) Type of Rulemaking (check one)</p> <p>Proposed Rulemaking <input checked="" type="checkbox"/> XXX</p> <p>Final Order Adopting Regulation</p> <p>Final Order, Proposed Rulemaking Omitted</p>	<p>(7) Is a 120-Day Emergency Certification Attached?</p> <p>No <input checked="" type="checkbox"/> XXX</p> <p>Yes: By the Attorney General</p> <p>Yes: By the Governor</p>	
<p>(8) Briefly explain the regulation in clear and nontechnical language.</p> <p>This regulation would draw 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.</p> <p>The regulation would bring the Commonwealth's food safety standards into step with the current national standards for food safety set forth in the 1999 edition of the United States Public Health Service Food Code ("1999 Federal Recommended Food Code").</p> <p>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.</p> <p>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 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.</p>		

(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.

### Regulatory Analysis Form

(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 establishments" will be required to comply with the regulation. "Food establishments" 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 1999 Federal Recommended Food Code ("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 § 46.104 (relating to definitions), and is used in the regulation at § 46.390 (relating to additional safeguards for a food facility that serves a highly susceptible population).

(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.



**FACE SHEET  
FOR FILING DOCUMENTS  
WITH THE LEGISLATIVE REFERENCE  
BUREAU**

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#2255

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

*Cristina L. Caputo*

By: (Deputy Attorney General)

FEB 01 2002

DATE OF APPROVAL

☒ Check if applicable  
Copy not approved. Objections attached.

Copy below is hereby certified to be true and  
correct copy of a document issued, prescribed or  
promulgated by:

DEPARTMENT OF AGRICULTURE

DOCUMENT/FISCAL NOTE NO. 2-137

DATE OF ADOPTION Dec. 12, 2001

BY *Samuel E. Hayes, Jr.*  
Samuel E. Hayes, Jr. Secretary

TITLE

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

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

*Sandra W. Stoner*

*1/8/02*  
DATE OF APPROVAL

(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 Proposed Rulemaking**

Title 7 - AGRICULTURE  
7 Pa. Code Chapter 46

The Food Code

**PROPOSED RULEMAKING**  
**DEPARTMENT OF AGRICULTURE**  
**THE FOOD CODE**  
**[7 PA. CODE CH. 46]**

The Department of Agriculture (Department) proposes to adopt new regulations at 7 Pa. Code Chapter 46, to read as set forth in Annex A. The Department also proposes to rescind 7 Pa. Code 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 (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.

## ***Purpose***

This regulation would draw 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 would bring the Commonwealth's food safety standards into step with the current national standards for food safety set forth 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 Food Act or a "public eating and drinking place" as described in the Public Eating and Drinking Places Law. For this reason, the regulation 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 regulation 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 regulation, as well as the administrative requirements of the Department.

The standards set forth in the proposed regulation 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 regulation presents a set of standards with which a large segment of the 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 regulation.

The food safety standards set forth in the proposed regulation 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 regulation. The Department is also satisfied the proposed regulation meets the requirements of Executive Order No. 1996-1, "Regulatory Review and Promulgation."

### ***Overview of the Major Provisions of the Proposed Rulemaking***

Proposed § 46.104 (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 Food Act or the Public Eating and Drinking Places 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 §§ 46.302 (relating to food sources) through 46.312 (relating to game animals) would establish limitations and restrictions with respect to the sources from which a food facility may obtain various foods.

Proposed §§ 46.314 (relating to receiving temperature of food) through 46.323 (relating to shellstock: maintaining identification) 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 §§ 46.330 (relating to preventing contamination from food employees' hands) through 46.344 (relating to refilling returnables) 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 §§ 46.345 (relating to food storage) through 46.352 (relating to miscellaneous sources of contamination) would establish requirements to help prevent contamination of food from the premises of the food facility or from contact with consumers.

Proposed §§ 46.353 (relating to cooking raw animal foods) through 46.357 (relating to reheating food) 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 § 46.356 (relating to parasite destruction in fish other than molluscan shellfish by freezing) would establish specific freezing time/temperature requirements and record keeping requirements for fish.

Proposed §§ 46.360 (relating to stored frozen food) through 46.364 (relating to potentially hazardous food: hot and cold holding) 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 regulation 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 § 46.370 (relating to variance requirement for specialized processing methods).

Proposed § 46.376 (relating to labeling) would require particular label information on packaged foods and certain bulk foods. Proposed § 46.377 (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 § 46.390 (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. These provisions are at proposed §§ 46.501 (relating to sources of drinking water) through 46.506 (relating to distribution, delivery and retention of water). 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 Food Act or the license required of a public eating or drinking place under the Public Eating or Drinking Places Law.

### ***Affected Individuals and Organizations***

The proposed regulation 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 regulation, would also be affected by the regulation. 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 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 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 the Commonwealth are currently meeting these standards or would have relatively little difficulty meeting them. In addition, the proposed 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. This savings is 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 the Commonwealth. This should result in some indeterminate cost savings to the general public.

#### ***Paperwork Requirements***

The proposed regulation 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 this regulation on an ongoing basis.

#### ***Public Comment Period/Contact Person***

Interested persons are invited to submit written comments regarding the proposed regulations 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***

The Department submitted a copy of the proposed regulation to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs on February 8, 2002, in accordance with section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)). 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.

If IRRC has an objection to any portion of the proposed regulation, 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 regulation.

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SAMUEL E. HAYES, Jr., *Secretary*



## **Annex "A"**

### **Title 7. Agriculture.**

#### **CHAPTER 46. THE FOOD CODE**

<b>Subchapter</b>	<b>Sec.</b>
A. Purpose and Definitions .....	46.101
B. Management and Personnel .....	46.201
C. Food .....	46.301
D. Equipment, utensils and linens .....	46.401
E. Water, Plumbing, and Waste .....	46.501
F. Physical Facilities .....	46.601
G. Poisonous or Toxic Materials .....	46.701
H. Administrative Procedures .....	46.801

##### **Subchapter A. PURPOSE AND DEFINITIONS**

<b>Sec.</b>	<b>Title.</b>
46.101.	Title.
46.102.	Purpose.
46.103.	Scope.
46.104.	Definitions.

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

###### **SUPERVISION**

<b>Sec.</b>	<b>Title.</b>
46.201.	Designation of person in charge.
46.202.	Duties of the person in charge.

###### **EMPLOYEE HEALTH**

46.203.	Duty to report disease or medical condition.
46.204.	Diseases or medical conditions that must be reported.
46.205.	Duty to impose exclusions and restrictions.
46.206.	Duty to comply with exclusions and restrictions.
46.207.	Removing exclusions and restrictions.

###### **PERSONAL CLEANLINESS**

46.210.	Cleanliness of hands and exposed portions of arms.
46.211.	Duty of food employees to wash.

- 46.212. Required washing locations.
- 46.213. Hand sanitizers.
- 46.214. Cleanliness of fingernails.
- 46.215. Jewelry.
- 46.216. Cleanliness of outer clothing.

#### **HYGIENIC PRACTICES**

- 46.220. Food contamination prevention.
- 46.221. Hair restraints.
- 46.222. Animals.

### **Subchapter C. FOOD**

#### **CHARACTERISTICS**

- 46.301. Food must be safe, unadulterated and honestly presented.

#### **FOOD SOURCES**

- 46.302. Food sources.
- 46.303. Food prepared in a private home.
- 46.304. Packaged food.
- 46.305. Whole-muscle, intact beef.
- 46.306. Packaged meat and poultry that is not a ready-to-eat food.
- 46.307. Food in a hermetically sealed container.
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## **Subchapter A. PURPOSE AND DEFINITIONS**

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### **§ 46.101. Title.**

The provisions of this chapter shall be known as the Food Code.

### **§ 46.102. 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.

### **§ 46.103. 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.

### **§ 46.104. Definitions.**

The following terms, when used in this chapter, have the following meanings:

*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 shall 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 Food Act (31 P.S. § 20.11). This paragraph 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 Food Act, (31 P.S. § 20.11), except that, where 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 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 shall, notwithstanding the provisions of section 11 of the Food Act and this paragraph, 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 Food Act (31 P.S. § 20.11) 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 Food Act (31 P.S. § 20.11) 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 Food Act (31 P.S. § 20.11) 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.

*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.

*CFR or Code of Federal Regulations* - The Code of Federal Regulations. The compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government.

*CIP or 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.

*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. The term includes black, white, and intermediate grays. The term does not include any materials, which the Secretary of Agriculture, by regulation, determines is used, or intends to be used, solely for a purpose or purposes other than coloring. This term shall 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 2 or more types of meat that have been reduced in size and combined, such as sausages made from 2 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, non-respiring 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.

***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.

***EPA*** - The Environmental Protection Agency of the United States of America.

***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* -

- (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 such animals), other than birds or mammals, if such 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 2 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 1 or more people 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 Act* - The act of July 7, 1994 (P.L. 421, No. 70), as amended (31 P.S. §§ 20.1-20.18).

*Food additive* - 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:

- (i) 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.
- (ii) 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.

The term does not include the following:

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

(ii) 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.

(iii) A color additive.

(iv) Any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to a statute repealed by the Food Act, pursuant to the Poultry Products Inspection Act (Public Law 85-172, 21 U.S.C. § 451 et. seq.) or pursuant to the Wholesome Meat Inspection Act (Public Law 90-201, 21 U.S.C. § 601 et. seq.).

(v) A new animal drug.

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

*Food establishment* - 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. 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 the USDA regulations at 9 CFR Subchapter A, Part 301 (Mandatory Meat Inspection) or any subsequent revision or restatement thereof.

(C) Poultry, as that term is used in the USDA regulations at 9 CFR Subchapter C, Part 381 (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 the Federal regulations at 40 CFR § 152.175, or any subsequent revision or restatement thereof.

*HACCP or 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 an 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 either or both 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 such liquid or purée. This definition does not apply to standards of identity established by 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.



*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 § 46.312(b) and (c) (relating to game animals).

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

*Milk Sanitation Law* - The act of July 2, 1935 (P.L. 589, No. 210), as amended (31 P.S. Sec. 645 *et. seq.*)

*Modified atmosphere packaging* - 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. Modified atmosphere packaging 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* - Any 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.

*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 non-durable 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* - The act of November 10, 1999 (P.L. 491, No. 45) (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.

*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.

***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, 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 the USDA regulations at 9 CFR Subchapter C, Part 381 (Mandatory Poultry Products Inspection) 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 at 9 CFR Subchapter

C, Part 362 (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 Places Law* - The act of May 23, 1945, as amended (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 Places Law.

*Public eating or drinking place* - A place within this Commonwealth where food or drink is served to or provided for the public, with or without charge: Provided, however, That nothing herein contained shall 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. The term includes collection, treatment, storage and distribution facilities under control of the operator of the system and used in connection with the system. 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 § 46.353 (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, and

(ii) A process as specified in subparagraph (i) of this definition 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 § 14(a) of the Food Act (31 P.S. § 20.14(a)).

**Restricted use pesticide** - A pesticide classified for restricted use under § 3(d) of the Federal Insecticide, Fungicide and Rodenticide Act of 1947, as amended (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 § 409 or § 706 of the Federal Food, Drug, and Cosmetic Act (21 USCA § 301).

(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 5 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 Agriculture of the Commonwealth 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 such things 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 the provisions of 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:

- (i) Is legally responsible for the operation of the food facility such as the owner, owner's agent, or other person; and
- (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 §§ 46.402(a) (relating to materials in multiuse utensils and food contact surfaces), 46.410(a) (relating to durability and strength) and 46.411(a) and (b) (relating to 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 re-used to cook non-potentially 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 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**

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## **§ 46.201. 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.

## **§ 46.202. 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 § 46.611(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 in order 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 §§ 46.420 (relating to accuracy of temperature measuring devices for food) and 46.477(b) (relating 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 § 46.377 (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 § 46.343 (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**

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

(a) *Responsibility of a food facility operator to require reporting.* A food facility operator shall require any food employee and any 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 § 46.204 (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 § 46.204 (relating to diseases or medical conditions that must be reported).

### **§ 46.204. 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.

## **§ 46.205. 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 § 46.204(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 § 46.204(3) or (4) (relating to diseases or medical conditions that must be reported).

(ii) Not experiencing a symptom of acute gastroenteritis specified in § 46.204(3) (relating to diseases or medical conditions that must be reported), 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 § 46.204(3) (relating to diseases or medical conditions that must be reported) and meets any of the high-risk conditions specified in § 46.204(5), (6), (7) or (8) (relating to diseases or medical conditions that must be reported).

(2) Is not experiencing a symptom of acute gastroenteritis specified in § 46.204(3) (relating to diseases or medical conditions that must be reported), 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.

## **§ 46.206. 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 § 46.205 (relating to duty to impose exclusions and restrictions).

## **§ 46.207. Removing exclusions and restrictions.**

(a) *Disease or medical condition described in § 46.204(1).* A person in charge may remove an exclusion imposed as a result of a disease or medical condition described in § 46.204(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 § 46.205(a)(2)(i).* A person in charge may remove a restriction imposed under authority of § 46.205(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 § 46.204(3) and (4) (relating to diseases or medical conditions that must be reported), 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 § 46.203(3) and (4) (relating to diseases or medical conditions that must be reported).

(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 § 46.205(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 § 46.205(a)(2)(ii) (relating to duty to impose exclusions and restrictions) 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 § 46.205(b).* A person in charge may remove an exclusion or restriction imposed as a result of a disease or medical condition described in § 46.205(b) (relating to duty to impose exclusions and restrictions) 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 § 46.205(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 § 46.205(c) (relating to duty to impose exclusions and restrictions) 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**

### **§ 46.210. 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 § 46.508(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.

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

Food employees shall clean their hands and exposed portions of their arms as specified in § 46.210 (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 § 46.222(b) (relating to animals).

(5) Except as specified in § 46.220(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.

#### **§ 46.212. Required washing locations.**

Food employees shall clean their hands in a handwashing lavatory or approved automatic handwashing facility. Food employees shall 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.

#### **§ 46.213. 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 (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 (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 (Substances Generally Recognized as Safe), 21 CFR 184 (Direct Food Substances Affirmed as Generally Recognized as Safe), or 21 CFR 186 (Indirect Food Substances Affirmed as Generally Recognized as Safe for Use in Contact with Food).

(iii) Be limited to situations where use is followed by a thorough hand rinsing in clean water before hand contact with food, or where 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 § 46.210(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.

#### **§ 46.214. 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 shall not wear fingernail polish or artificial fingernails when working with exposed food.

#### **§ 46.215. Jewelry.**

Food employees shall 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.

#### **§ 46.216. 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**

### **§ 46.220. Food contamination prevention.**

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

(1) *General prohibition.* An employee 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 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 shall not work with exposed food; clean equipment, utensils and linens; or unwrapped single-service or single-use articles.

### **§ 46.221. 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.

### **§ 46.222. Animals.**

(a) *Circumstances under which handling of animals is prohibited.* Food employees 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 § 46.641 (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 §§ 46.210(b) (relating to cleanliness of hands and exposed portions of arms) and 46.211(4) (relating to duty of food employees to wash).

## **Subchapter C. FOOD**

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#### **CHARACTERISTICS**

##### **§ 46.301. Food must be safe, unadulterated and honestly presented.**

Food shall be safe, unadulterated and - in accordance with § 46.375(b) (relating to accurate representation) - honestly presented.

#### **FOOD SOURCES**

##### **§ 46.302. Food sources.**

Food shall be obtained from sources that comply with the Food Act, the Public Eating and Drinking Places Law and this chapter.

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

Food prepared in a private home, not approved by the department, shall not be used or offered for human consumption in a food facility.

#### **§ 46.304. Packaged food.**

Packaged food shall be labeled as specified in the Food Act, this chapter, 21 CFR 101 (Food Labeling), 9 CFR 317 (Labeling, Marking Devices, and Containers) and 9 CFR 381, Subpart N (Labeling and Containers).

#### **§ 46.305. 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 § 46.353(c) (relating to cooking raw animal foods) shall be either 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.

#### **§ 46.306. 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 Food Act, including 9 CFR 317.2(I) (Labels) and 9 CFR 381.125(b) (Label Requirements).

#### **§ 46.307. 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.

### **§ 46.308. Milk and milk products.**

Milk and milk products shall be obtained from sources that comply with the Pennsylvania Milk Sanitation Law (31 P.S. §§ 645 - 660g).

### **§ 46.309. Fish.**

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

- (1) Commercially and legally caught or harvested.
- (2) Approved for sale or service.

(b) *Non-molluscan fish for raw consumption.* Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified in § 46.353(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 § 46.356(a) and (b) (relating to parasite destruction in fish other than molluscan shellfish by freezing); or frozen on the premises as specified in § 46.356(a) and (b) and records are retained as specified in § 46.356(c).

### **§ 46.310. Molluscan shellfish.**

(a) *Sources.* Molluscan Shellfish shall be obtained from sources according to the Food Act and this chapter, and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(b) *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 shall not be received for sale or service.

### **§ 46.311. 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.

#### **§ 46.312. 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 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 or rabbits that are "inspected and certified" in accordance with the Rabbit Inspection Program established in 9 CFR 354.

(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 both of the following are accurate:

(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 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.

(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 all of 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 shall not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 (Endangered and Threatened Wildlife and Plants).

### **§ 46.313. Ice.**

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

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

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

(a) *Refrigerated potentially hazardous food.* Except as specified in § 46.316(b) (relating to receiving shell eggs) and 46.317(b) (relating to 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 §§ 46.353 (relating to cooking raw animal foods), 46.354 (relating to microwave cooking) and 46.355 (relating to 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.

### **§ 46.315. Additives.**

Food shall not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170-180 (Food Additives), generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186 (Food Substances Generally Recognized as Safe), substances that exceed amounts specified in 9 CFR 318.7 (Approval of Substances for Use in the Preparation of Products), or pesticide residues that exceed provisions specified in 40 CFR 185 (Tolerances for Pesticides in Food).

### **§ 46.316. Receiving shell eggs.**

(a) *General.* Shell eggs shall be received clean and sound and 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).

(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 (relating to standards for grading and marketing eggs) and include safe handling instructions as specified in 21 CFR 101.17(h) (Food Labeling).

### **§ 46.317. 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 (Cheeses and Related Cheese Products).

### **§ 46.318. 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.

### **§ 46.319. 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 (one-half gallon): the "sell by" date.

(3) For packages with a capacity of 1.87 L (one-half 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 Food Act (31 P.S. § 20.6).

#### **§ 46.320. 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), (iii) and (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 Food 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 paragraph (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 subparagraphs (a)(2)(i) and (ii), individual dealer tags or labels need not be provided.

#### **§ 46.321. 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.

#### **§ 46.322. Molluscan shellfish: original container.**

(a) *General requirement.* Molluscan shellfish 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 § 46.320 (relating to shellstock identification) and recorded as specified in § 46.323 (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 occur:

(1) The labeling information for the shellfish on display as specified in § 46.319 (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; and

(2) The shellfish are protected from contamination.

### **§ 46.323. 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 paragraph (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 1 tagged or labeled container at a time.

(ii) Using more than 1 tagged or labeled container at a time and obtaining a variance from the department as specified in § 46.803(a) (relating to variances) based on a HACCP plan that:

(A) Is submitted by the permit holder and approved as specified in § 46.803(b) (relating to variances).

(B) Preserves source identification by using a record keeping system as specified in paragraph (b)(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**

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

(a) *Hand washing required.* Food employees shall wash their hands as specified in § 46.210 (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 § 46.336 (relating to washing raw fruits and vegetables) or when otherwise approved, food employees shall not contact exposed, ready-to-eat food with their bare hands, unless hands have been washed as specified in § 46.210(b) (relating to cleanliness of hands and exposed portions of arms) 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.

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

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

## **PREVENTING FOOD AND INGREDIENT CONTAMINATION**

### **§ 46.332. 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 both of 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 46.481(a) (relating to frequency of cleaning equipment food-contact surfaces and utensils) and sanitizing as specified in § 46.489(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 § 46.633 (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 § 46.336 (relating to washing raw fruits and vegetables).

(b) *Exception to the requirement of storing foods in packages, covered containers or wrappings.*  
Paragraph (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 § 46.363(d)(2) (relating to potentially hazardous food: cooling).

(5) Shellstock.

#### **§ 46.333. 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.

#### **§ 46.334. 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 § 46.353(a)(1) or (2) (relating to cooking raw animal foods).

(2) Included in § 46.353(d) (relating to cooking raw animal foods).

#### **§ 46.335. 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 § 46.315 (relating to additives).

(b) *Sulfiting agents.* A food employee shall not:

(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 B<sub>1</sub>, as that term is defined in 21 CFR § 101.54(c) (Nutrient Content Claims); or

(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.

#### **§ 46.336. 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 § 46.713(b) (relating to chemicals: use criteria).

#### **§ 46.337. Preventing contamination from ice used as a coolant.**

(a) *Ice used as exterior coolant is prohibited as ingredient.* Ice 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 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) 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**

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

Food shall only contact surfaces of equipment and utensils that are cleaned as specified in §§ 46.480 (relating to objective of cleaning equipment and utensils) through 46.488 (relating to

washing returnable containers for refilling), and sanitized as specified in § 46.489 (relating to sanitization: requirement, frequency and methods).

#### **§ 46.339. 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 §§ 46.481 (relating to frequency of cleaning equipment food-contact surfaces and utensils) and 46.489(b) (relating to 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 § 46.481(d)(7) (relating to frequency of cleaning equipment food-contact surfaces and utensils)

#### **§ 46.340. Linens and napkins: use limitations.**

Linens and napkins shall 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.

#### **§ 46.341. 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 § 46.490(b)(4) (relating to requirement and frequency of laundering) stored in a chemical sanitizer at a concentration specified in § 46.474(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.

#### **§ 46.342. 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 §§ 46.353 (relating to cooking raw animal foods) through 46.357 (relating to reheating food), 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 shall not be used in direct contact with food unless the food is subsequently cooked as required in §§ 46.353 (relating to cooking raw animal foods) through 46.357 (relating to reheating food), such as frozen food or a primal cut of meat.

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

(a) *General.* A food employee 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 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 § 46.432(1), (2) and (4) (relating to dispensing equipment: protection of equipment and food).



#### **§ 46.344. Refilling returnables.**

(a) *Refilling with potentially hazardous food prohibited.* A take-home food container returned to a food facility 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 § 46.488(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 § 46.432(1), (2) and (3) (relating to dispensing equipment: protection of equipment and food).

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

#### **§ 46.345. 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 § 46.446 (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 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 source of contamination.

#### **§ 46.346. 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.

#### **§ 46.347. Food preparation.**

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

### **PREVENTING CONTAMINATION BY CONSUMERS**

#### **§ 46.348. 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.

#### **§ 46.349. 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.

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

(a) *Raw, unpackaged animal foods.* Raw, unpackaged animal food (such as beef, lamb, pork, poultry, and fish) shall not be offered for consumer self-service. This Paragraph 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.

#### **§ 46.351. 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 shall not be offered as food for human consumption.

(b) *Exception for certain foods and packages.* Except as specified in § 46.390(c) (relating to additional safeguards for a food facility that serves a highly susceptible population), 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.

#### **§ 46.352. Miscellaneous sources of contamination.**

Food shall be protected from contamination that may result from a factor or source not specified in §§ 46.330 (relating to preventing contamination from food employees' hands) through 46.351 (relating to returned food and reservice of food).

### **DESTRUCTION OF ORGANISMS OF PUBLIC HEALTH CONCERN**

#### **§ 46.353. Cooking raw animal foods.**

(a) *General cooking requirement.* Except as specified in subsections (b), (c) and (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 subparagraphs (2) and (3), and subsection (b), fish, meat, and pork, including game animals commercially raised for food as specified in § 46.312(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 § 46.312(a) (relating to game animals); and raw eggs that are not broken and prepared in response to a consumer's order and for immediate service:

<i>Minimum Temperature</i>	<i>Minimum Time</i>
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 § 46.312(b) and (c) (relating to game animals), 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:

<i>Oven Type</i>	<i>Oven Temperature for Roast Weighing Weighing less than 4.5 kg (10 lbs.)</i>	<i>Oven Temperature for Roast Weighing 4.5 kg (10 lbs.) or more</i>
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:

<i>Minimum Temperature</i>	<i>Minimum Time</i>
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 all of the following occur:

(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 § 46.305 (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 § 46.377 (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 subsections (a) or (b) as specified in § 46.803(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 § 46.803(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.

## **§ 46.354. Microwave cooking.**

Raw animal foods cooked in a microwave oven shall be all of the following:

(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.

#### **§ 46.355. 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).

#### **§ 46.356. 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:

(1) -20°C (-4°F) or below for 168 hours (7 days) in a freezer; or

(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).

#### **§ 46.357. 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 § 46.364(a)(2) or (3) (relating to potentially hazardous food: hot and cold holding) and 74°C (165°F) 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 § 46.354 (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 § 46.353(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 § 46.353(b).

## **TEMPERATURE AND TIME CONTROL FOR LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN**

### **§ 46.360. Stored frozen food.**

Stored frozen foods shall be maintained frozen.

### **§ 46.361. 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 § 46.364(a)(3) (relating to potentially hazardous food: hot and cold holding).

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

### **§ 46.362. 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 § 46.364(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 § 46.364(a)(3) (relating to potentially hazardous food: hot and cold holding).

(ii) A period of time that does not allow thawed portions of a raw animal food requiring cooking as specified in § 46.353(a) or (b) (relating to cooking raw animal foods) to be above 5°C (41°F), or 7°C (45°F) as specified in § 46.364(a)(3) (relating to potentially hazardous food: hot and cold holding) 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 § 46.364(a)(3) (relating to potentially hazardous food: hot and cold holding).

(3) As part of a cooking process if the food that is frozen is one of the following:

(i) Cooked as specified in § 46.353(a) or (b) (relating to cooking raw animal foods) or § 46.354 (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.

### **§ 46.363. Potentially hazardous food: cooling.**

(a) *Cooling cooked potentially hazardous food.* Cooked potentially hazardous food shall be cooled:

(1) Within 2 hours, from 60°C (140°F) to 21°C (70°F); and

(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 § 46.364(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 § 46.364(a)(3) (relating to potentially hazardous food: hot and cold holding) 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 § 46.345(a)(2), during the cooling period to facilitate heat transfer from the surface of the food.

#### **§ 46.364. 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 § 46.353(b) (relating to cooking raw animal foods) or reheated as specified in § 46.357(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 § 46.433(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 within 5 years of the department's adoption 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 shall in no way 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 must 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 § 46.363(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 - shall not be used as the public health control for raw eggs.

## **SPECIALIZED PROCESSING METHODS**

### **§ 46.370. Variance requirement for specialized processing methods.**

A food facility shall obtain a variance from the department as specified in § 46.803(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.

### **§ 46.371. 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 § 46.370 (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 § 46.811(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 (Approval of Substances for Use in the Preparation of Products) and 9 CFR 381.147 (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 § 46.811(b)(4) (relating to HACCP plans).

(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**

### **§ 46.375. Accurate representation.**

(a) *Standards of Identity.* Packaged food shall comply with standard of identity requirements in the following:

(1) The Food Act.

(2) 21 CFR 131-169 (Definitions) and 9 CFR 319 (Standards of Identity or Composition) and any subsequent amendment or revision thereof.

(3) 21 CFR 130 (Food Standards: General) and any subsequent amendment or revision thereof.

(4) 9 CFR 319 Subpart A (General) and any subsequent amendment or revision thereof.

(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 shall not be used to misrepresent the true appearance, color, or quality of a food.

### **§ 46.376. Labeling.**

(a) *Labels required on packaged foods.* Food packaged in a food facility shall be labeled as specified in The Food Act, 21 CFR 101 (Food Labeling), 9 CFR 317 (Labeling, Marking Devices, and Containers) and 9 CFR 381 Subpart N (Labeling and Containers) and any subsequent amendment or revision thereof.

(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 § 403(Q)(3)-(5) of the Federal Food, Drug, and Cosmetic Act, nutritional labeling as specified in 21 CFR 101 (Food Labeling) and 9 CFR 317 Subpart B (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 either of the following information 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 paragraphs (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 paragraphs (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 shall not be concealed or altered.

### **§ 46.377. Consumer advisory required with respect to animal foods that are raw, undercooked or not otherwise processed to eliminate pathogens.**

Except as specified in § 46.353(c) and (d)(3) (relating to cooking raw animal foods) and in § 46.390(d) (relating to 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 such foods in raw or undercooked form.

## **CONTAMINATED FOOD**

### **§ 46.380. 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 § 46.301 (relating to food must 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 §§ 46.302 (relating to food sources) through 46.312 (relating to game animals)

(3) Ready-to-eat food that may have been contaminated by an employee that has been restricted or excluded as specified in § 46.205 (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**

### **§ 46.390. 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, Section 101.17(g) (Food Labeling), shall 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 shall not be re-served.

(d) *Prohibited ready-to-eat foods.* In a food facility that serves a highly susceptible population, the following foods shall 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) shall 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 § 46.353(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 § 46.353(a)(2) (relating to cooking raw animal foods).

(iv) Contains the information specified in § 46.811(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.

- 46.401. Acceptability of food equipment certified or classified for sanitation by an ANSI-accredited certification program.

#### **MATERIALS FOR USE IN CONSTRUCTION AND REPAIR**

- 46.402. Materials in multiuse utensils and food contact surfaces.  
46.403. Materials for surfaces that are nonfood-contact surfaces.  
46.404. Single-service and single-use articles: required characteristics.

#### **DESIGN AND CONSTRUCTION**

- 46.410. Durability and strength.  
46.411. Cleanability of multiuse food-contact surfaces and CIP equipment.  
46.412. "V" threads: use limitation.  
46.413. Cleanability of hot oil filtering equipment, can openers, nonfood-contact surfaces, kick plates and ventilation hood systems.

#### **ACCURACY**

- 46.420. Accuracy of temperature measuring devices for food.  
46.421. Accuracy of temperature measuring devices for ambient air and water.  
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#### **FUNCTIONALITY**

- 46.430. Ventilation hood systems, drip prevention.  
46.431. Equipment openings, closures and deflectors.  
46.432. Dispensing equipment: protection of equipment and food.  
46.433. Vending machines.  
46.434. Bearings and gear boxes: leakproof.  
46.435. Beverage tubing: separation.  
46.436. Ice units: separation of drains.  
46.437. Condenser unit: separation.  
46.438. Molluscan shellfish tanks.  
46.439. Temperature measuring devices.  
46.440. Warewashing machines.  
46.441. Manual warewashing machines.  
46.442. Warewashing sinks and drainboards: self-draining.  
46.443. Equipment compartments: drainage.  
46.444. Case lot handling equipment: moveability.

#### **NUMBERS AND CAPACITIES OF EQUIPMENT**

- 46.450. Cooling, heating and holding capacities.  
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## **NUMBERS AND CAPACITIES OF UTENSILS, TEMPERATURE MEASURING DEVICES AND TESTING DEVICES**

- 46.460. Consumer self-service utensils.
- 46.461. Food temperature measuring devices.
- 46.462. Temperature measuring devices for manual warewashing.
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## **LOCATION AND INSTALLATION OF EQUIPMENT**

- 46.465. Location of equipment, clothes washers and dryers and storage cabinets to prevent contamination.
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## **MAINTENANCE AND OPERATION OF EQUIPMENT**

- 46.471. Equipment: good repair and proper adjustment.
- 46.472. Cutting surfaces.
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- 46.475. Mechanical warewashing equipment.
- 46.476. Manual warewashing equipment.

## **MAINTENANCE AND OPERATION OF UTENSILS AND TEMPERATURE AND PRESSURE MEASURING DEVICES**

- 46.477. Utensils and temperature and pressure measuring devices: repair and calibration.
- 46.478. Single-service and single-use articles.
- 46.479. Mollusk and crustacean shells used as serving containers.

## **CLEANING OF EQUIPMENT AND UTENSILS**

- 46.480. Objective of cleaning equipment and utensils.
- 46.481. Frequency of cleaning equipment food-contact surfaces and utensils.
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- 46.484. Methods of cleaning.
- 46.485. Washing: loading of soiled items into warewashing machines.
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- 46.489. Sanitization: requirement, frequency and methods.

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- 46.490. Requirement and frequency of laundering.
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## **PROTECTION OF CLEAN ITEMS**

46.493. Drying clean equipment and utensils.

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46.495. Lubricating and reassembling clean food contact surfaces and equipment.

46.496. Storing clean items.

46.497. Handling clean items.

## **GENERAL STANDARD**

### **§ 46.401. 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 §§ 46.402 (relating to materials in multiuse utensils and food contact surfaces) through 46.446 (relating to case lot handling equipment: moveability).

## **MATERIALS FOR USE IN CONSTRUCTION AND REPAIR**

### **§ 46.402. 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 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 non-absorbent.
- (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 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:

<i>Utensil Category</i>	<i>Description</i>	<i>Maximum Lead in Mg/L (ppm)</i>
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) 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 pre-fermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

(e) *Galvanized metal: use limitation.* Galvanized metal 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 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% 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% shall not be used as a food-contact surface.

(i) *Wood: use limitation.* Except as specified in paragraphs (1), (2) and (3), wood and wood wicker 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, 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 (Preservative 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 non-scoring or non-scratching utensils and cleaning aids.

#### **§ 46.403. 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.

#### **§ 46.404. 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 shall not allow the migration of deleterious substances, or impart colors, odors, or tastes to food.

### **DESIGN AND CONSTRUCTION**

#### **§ 46.410. 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 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.

#### **§ 46.411. Cleanability of multiuse food-contact surfaces and CIP equipment.**

(a) 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.* Paragraph (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 paragraphs (a)(1) through (a)(5) 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.

#### **§ 46.412. "V" threads: use limitation.**

Except for hot oil cooking or filtering equipment, "V" type threads shall not be used on food-contact surfaces.

#### **§ 46.413. 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 § 46.411 (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 § 46.411(a)(5) (relating to cleanability of multiuse food-contact surfaces and CIP equipment) 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**

### **§ 46.420. 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.

### **§ 46.421. 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.

### **§ 46.422. 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**

### **§ 46.430. 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.

### **§ 46.431. 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 (two-tenths 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).

### **§ 46.432. 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.

### § 46.433. 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.

(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 § 46.364(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 shall 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 paragraph (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 one-sixteenth 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 one-sixteenth 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 one-half 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 one-sixteenth inch.

**§ 46.434. 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.

**§ 46.435. Beverage tubing: separation.**

Beverage tubing and cold-plate beverage cooling devices 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.

**§ 46.436. Ice units: separation of drains.**

Liquid waste drain lines shall not pass through an ice machine or ice storage bin.

**§ 46.437. 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.

#### **§ 46.438. Molluscan shellfish tanks.**

(a) *General.* Except as specified in subsection (b), molluscan shellfish life support system display tanks 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 both of the following:

(1) A variance granted by the department in accordance with the procedure described in § 46.803(a) (relating to variances).

(2) A HACCP plan that is submitted by the food facility operator and approved as specified in § 46.803(b) (relating to variances), 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 § 46.323 (relating to shellstock: maintaining identification)

#### **§ 46.439. 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.

#### **§ 46.440. 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 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 one-fourth inch Iron Pipe Size (IPS) valve. This subsection does not apply to a machine that uses only a pumped or recirculated sanitizing rinse.

#### **§ 46.441. Manual warewashing machines.**

If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be both of the following:

(1) Designed with an integral heating device that is capable of maintaining water at a temperature not less than 77°C (171°F).

(2) Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

**§ 46.442. Warewashing sinks and drainboards: self-draining.**

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

**§ 46.443. 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.

**§ 46.444. 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**

**§ 46.450. 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.

**§ 46.451. Manual warewashing: sink compartment requirements.**

(a) *General: three compartments required.* Except as specified in subsection (c), a sink with at least 3 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) 2-compartment sinks as specified in subsection (d).

(6) Receptacles that substitute for the compartments of a multi-compartment sink.

(d) *Use of two compartment sink.* A 2-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 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 § 46.476(e) (relating to manual warewashing equipment), or a hot water sanitization immersion step is used as specified in § 46.487(3) (relating to rinsing procedures).

#### **§ 46.452. 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.

#### **§ 46.453. 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.

#### **§ 46.454. 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 shall 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 § 46.494 (relating to wiping cloths: air-drying locations).

## **NUMBERS AND CAPACITIES OF UTENSILS, TEMPERATURE MEASURING DEVICES AND TESTING DEVICES**

### **§ 46.460. 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).

### **§ 46.461. 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.

### **§ 46.462. 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.

### **§ 46.463. 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**

### **§ 46.465. 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 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.

#### **§ 46.466. 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 one thirty-second 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 paragraphs (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**

### **§ 46.471. 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 §§ 46.401 (relating to acceptability of food equipment certified or classified for sanitation by an ANSI-accredited certification program) through 46.446 (relating to case lot handling equipment: moveability).

(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.

### **§ 46.472. 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.



### § 46.473. Microwave ovens.

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 (Microwave Ovens).

### § 46.474. 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 § 46.452 (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 § 46.451(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 § 46.489(c)(3) (relating to sanitization: requirement, frequency and methods) shall be listed in 21 CFR 178.1010 (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:

<i>Minimum Concentration</i>	<i>Minimum Temperature for Solution with pH of 10 or less</i>	<i>Minimum Temperature for Solution with pH of 8 or less</i>
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.

#### **§ 46.475. 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 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 multi-tank, conveyor, multi-temperature 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 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 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 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.

#### **§ 46.476. Manual warewashing equipment.**

(a) *Warewashing sinks: use limitation.* A warewashing sink shall 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 § 46.474(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 § 46.489 (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**

### **§ 46.477. 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 §§ 46.401 (relating to acceptability of food equipment certified or classified for sanitation by an ANSI-accredited certification program) through 46.446 (relating to case lot handling equipment: moveability) 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.

### **§ 46.478. Single-service and single-use articles.**

(a) *Required use.* A food facility without facilities specified in §§ 46.480 (relating to objective of cleaning equipment and utensils) through 46.489 (relating to sanitization: requirement, frequency and methods) 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 shall not be reused.

(2) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.

### **§ 46.479. Mollusk and crustacean shells used as serving containers.**

Mollusk and crustacean shells shall not be used more than once as serving containers.

## **CLEANING OF EQUIPMENT AND UTENSILS**

### **§ 46.480. 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 surfaces.* Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris.

#### **§ 46.481. 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.* Paragraph (a)(1) does not apply if the food-contact surface or utensil is in contact with a succession of different raw animal foods each requiring a higher cooking temperature as specified in § 46.353 (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), 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 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 following chart 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:

<i>Temperature</i>	<i>Cleaning Frequency</i>
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 § 46.484(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.

#### **§ 46.482. 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 § 46.481(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.

#### **§ 46.483. Frequency of cleaning nonfood-contact surfaces.**

Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

#### **§ 46.484. 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 shall 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 shall 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.

#### **§ 46.485. 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.

#### **§ 46.486. 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 § 46.451(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 § 46.484(c)(1) (relating to methods of cleaning).

#### **§ 46.487. 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 3-compartment sink.

(ii) Alternative manual warewashing equipment equivalent to a 3-compartment sink as specified in § 46.451(c) (relating to manual warewashing: sink compartment requirements).

(iii) A 3-step washing, rinsing, and sanitizing procedure in a warewashing system for CIP equipment.



(2) Use of a detergent-sanitizer as specified in § 46.476(f) (relating to manual warewashing equipment) if using either of the following:

(i) Alternative warewashing equipment as specified in § 46.451(c) (relating to manual warewashing: sink compartment requirements) that is approved for use with a detergent-sanitizer.

(ii) A warewashing system for CIP equipment.

(3) Use of a non-distinct water rinse that is integrated in the hot water sanitization immersion step of a 2-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 non-distinct 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 non-distinct water rinse that is integrated in the application of the sanitizing solution.

#### **§ 46.488. 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 § 46.344(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**

### **§ 46.489. 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 § 46.476(d) (relating to manual warewashing equipment).

(2) In hot water mechanical operations: by being cycled through equipment that is set up as specified in § 46.475(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 § 46.474(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 § 46.474(d)(1) (relating to warewashing equipment: mechanical or manual).

(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**

### **§ 46.490. 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 § 46.342(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 § 36.340 (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.

### **§ 46.491. 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 § 46.454(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 § 46.474(a) (relating to warewashing equipment: mechanical or manual).

### **§ 46.492. 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**

### **§ 46.493. 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 (Sanitizing Solutions) before contact with food.

(b) *Cloth drying.* After cleaning and sanitizing, equipment and utensils shall not be cloth-dried, except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

### **§ 46.494. 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 § 46.454(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 § 46.474(d) (relating to warewashing equipment: mechanical or manual).

### **§ 46.495. 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.

### **§ 46.496. 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 § 46.446 (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 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.

## **§ 46.497. 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 pre-wrapped 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.

- 46.501. Sources of drinking water.
- 46.502. Drinking water system flushing and disinfection.
- 46.503. Bottled drinking water.
- 46.504. Quality of water.
- 46.505. Quantity and availability of water: capacity and pressure.
- 46.506. Distribution, delivery and retention of water.

### **PLUMBING SYSTEM**

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### **MOBILE WATER TANK AND MOBILE FOOD FACILITY WATER TANK**

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- 46.520. Capacity and drainage of a sewage holding tank in a mobile food facility.
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### **REFUSE, RECYCLABLES AND RETURNABLES**

- 46.525. Storage areas and receptacles for refuse, recyclables and returnables: materials, design, construction and installation.

- 46.526. Storage areas and receptacles for refuse, recyclables and returnables: numbers and capacities.
- 46.527. Location of storage areas, redeeming machines, receptacles and waste handling units.
- 46.528. Operation and maintenance of storage areas, redeeming machines, receptacles and waste handling units.
- 46.529. Removal of refuse, recyclable and returnables.
- 46.530. Facilities for disposal and recycling refuse, recyclables and returnables.

## **WATER**

### **§ 46.501. 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, Safe Drinking Water, which are regulations of the Pennsylvania Department of Environmental Protection. 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 non-community water system as defined in 25 Pa. Code Chapter 109, Safe Drinking Water.

### **§ 46.502. 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.

### **§ 46.503. 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, Safe Drinking Water.

### **§ 46.504. 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, Safe Drinking Water.

(b) *Nondrinking Water.*

- (1) A non-drinking water supply shall be used only if approved by the department.

(2) Non-drinking water shall be used only for non-culinary 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 (relating to safe drinking water) for a transient non-community public water system that serves 25 people daily. All analytical work must be performed in accordance with 25 Pa. Code Chapter 109, Safe Drinking Water.

(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 Pennsylvania Department of Environmental Protection approved self-contained public water system shall maintain test result records in accordance with 25 Pa. Code Chapter 109 (relating to safe drinking water).

#### **§ 46.505. 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 § 46.506(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.

#### **§ 46.506. 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 Pennsylvania 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 (relating to safe drinking water):

(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 §§ 46.501 (relating to sources of drinking water) through subsection (a) of this section 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**

### **§ 46.507. 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.

### **§ 46.508. 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, or 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 shall 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 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.

#### **§ 46.509. 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 § 46.510(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 1 toilet and not fewer than the toilets (and urinals, if used) required by the department or the Pennsylvania Department of Labor and Industry shall be provided.

(c) *Utility sink.* At least 1 utility sink or 1 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 § 46.508(c) (relating to design, construction and installation of plumbing systems).

(2) Installing an approved backflow prevention device as specified in § 46.508(d) (relating to design, construction and installation of plumbing systems).

#### **§ 46.510. 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.

#### **§ 46.511. 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 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 shall not create a cross connection by connecting a pipe or conduit between the drinking water system and a non-drinking water system or a water system of unknown quality.

(2) The piping of a non-drinking 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**

### **§ 46.515. 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.

(3) Finished to have a smooth, easily cleanable surface.

### **§ 46.516. 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 (one-half 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 non-absorbent.
- (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.

#### **§ 46.517. 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 (three-fourths 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.

#### **§ 46.518. 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 § 46.517(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**

#### **§ 46.520. 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 percent 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.

#### **§ 46.521. 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 § 46.508(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 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 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.

**§ 46.522. Disposal of sewage and non-sewage.**

*(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 non-sewage liquids and rainwater shall be drained from point of discharge to disposal according to the Pennsylvania Construction Code Act.

## **REFUSE, RECYCLABLES AND RETURNABLES**

### **§ 46.525. 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 §§ 46.601 (relating to indoor areas of food facilities: surface characteristics), 46.610 (relating to cleanability of floors, walls and ceilings) and 46.611(e) and (f) (relating to 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 non-absorbent 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 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 on-site 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.

### **§ 46.526. 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.

#### **§ 46.527. 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.

#### **§ 46.528. 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 § 46.525(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) 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 § 46.640(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 § 46.521(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.

## **§ 46.529. 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.

## **§ 46.530. 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.

- 46.601. Indoor areas of food facilities: surface characteristics.
- 46.602. Outdoor areas of food facilities: surface characteristics.

#### **DESIGN, CONSTRUCTION, AND INSTALLATION**

- 46.610. Cleanability of floors, walls and ceilings.
- 46.611. Functionality of various physical facilities of a food facility.

#### **NUMBERS AND CAPACITIES**

- 46.620. Handwashing facilities: numbers and capacities.
- 46.621. Toilets and urinals: numbers and capacities.
- 46.622. Lighting: intensity.
- 46.623. Mechanical ventilation as needed.
- 46.624. Requirement and designation of dressing areas and storage areas.
- 46.625. Utility sinks.

#### **LOCATION AND PLACEMENT**

- 46.630. Handwashing facilities: located for convenience.
- 46.631. Toilet rooms: located for convenience.
- 46.632. Employee accommodations: located to prevent contamination.
- 46.633. Distressed merchandise: segregated.
- 46.634. Refuse, recyclables and returnables: receptacles, waste handling units and designated storage areas.

#### **MAINTENANCE AND OPERATION**

- 46.640. Premises, structures, attachments and fixtures: methods.
- 46.641. Limitations on animals.

## **MATERIALS FOR CONSTRUCTION AND REPAIR**

### **§ 46.601. 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.

### **§ 46.602. 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**

### **§ 46.610. 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 anti-slip floor coverings or applications may be used for safety reasons.

**(b) *Utility lines.***

- (1) Utility service lines and pipes in a food facility 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 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 (one thirty-second 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 shall 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 shall not be exposed in areas subject to moisture. This requirement does not apply to temporary food facilities.

#### **§ 46.611. 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), (3), (4) and (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) screens.
- (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, 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 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 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**

### **§ 46.620. Handwashing facilities: numbers and capacities.**

(a) *Minimum number.* Handwashing facilities shall be provided in a food facility as specified in § 46.509(a) (relating to numbers and capacities of plumbing facilities).

(b) *Availability of handwashing cleanser.* Each handwashing lavatory or group of 2 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, shall not be provided with the handwashing aids and devices required for a handwashing lavatory as specified in subsections (b) and (c) and § 46.526(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 § 46.526(a)(3) (relating to storage areas and receptacles for refuse, recyclables and returnables: numbers and capacities).



#### **§ 46.621. Toilets and urinals: numbers and capacities.**

(a) *Minimum number.* Toilets and urinals shall be provided in a food facility as specified in subsection 46.509(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.

#### **§ 46.622. 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.

#### **§ 46.623. 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.

#### **§ 46.624. 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.

## **§ 46.625. Utility sinks.**

A utility sink or curbed cleaning facility shall be provided as specified in § 46.509(c) (relating to numbers and capacities of plumbing facilities).

## **LOCATION AND PLACEMENT**

### **§ 46.630. Handwashing facilities: located for convenience.**

Handwashing facilities in a food facility shall be conveniently located as specified in § 46.510(a) (relating to location and placement of plumbing facilities).

### **§ 46.631. Toilet rooms: located for convenience.**

Toilet rooms in a food facility shall be conveniently located and accessible to employees during all hours of operation.

### **§ 46.632. 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.

### **§ 46.633. 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.

### **§ 46.634. 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 § 46.527 (relating to location of storage areas, redeeming machines, receptacles and waste handling units)

## MAINTENANCE AND OPERATION

### § 46.640. 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 shall 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 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 paragraph (c)(2), sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials 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 § 46.511(a) (relating to operation and maintenance of plumbing facilities).

(i) *Closing toilet room doors.* Toilet room doors as specified in § 46.611(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 § 46.715(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.

## **§ 46.641. Limitations on animals.**

(a) *General.* Live animals 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 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.

46.701. Poisonous or toxic substances: original containers to display identifying information.

46.702. Poisonous or toxic substances: working containers labeled with common name.

### **OPERATIONAL SUPPLIES AND APPLICATIONS**

46.710. Poisonous or toxic substances: storage.

46.711. Poisonous or toxic substances: limitations on presence and use.

46.712. Prohibition of use of poisonous or toxic material containers to store food.

46.713. Chemicals: use criteria.

46.714. Lubricants that have incidental contact with food: criteria.

46.715. Pesticides.

46.716. Medicines.

46.717. First aid supplies: storage.

46.718. Other personal care items: storage.

## **STOCK AND RETAIL SALE**

46.720. Storage and display: separation of poisonous or toxic materials from food.

## **LABELING AND IDENTIFICATION**

### **§ 46.701. 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.

### **§ 46.702. 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**

### **§ 46.710. 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.

### **§ 46.711. 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) *The 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.

#### **§ 46.712. Prohibition of use of poisonous or toxic material containers to store food.**

A container previously used to store poisonous or toxic materials shall not be used to store, transport, or dispense food.

#### **§ 46.713. Chemicals: use criteria.**

(a) *Sanitizers.* Chemical sanitizers and other chemical anti-microbials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010 (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 (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 (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 (Substances Generally Recognized as Safe), or 21 CFR 184 (Direct Food Substances Affirmed as Generally Recognized as Safe).

(ii) Generally recognized as safe for the intended use as specified in 21 CFR 186 (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 (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 (Indirect Food Additives).

(v) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 (Threshold of Regulation for Substances Used in Food-Contact Articles); and

(2) When sanitization is with chemicals, the approval required in subparagraphs (1)(iii) or (1)(v), or the regulation as an indirect food additive required in Subparagraph (1)(iv), shall be specifically for use with chemical sanitizing solutions.

#### **§ 46.714. Lubricants that have incidental contact with food: criteria.**

Lubricants shall meet the requirements specified in 21 CFR 178.3570 (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.

#### **§ 46.715. Pesticides.**

(a) *Restricted use pesticides: criteria.* Restricted use pesticides specified in § 46.711(d) (relating to poisonous or toxic substances: limitations on presence and use) shall meet the requirements of a restricted use pesticide as specified in 7 Pa. Code § 128.2 (relating to definitions). This regulation requires restricted use pesticides be one of the following:

(1) Classified for restricted use under § 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 § 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 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.

#### **§ 46.716. 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 § 46.701 (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 both of 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.

#### **§ 46.717. 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 § 46.701 (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.

#### **§ 46.718. Other personal care items: storage.**

Except as specified in § 46.716(b) (relating to medicines) and 46.717 (relating to first aid supplies: storage), employees shall store their personal care items in facilities as specified in § 46.624(b) (relating to requirement and designation of dressing areas and storage areas).

## **STOCK AND RETAIL SALE**

### **§ 46.720. 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**

Sec.

- 46.801. Application for intended purpose: public health protection.
- 46.802. Access to food facilities.
- 46.803. Variances.

### **PLAN SUBMISSION AND APPROVAL**

- 46.810. Facility and operating plans.
- 46.811. HACCP plans.
- 46.812. Confidentiality of trade secrets.
- 46.813. Preoperational inspection of construction.

### **REQUIREMENTS FOR OPERATION**

- 46.820. Requirement: permit, license or registration.
- 46.821. Application procedure for appropriate permit, license or registration.
- 46.822. Issuance.
- 46.823. Conditions of retention: responsibilities of the food facility operator.

## **CHAPTER APPLICABILITY**

### **§ 46.801. Application for intended purpose: public health protection.**

The department shall apply this chapter to promote its underlying purpose - as specified in § 46.102 (relating to purpose) - of safeguarding public health and ensuring that food is safe, unadulterated and honestly presented when offered to the consumer.

### **§ 46.802. 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 Places Law, the Food Act and any other relevant statutory or regulatory authority, during the food facility's hours of operation and other reasonable times.

### **§ 46.803. 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 shall 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 § 46.811(a)(1) (relating to HACCP plans) - that includes the information specified in § 46.811(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 § 46.811(a) (relating to HACCP plans), the food facility operator shall do the following:

(1) Comply with the HACCP plans and procedures that are submitted as specified in § 46.811(b) (relating to HACCP plans) and approved as a basis for the modification or waiver.

(2) Maintain and provide to the department, upon request, records specified in § 46.811(b)(4) and (5) (relating to HACCP plans) that demonstrate that all of 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**

### **§ 46.810. 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 Places Law to have plans and specifications reviewed by the department shall 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 § 46.811(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 the provisions of 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.

## **§ 46.811. 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 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 a HACCP plan is required according to applicable Federal or state laws.

(ii) A variance is required as specified in §§ 46.370 (relating to variance required for specialized processing methods), 46.438(b) (relating to molluscan shellfish tanks), 46.323(b)(2)(ii) (relating to shellstock: maintaining identification) or 46.353(d)(3) (relating to cooking raw animal foods).

(iii) The department determines that a food preparation or processing method requires a variance based on a plan submittal specified in § 46.810(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 § 46.361 (relating to reduced oxygen packaging).

### ***(b) Contents of a HACCP plan.*** For a food facility that is required in subsection (a) to have 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.

(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.

### **§ 46.812. Confidentiality of trade secrets.**

The department shall 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 § 46.810(b) (relating to facility and operating plans) and § 46.811(b) (relating to HACCP plans).

### **§ 46.813. Preoperational inspection of construction.**

The department shall 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 § 46.803 (relating to variances). The department shall also verify the food facility is otherwise in compliance with this chapter and the Public Eating and Drinking Places Law.

## **REQUIREMENTS FOR OPERATION**

### **§ 46.820. Requirement: permit, license or registration.**

A person shall not operate a food facility without a valid permit, license or registration issued by the department.

### **§ 46.821. 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.

### **§ 46.822. Issuance.**

(a) *New, converted or remodeled food facilities.*

(1) For food facilities that are required to submit plans as specified in § 46.810(a) (relating to facility and operating plans), the department shall 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 § 46.813 (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 § 46.810(a) (relating to facility and operating plans), the department shall 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 must 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 must 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 non-transferable. New owners must apply to the department in accordance with § 46.821 (relating to application procedure for appropriate permit, license or registration).

### **§ 46.823. Conditions of retention: responsibilities of the food facility operator.**

In order 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 the provisions of this chapter - including the conditions of a granted variance as specified in § 46.803(c) (relating to variances) - and approved plans as specified in § 46.810(b) (relating to facility and operating plans).
- (3) If a food facility is required in § 46.811(a) (relating to HACCP plans) to operate under a HACCP plan, comply with the plan as specified in § 46.803(c) (relating to variances).

(4) Immediately contact the department to report an illness of an employee as specified in § 46.203(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 Places Law or the Food Act until approval is obtained from the department.

(7) Allow representatives of the secretary access to the food facility as specified in §46.802 (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 § 46.364(a)(3) (relating to potentially hazardous food: hot and cold holding) within 5 years after the effective date of this chapter, if the circumstances specified in subparagraphs (8)(i) and (ii) do not occur first, and unless a variance has been approved as specified in § 46.803 (relating to variances).

(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 Places Law or the Food Act.



COMMONWEALTH OF PENNSYLVANIA



GOVERNOR'S OFFICE OF GENERAL COUNSEL

DEPARTMENT OF AGRICULTURE

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February 8, 2002

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The Independent Regulatory Review Commission  
14<sup>th</sup> Floor  
333 Market Street  
Harristown #2  
Harrisburg, PA 17120

**Re: NOTICE OF PROPOSED RULEMAKING**  
**Department of Agriculture**  
**7 Pa. Code Chapter 46**  
**The Food Code**  
**I.D. No. 2-137**

Dear Sirs:

Please find enclosed copies of the Face Sheet, Preamble, Annex "A" and Regulatory Analysis Form with respect to the above proposed regulation.

Copies of these documents have been submitted to the majority and minority chairpersons of the House and Senate Agriculture and Rural Affairs Committees and to the Legislative Reference Bureau on this date.

The proposed regulation will be published in the February 23, 2002 edition of the *Pennsylvania Bulletin*. If I may be of further information, please advise.

Sincerely,

A handwritten signature in cursive script, reading "Dwight Jared Smith".

Dwight Jared Smith  
Assistant Counsel

Enclosures

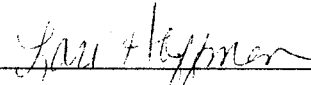


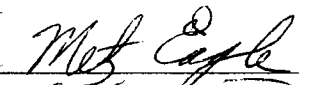
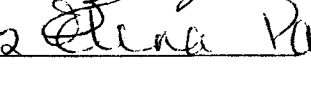
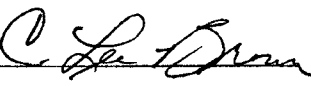
**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

I.D. NUMBER: 2-137  
SUBJECT: The Food Code  
AGENCY: DEPARTMENT OF AGRICULTURE

**TYPE OF REGULATION**

X Proposed Regulation  
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

**FILING OF REGULATION**

DATE	SIGNATURE		DESIGNATION
2/8/02		Bunt	HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
2/8		Daley	
2/8/02		Boyer	SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
		O'Pake	
2-8-02		Vasquez	INDEPENDENT REGULATORY REVIEW COMMISSION
			ATTORNEY GENERAL
2/8/02			LEGISLATIVE REFERENCE BUREAU

February 5, 2002