

**RULES  
OF  
ALABAMA STATE BOARD OF HEALTH  
BUREAU OF ENVIRONMENTAL SERVICES  
CHAPTER 420-3-20  
FOOD PROCESSING ESTABLISHMENT SANITATION  
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**420-3-20-.01 General Provisions.**

**(1) Purpose.** The criteria in these rules shall apply in determining whether the facilities, methods, practices, and controls used in the manufacture, processing, packing, or holding of food are in conformance with, or are operated or administered in conformity with, good manufacturing practices to assure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions.

**(2) Statutory Authority.** The State Board of Health is authorized to adopt and promulgate these rules under and by virtue of the authority of Code of Ala. 1975, §§ 22-2-2(6), 22-2-5, and 22-20-5.

**(3) Definitions.** For the purposes of these rules:

(a) **Adulterated Food** means any food that bears or contains any poisonous or deleterious substance which may render it injurious to health; or if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or if it is otherwise defined as adulterated under § 402(A) of the Food, Drug, and Cosmetic Act (21 USC § 342).

(b) **Board** means the Board of Health of the State of Alabama as defined by Code of Ala. 1975, § 22-2-1, or the State Health Officer or his or her designee,

when acting for the Board, or for the purposes of these rules, the Alabama Department of Public Health's Bureau of Environmental Services.

(c) **CFR** means Code of Federal Regulations. Citations in this rule to the CFR refer sequentially to the Title, Part, and Section numbers, such as 21 CFR 110.80 refers to Title 21, Part 110, Section 80.

(d) **Department** means the Alabama Department of Public Health.

(e) **Employee** means the permit holder, individuals having supervisory or management duties, and any other person working in a food processing establishment.

(f) **Food** means any raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale, in whole or in part, for human consumption, or chewing gum.

(g) **Food Processing Establishment** means a commercial food processing establishment, plant, or operation that manufactures, packages, labels, or stores food for human consumption and does not provide food directly to a consumer. *The term does not include a food service establishment or a retail food store in which such foods are processed if:*

*i. The food items are sold to, or sold from, no more than two other retail food establishments during the annual period coinciding with the food permit issuance and expiration date, and*

*ii The total value of food sales to other retail establishments during the annual period coinciding with the food permit issuance and expiration date is less than \$25,000.00.*

The term includes stand-alone ice manufacturing facilities that require servicing by entering (walking inside) the ice manufacturing facility.

(h) **Health Officer** means the Health Officer, or his or her designee, of the county or district in which the food processing establishment in question is located as provided in Code of Ala. 1975, § 22-3-2.

(i) **Label** means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement of these rules that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article, or is easily legible through the outside container or wrapper.

(j) **Labeling** means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

(k) **Law** includes federal, state and local statutes, ordinances and rules.

(l) **Permit** means the document issued by the Health Officer which authorizes a person to operate a food processing establishment.

(m) **Person** includes any individual, partnership, corporation, association, or other legal entity.

(n) **Person in Charge** means the individual present in a food processing establishment who is the apparent supervisor of the food processing establishment at the time of inspection. If no individual is the apparent supervisor, then any employee present is the person in charge.

(o) **Potentially Hazardous Food** means a food that requires temperature control to limit pathogenic microorganism growth or toxin formation and includes an animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, or garlic-in-oil mixtures that are not modified in a way that result in mixtures that do not support pathogenic microorganism growth or toxin formation. The term does not include a food that, due to any combination of intrinsic and extrinsic factors, does not support the growth or toxin formation of pathogenic microorganisms.

(p) **Priority Category 1 Food Processing Establishment** means any food processing establishment producing foods that, in final packaged form, do not require refrigeration to prevent growth of pathogenic microorganisms or do not require a specialized process under 21 CFR 113, 114, 120, or 123 for food manufacturing.

(q) **Priority Category 2 Food Processing Establishment** means an establishment which manufactures a food product that:

1. In final packaged form is a potentially hazardous food requiring refrigeration to prevent growth of pathogenic microorganisms, or
2. Includes a specialized process for food manufacturing or production required in 21 CFR Part 113 (thermally processed low acid foods), 21 CFR Part 114 (acidified foods), 21 CFR Part 120 (Hazard Analysis Critical Control Point [HACCP] plan required), or 21 CFR Part 123 (seafood HACCP plan required).

(r) **Priority Item** means a provision of these rules that, if in non-compliance, is likely to be a direct cause of food adulteration, contamination, or illness. Priority item provisions are listed in Appendix A.

(s) **Raw Agricultural Commodity** means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. Fish and fishery products are not to be considered as raw agricultural commodities.

**(4) Exclusions.** Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities, as defined in Rule 420-3-20-.01(03)(s), which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the public for consumption, are not covered by the provisions of these rules.

**Authors:** Ronald Dawsey, Mitzi Waldo.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010. Amend: Filed November 19, 2014; effective date December 24, 2014.

#### **420-3-20-.02 Adoption by Reference**

**(1) Adoption by reference of 21 CFR parts 1 through 100.** The following listed parts of Title 21 Code of Federal Regulations, Parts 1 through 100, 2013 Revision, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, are hereby incorporated by reference and made a part of these rules as if set out in full and all provisions thereof are adopted as rules of the State Board of Health.

- (a) Parts 1.20 through 1.24 (accurate labeling).
- (b) Parts 7.1 through 7.13 (guaranty).
- (c) Parts 7.40 through 7.59 (recalls).
- (d) Parts 70.20 through 70.25 (packaging and labeling requirements for colors).
- (e) Parts 73.1 through 73.615 (listing of color additives exempt from certification).
- (f) Parts 74.101 through 74.706 (listing of color additives subject to certification).
- (g) Part 81 (general specifications and restrictions for provisional color additives).
- (h) Parts 82.3 through 82.706 (listing of certified provisionally listed colors and specifications).
- (i) Part 100.155 (labeling of iodized salt).

**(2) Adoption by reference of 21 CFR Parts 101 through 190.** Except as excluded in Rule 420-3-20-.02(3), Title 21, Code of Federal Regulations, Parts 101 to 190, 2013 Revision, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, is hereby incorporated by reference and made a part of these rules as if set out in full and all provisions thereof are adopted as rules of the State Board of Health.

**(3) Exclusion.** This adoption by reference of Title 21, Code of Federal Regulations, Chapter 1, Subchapter B, Parts 101 to 190, 2013 Revision, promulgated by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, specifically excludes these parts:

- (a) Part 101.69 (refers to application to FDA for nutrient labeling).
- (b) Part 101.108 (refers to FDA food labeling experiments).

- (c) Part 102.19 (refers to petitions to FDA for food names).
- (d) Part 106.120 (refers to infant formula quality procedures).
- (e) Part 107.200 (refers to FDA-mandated recall of infant formula).
- (f) Part 107.280 (refers to records retention of FDA-mandated recall of infant formula).
- (g) Part 108 except Parts 108.25 and 108.35 (refers to FDA emergency permit control).
- (h) Part 111 (refers to dietary supplements).
- (i) Part 118 (refers to shell egg producers).
- (j) Part 130.5-6 (refers to FDA procedure for establishing a food standard).
- (k) Part 130.17 (refers to FDA allowance for temporary food standards).
- (l) Part 170.6 (refers to FDA opinion letters on food additives).
- (m) Parts 170.15 and 170.17 (refers to FDA commissioner).

**(4) Availability.** The above referenced Title 21, Code of Federal Regulations, is available at the office of Director, Division of Food, Milk, and Lodging, RSA Tower, Suite 1250, 201 Monroe Street, Montgomery, Alabama 36104.

**(5) Control.** Where there is inconsistency between Chapter 420-3-20 and parts incorporated by reference of Title 21 Code of Federal Regulations, Parts 1 to 190, 2013 Revision, these rules control. Where these rules are silent, those parts incorporated by reference of Title 21 Code of Federal Regulations, Parts 1 to 190, 2013 Revision, control.

**Authors:** Ronald Dawsey, Mitzi Waldo.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010. Amend: Filed November 19, 2014; effective date December 24, 2014.

#### **420-3-20-.03 Special Provisions.**

**(1) Enforcement of certain parts reserved.** Due to special circumstances, enforcement of Title 21, Code of Federal Regulations Parts 123, 131, 133, 135, and 161 is reserved for the State Health Officer.

#### **(2) Water and plumbing.**

(a) When a sample of a non-public water system shows coliform present as reported by the Alabama Department of Public Health's Bureau of Clinical Laboratories, a resample shall be taken within seven days. Whenever two consecutive samples taken on separate days show coliform present, the permit to operate shall be suspended by the Health Officer in accordance with Rule 420-3-20-.04(3). A sample result of coliform absent with no confluent growth is required prior to reinstatement of the permit.

(b) Plumbing standards, sizes, and numbers, other than when a minimum is specified in these rules, are enforced by local plumbing officials.

**(3) Labels.** Any word, statement, or other information required to appear on the label shall not be considered to be in compliance unless such word, statement, or other information appears on the outside container or wrapper of the retail package of such article, or is easily legible through the outside container or wrapper. Food labeling required by these rules shall not be false or misleading.

**(4) Multiple food establishments located at a shared physical facility.** Multiple food establishments located at a shared physical facility shall submit as part of the application for a permit a plan of operations specifying how each permitted establishment's food processing operation is separated by time or space from other food processing operations. Failure to operate in accordance with the approved plan of operations shall be cause for permit suspension under Rule 420-3-20-.04.

**Authors:** Ronald Dawsey, Mitzi Waldo.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010. Amend: Filed November 19, 2014; effective date December 24, 2014.

#### **420-3-20-.04 Permits.**

**(1) General.** It shall be unlawful for any person to operate a food processing establishment unless such person possesses a valid permit issued by the Health Officer for the operation of such establishment. Only persons who comply with the provisions of these rules shall be entitled to receive and retain such a permit. Permits shall not be transferable with respect to person, food processing establishment, or location. The permit shall be kept posted in a conspicuous place within the food processing establishment, but shall remain the property of the Health Department.

#### **(2) Issuance of permits.**

(a) Any person desiring to operate a food processing establishment shall make written application for a permit on forms provided by the Department. Such application shall include the name and address of each applicant, the location and type of the proposed food processing establishment, and the signature of each applicant. The permits shall be applied for and issued on forms prescribed by the Board. Permits shall automatically expire on the date upon which state, county, and municipal annual privilege licenses expire or on a date designated by the Health Officer, and shall be renewable each year upon written application from the permit holder within 90 days prior to the stated date of expiration and upon compliance with these rules.

(b) Prior to approval of an application for a permit, the Health Officer shall inspect the proposed food processing establishment or review the most recent twelve months inspection history to determine compliance with the requirements of these rules.

(c) The Health Officer may issue a permit to the applicant if his or her inspection or review of the inspection history reveals that the proposed food processing establishment complies with the requirements of these rules.

(d) It shall be unlawful for the operator of a food processing establishment to distribute products in commerce if the operator does not possess a valid permit.

(e) The Department is hereby authorized to function as a clearinghouse for information concerning compliance of Alabama food processing establishments which distribute products in intercounty or interstate commerce.

(f) The Health Officers of recipient counties are hereby authorized to prohibit the sale and distribution of all products from any food processing establishment located outside their jurisdiction which does not hold a valid permit.

**(3) Permit denials, suspensions, and revocations.** The Health Officer's denial, suspension, and/or revocation of a permit shall be governed by the Alabama Administrative Procedure Act, Code of Ala. 1975, § 41-22-1, et seq., and the State Board of Health's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code.

**(4) Hearings.** Contested case hearings shall be provided in accordance with the Alabama Administrative Procedure Act, Code of Ala. 1975, § 41-22-1, et seq., and the State Board of Health's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code. Informal settlement conferences may be conducted as provided in the State Board of Health's Rules for Hearing of Contested Cases, Chapter 420-1-3, Ala. Admin. Code.

**(5) Suspension of permits.** Permits may be temporarily suspended by an emergency order of the Health Officer for a permit holder's failure to comply with one or more requirements of these rules that pose an imminent hazard to the public's health.

**(6) Revocation of permits.** The Health Officer may, after providing opportunity for hearing, revoke a permit for serious or repeated violations of any of the requirements of these rules or for interference with the Health Officer in the performance of his or her duties or for failure to comply with the provisions of a notice of permit suspension issued pursuant to Rule 420-3-20-.04(5).

**(7) Application after revocation.** Whenever the revocation of a permit has become final, the holder of the revoked permit may make written application for a new permit after 90 days from the date of revocation.

**(8) Service of notice.** A notice provided for in these rules is properly served when it is delivered to the permit holder or the person in charge, or when it is sent by registered or certified mail, return receipt requested, to the last known address of the permit holder. A copy of the notice shall be filed in the records of the Health Officer.

**Authors:** Ronald Dawsey, Mitzi Waldo.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010. Amend: Filed November 19, 2014; effective date December 24, 2014.

#### **420-3-20-.05 Inspections.**

**(1) Inspection frequency.** Food processing establishments shall be inspected:

(a) At least two times each year with a maximum lapse of 210 days between inspections for Priority Category 1 food processing establishments.

(b) At least four times each year with a maximum lapse of 120 days between inspections for Priority Category 2 food processing establishments.

(c) Establishments with less than a satisfactory compliance level on the most recent inspection as evidenced by observations of ten or more enumerated violations shall be inspected again within 10 days.

(d) Legal notices shall be issued when priority items including: food source and condition; potentially hazardous food temperatures; facilities to maintain product temperature; failure to follow a HACCP plan when such plan is required by these rules; infected persons; good hygienic practices; sanitization; water supply; sewage; cross connections, back-siphonage and back-flow; toilet and handwashing facilities; vermin control; and toxic items are violated. Necessary reinspections shall be made in accordance with Rule 420-3-20-.05(4).

(e) Additional inspections of food processing establishments shall be performed as often as necessary for the enforcement of these rules.

**(2) Access.** The Health Officer, after proper identification, shall be permitted to enter any food processing establishment at any reasonable time for the purpose of making inspections to determine compliance with these rules. The Health Officer shall be permitted to examine the records of the establishment to obtain information pertaining to food and supplies purchased, received, or used, or to



persons employed, copy records if necessary as part of an inspection or investigation, and to make photographs for documentation purposes.

**(3) Report of inspections.** Whenever an inspection of a food processing establishment is made, the findings shall be recorded on the inspection report form prescribed by the Board. Inspection remarks shall be written to reference, by rule number, the rule violated and shall state the corrections to be made. The original of the inspection report form shall be conspicuously displayed for public view within the establishment. A copy of the inspection report shall be filed with the records of the County Health Department. The completed inspection report form is a public document that shall be made available for public disclosure.

**(4) Correction of violations.**

(a) The complete inspection report form shall specify a reasonable period of time for the correction of the violations found; and correction of the violations shall be accomplished within the period specified, in accordance with the following provisions:

1. If an imminent health hazard exists, such as extended interruption of electrical or water service, complete lack of refrigeration, complete lack of hot water under pressure when required for sanitary operation, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health, the establishment shall immediately cease operations. Operations shall not be resumed until authorized by the Health Officer. *A permit holder need not discontinue operations in an area of an establishment if, in the opinion of the Health Officer, the area is unaffected by the imminent health hazard.*

2. Violations of priority items shall be corrected as soon as possible, but in any event, within 10 days following the inspection.

3. All other items shall be corrected as soon as possible, but in any event, by the time of the next routine inspection.

(b) The inspection report shall state that failure to comply with any time limits to take corrective actions may result in a proposed suspension or revocation of the permit.

(c) A deviation from a required HACCP plan that has been corrected, with the corrective action documented by the time of the inspection, is not considered a violation. This allowance does not preclude the Health Officer from taking necessary action under 420-3-20-.06 if potentially contaminated food has entered commerce.

**(5) Surveys and training.** The Department shall make Food Processing Establishment Sanitation Surveys and Program Evaluations as deemed necessary by the Board. The survey shall be made in accordance with these rules, and the results shall be incorporated in the Annual Alabama Public Health Report. The Department shall provide education and training in food processing establishment sanitation; in standardized inspection techniques; in enforcement procedures; and issue rule interpretations as needed.

**Authors:** Ronald Dawsey, Mitzi Waldo.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010. Amend: Filed November 19, 2014; effective date December 24, 2014.

#### **420-3-20-.06 Examination and Condemnation of Food.**

(a) Food may be examined or sampled by the Health Officer as often as necessary for enforcement of these rules.

(b) The Health Officer may, upon written notice to the owner or person in charge of the establishment and specifying with particularity the reason therefore, place a hold order on any food which he or she believes to be in violation of these rules. The Health Officer shall tag, label, or otherwise identify any food subject to the hold order.

(c) No food subject to a hold or do not sell order shall be used or moved from the establishment. The Health Officer shall permit storage of the food under conditions specified in the hold order, unless storage is not possible without risk to the public's health, in which case the food shall be destroyed in accordance with Code of Ala. 1975, § 22-10-3.

(d) The hold or do not sell order shall state that a request for hearing may be filed within 15 days and that if no hearing is requested, the food shall be destroyed. If a request for hearing is received, the hearing shall be held in accordance with the Board's Rules for Hearing Contested Cases.

(e) Nothing in these rules shall be construed to prevent the Health Officer from imposing additional requirements to protect against a potential health hazard, including removing from sale or distribution in commerce a potentially adulterated food, or misbranded or mislabeled food, when, in his/her opinion, such additional requirements are necessary to protect public health.

**Authors:** Ronald Dawsey, Mitzi Waldo.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010. Amend: Filed November 19, 2014; effective date December 24, 2014.

**420-3-20-.07 Food Processing Establishments Outside the Jurisdiction of the Health Officer.** Food from food processing establishments outside the jurisdiction of the State Health Officer may be sold within Alabama if such establishments conform to the provisions of these rules or to substantially equivalent rules or regulations. To determine the extent of compliance with such provisions, the State Health Officer may accept reports from responsible authorities in other jurisdictions where such food processing establishments are located.

**Author:** Ronald Dawsey

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010.

**420-3-20-.08 Review of Plans.**

**(1) Submission of plans.**

(a) Whenever a food processing establishment is constructed or remodeled and whenever an existing structure is converted for use as a food processing establishment, properly prepared plans and specifications for such construction, remodeling, or conversion shall be submitted to the Health Officer for review and approval before construction, remodeling, or conversion is begun.

(b) The plans and specifications shall indicate the proposed layout, arrangement, mechanical plans, and construction materials of work areas, and the type and model of proposed fixed equipment and facilities and, upon request of the Health Officer, a description or list of the foods to be processed, packaging labels to be used, and processing steps for the food.

(c) The Health Officer shall approve the plans and specifications if they meet the requirements of these rules. No food processing establishment shall be constructed, remodeled, or converted except in accordance with plans and specifications approved by the Health Officer.

(d) Plans shall be reviewed within 20 working days after receipt, including receipt of any required fees. Confidential material submitted to the Health Officer must be treated in accordance with the provisions of Code of Ala. 1975, § 36-12-40.

**(2) Preoperational inspection.** Whenever plans and specifications are required to be submitted to the Health Officer, he or she shall inspect the food processing establishment prior to the start of operations to determine compliance with the approved plans and specifications.

**Author:** Ronald Dawsey

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010.

**420-3-20-.09 Procedure When Infection Is Suspected.** When the Health Officer has reasonable cause to suspect possible disease transmission by one or more employees of a food processing establishment, he or she shall secure a morbidity history of the suspected employee or make any other investigation as indicated and shall take appropriate action. The Health Officer may require any or all of the following measures:

- (1) The immediate exclusion of the employee(s) from employment in food processing establishments.
- (2) The immediate closure of the food processing establishment concerned until, in the opinion of the Health Officer, no further danger of disease outbreak exists.
- (3) Restriction of the employee's or employees' services to some area of the establishment where there would be no danger of transmitting disease.
- (4) Adequate medical and laboratory examination of the employee(s) and of his or her body discharges.

**Author:** Ronald Dawsey

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010.

**420-3-20-.10 Repealer.** Except for those rules promulgated under the authority of Code of Ala. 1975, §§ 22-21-20, et seq., all rules promulgated by the Board which are in conflict with these rules or any portion thereof are hereby expressly repealed.

**Author:** Ronald Dawsey

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2(6), 22-20-5.

**History:** Filed March 23, 1984. Repeal and replace filed November 19, 2010; effective date December 24, 2010.

**CHAPTER 420-3-20  
FOOD PROCESSING ESTABLISHMENT SANITATION**

**APPENDIX A**

A priority item is a provision of these rules pertaining to food operations that, if in non-compliance, is more likely than other items to contribute to food contamination or illness. These are requirements of the rules, including provisions of parts of 21 CFR adopted by reference, on:

Food source, contamination or adulteration, and spoilage.

Time and temperature requirements of potentially hazardous foods.

Adequate facilities to maintain temperatures of potentially hazardous foods.

Prevention of cross contamination.

Damaged or detained food segregated from food intended to be sold or served.

Personnel infected with a communicable disease restricted from food operations.

Hygienic practices of employees including eating, drinking, or using tobacco in a food area in any manner other than expressly allowed in the rules, or improper or inadequate handwashing.

Sanitization of equipment and utensils when necessary to prevent food contamination or adulteration.

Water from an approved source.

Hot and cold water under pressure to all utensil washing sink compartments, when required for sanitary operations.

Sewage and waste water, including mop water, grease and spillage/runoff from garbage storage, disposed according to law.

Cross-connections, backflow and back siphonage potential.

Number, convenience and accessibility of toilets.

Number, convenience and accessibility of handwashing sinks.

Design of handwashing sink faucets, including mixing valves and timed, self-closing faucets.

Presence of insects, rodents, birds, turtles or other animals unless expressly allowed by the rules.

Failure to comply with the provisions of the establishment's Hazard Analysis Critical Control Point (HACCP) plan when such plan is required by CFR.

Toxic items stored, labeled, and used properly so that potential food contamination is avoided.

**Code of Federal Regulations**

**PART 110 - CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD**

**§ 110.3 Definitions.**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- (a) *Acid foods or acidified foods* means foods that have an equilibrium pH of 4.6 or below.
- (b) *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) *Blanching*, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) *Critical control point* means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- (f) *Food* means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- (g) *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
- (h) *Lot* means the food produced during a period of time indicated by a specific code.
- (i) *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.
- (j) *Pest* refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
- (k) *Plant* means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) *Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) *Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) *Safe-moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity ( $a_w$ ). An  $a_w$  will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given  $a_w$  will not support the growth of undesirable microorganisms.

(o) *Sanitize* means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) *Shall* is used to state mandatory requirements.

(q) *Should* is used to state recommended or advisory procedures or identify recommended equipment.

(r) *Water activity* ( $a_w$ ) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

#### **§ 110.5 Current good manufacturing practice.**

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated

(1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or

(2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264). (b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

#### **§ 110.10 Personnel.**

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such



contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) *Education and training.*

Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.(d) *Supervision.* Responsibility for assuring compliance by all personnel with all

requirements of this part shall be clearly assigned to competent supervisory personnel.

**§ 110.19 Exclusions.**

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more “raw agricultural commodities,” as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

**§ 110.20 Plant and grounds.**

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.*

Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation. (iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

**§ 110.35 Sanitary operations.**

*(a) General maintenance.*

Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

*(b) Substances used in cleaning and sanitizing; storage of toxic materials.*

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control.*

No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.*

All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) *Storage and handling of cleaned portable equipment and utensils.*

Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

**§ 110.37 Sanitary facilities and controls.**

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

- (1) Carry sufficient quantities of water to required locations throughout the plant.
- (2) Properly convey sewage and liquid disposable waste from the plant.
- (3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
- (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- (5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.*

Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.*

Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

- (1) Maintaining the facilities in a sanitary condition.
- (2) Keeping the facilities in good repair at all times.
- (3) Providing self-closing doors.
- (4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) *Hand-washing facilities.*

Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

- (1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
- (2) Effective hand-cleaning and sanitizing preparations.
- (3) Sanitary towel service or suitable drying devices.
- (4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.
- (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
- (6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

*(f) Rubbish and offal disposal.*

Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

**§ 110.40 Equipment and utensils.**

- (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.
- (b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
- (c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.
- (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
- (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the

temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

**§ 110.80 Processes and controls.**

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

*(a) Raw materials and other ingredients.*

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or

may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations.*

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity,  $a_w$ , pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 °F (7.2 °C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 °F (60 °C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.



(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling  $a_w$  that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of  $a_w$  for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the  $a_w$  of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the  $a_w$  of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of

adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

**§ 110.93 Warehousing and distribution.**

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

**§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.**

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

**Code of Federal Regulations**

**PART 114—ACIDIFIED FOODS**

Definitions. For the purposes of this part, the following definitions apply.

(a) *Acid foods* means foods that have a natural pH of 4.6 or below.

(b) *Acidified foods* means low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity ( $a_w$ ) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, “pickles” or “pickled \_\_\_\_.” Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage of this part.

(c) *Lot* means the product produced during a period indicated by a specific code.

(d) *Low-acid foods* means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity ( $a_w$ ) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(e) *Scheduled process* means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.

(f) *Shall* is used to state mandatory requirements.

(g) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(h) *Water activity* ( $a_w$ ) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

**§114.5 Current good manufacturing practice.**

The criteria in §§ 114.10, 114.80, 114.83, 114.89, and 114.100, as well as the criteria in part 110 of this chapter, apply in determining whether an article of acidified food is adulterated

(1) within the meaning of section 402(a)(3) of the act (21 U.S.C. 342(a)(3)) in that it has been manufactured under such conditions that it is unfit for food, or

(2) within the meaning of section 402(a)(4) of the act (21 U.S.C. 342(a)(4)) in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

**§114.10 Personnel.**

All operators of processing and packaging systems shall be under the operating supervisions of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. The Commissioner will consider students who have satisfactorily completed the required portions of the courses presented under § 108.35 and part 113 of this chapter before March 16, 1979, to be in compliance with the requirement of this section.

**§114.80 Processes and controls.**

(a) *Processing operations.* The manufacturer shall employ appropriate quality control procedures to ensure that finished foods do not present a health hazard.

(1) Acidified foods shall be so manufactured, processed, and packaged that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods. Manufacturing shall be in accordance with the scheduled process. Acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of nonhealth significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. Permitted preservatives may be used to inhibit reproduction of microorganisms of nonhealth significance (in lieu of thermal processing).

(2) Sufficient control, including frequent testing and recording of results, shall be exercised so that the finished equilibrium pH values for acidified foods are not higher than 4.6. Measurement of acidity of foods in-process may be made by potentiometric methods, titratable acidity, or colorimetric methods. If the finished equilibrium pH of the food is above 4.0, the measurement of the finished equilibrium pH shall be by a potentiometric method, and the in-process measurements by titration or colorimetry shall be related to the finished equilibrium pH. If the finished equilibrium pH is 4.0 or below, then the measurement of acidity of the final product may be made by any suitable method. Special care should be taken when food ingredients have been subjected to lye, lime, or similar high pH materials.

(3) Procedures for acidification to attain acceptable equilibrium pH levels in the final food include, but are not limited to, the following:

(i) Blanching of the food ingredients in acidified aqueous solutions.

(ii) Immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, care must be taken to ensure that the acid concentration is properly maintained.

(iii) Direct batch acidification, which can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification.

(iv) Direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than solid or pelleted acids. Care must be taken to ensure that the proper amount of acid is added to each container.

(v) Addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations.

(4) Testing and examinations of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination.

(b) *Coding*. Each container or product shall be marked with an identifying code permanently visible to the naked eye. If the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, as long as the label is securely affixed to the product container. The required identification shall specify in code the establishment where the product was packed, the product contained therein, and the year, day, and period during which it was packed. The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Codes may be changed periodically on one of the following bases: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers constituting the batch do not represent those processed during more than one personnel shift.

**§114.83 Establishing scheduled processes.**

The scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.

**§114.89 Deviations from scheduled processes.**

Whenever any process operation deviates from the scheduled process for any acidified food and/or the equilibrium pH of the finished product is higher than 4.6, the commercial processor of the acidified food shall either:

(a) Fully reprocess that portion of the food by a process established by a competent processing authority as adequate to ensure a safe product;

(b) thermally process it as a low-acid food under part 113 of this chapter; or

(c) set aside that portion of the food involved for further evaluation as to any potential public health significance. The evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless the evaluation demonstrates that the food has undergone a process that has rendered it safe, the food set aside shall either be fully reprocessed to render it safe, or be destroyed. A record shall be made of the procedures used in the evaluation and the results. Either upon completion of full reprocessing and the attainment of a safe food, or after the determination that no significant potential for public health hazard exists, that portion of the food involved may be shipped in normal distribution. Otherwise, the portion of the food involved shall be destroyed.

**§ 114.90 Methodology.**

Methods that may be used to determine pH or acidity for acidified foods include, but are not limited to, the following:

(a) *Potentiometric method for the determination of pH—*

(1) *Principles.* The term “pH” is used to designate the intensity or degree of acidity. The value of pH, the logarithm of the reciprocal of the hydrogen ion concentration in solution, is determined by measuring the difference in potential between two electrodes immersed in a sample solution. A suitable system consists of a potentiometer, a glass electrode, and a reference electrode. A precise pH determination can be made by making an electromotive force (emf) measurement of a standard buffer solution whose pH is known, and then comparing that measurement to an emf measurement of a sample of the solution to be tested.

(2) *Instruments.* The primary instrument for use in pH determination is the pH meter or potentiometer. For most work, an instrument with a direct-reading pH scale is necessary. Battery and line-operated instruments are available commercially. If the line voltage is unstable, line-operated instruments should be fitted with voltage regulators to eliminate drifting of meter-scale readings. Batteries should be checked frequently to ensure proper operation of battery operated instruments. An instrument using an expanded unit scale or a digital readout system is preferred since it allows more precise measurements.

(3) *Electrodes.* The typical pH meter is equipped with a glass membrane electrode and a reference electrode or a single probe combination electrode. Various types of electrodes designed for specific uses are available. The most commonly used reference electrode is the calomel electrode, which incorporates a salt bridge filled with saturated potassium chloride solution.

(i) *Care and use of electrodes.* Calomel electrodes should be kept filled with saturated potassium chloride solution or other solution specified by the manufacturer because they may become damaged if they are allowed to dry out. For best results, electrodes should be soaked in buffer solution, distilled or deionized water, or other liquid specified by the manufacturer for several hours before using and kept ready by storing with tips immersed in distilled water or in buffer solution used for standardization. Electrodes should be rinsed with water before immersing in the standard buffers and rinsed with water or the solution to be measured next between sample determinations. A lag in meter response may indicate aging effects or fouling of the electrodes, and cleaning and rejuvenation of the electrodes may be necessary and may be accomplished by placing the electrodes in 0.1 molar sodium hydroxide solution for 1 minute and then transferring them to 0.1 molar hydrochloric acid solution for 1 minute. The cycle should be repeated two times, ending with the electrodes in the acid solution. The electrodes should then be thoroughly rinsed with water and blotted with soft tissue before proceeding with the standardization.

(ii) *Temperature.* To obtain accurate results, a uniform temperature should be maintained for the electrodes, the standard buffer solutions, and the samples. Tests should be made at a temperature between 20° and 30 °C, the optimum being 25 °C. Any temperature determinations made without meter compensation may affect pH values. An automatic temperature compensator may be used.

(iii) *Accuracy.* The accuracy of most pH meters is stated to be approximately 0.1 pH unit, and reproducibility is usually  $\pm 0.05$  pH unit or less. Some meters permit the expansion of any pH unit range to cover the entire scale and have an accuracy of approximately  $\pm 0.01$  pH unit and a reproducibility of  $\pm 0.005$  pH units.

(4) *General procedure for determining pH.* When operating an instrument, the operator should use the manufacturer's instructions and should observe the following techniques for pH determinations:

(i) Switch the instrument on and allow the electronic components to warm up and stabilize before proceeding.

(ii) Standardize the instrument and electrodes with commercially prepared standard 4.0 pH buffer or with freshly prepared 0.05 molar potassium acid phthalate buffer solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980), section 50.007(c), under "Buffer Solutions for Calibration of pH Equipment—Official Final Action," which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Note the temperature of the buffer solution and set the temperature compensator control at the observed temperature (room temperature is near 25 °C).

(iii) Rinse the electrodes with water and blot, but do not wipe, with soft tissue.

(iv) Immerse the tips in the buffer solution and take the pH reading, allowing about 1 minute for the meter to stabilize. Adjust the standardization control so that the meter reading corresponds to the pH of the known buffer (for example, 4.0) for the temperature observed. Rinse the electrodes with water and blot with soft tissue. Repeat procedure with fresh portions of buffer solution until the instrument remains in balance on two successive trials. To check the operation of the pH meter, check the pH reading using another standard buffer such as one having a pH of 7.0, or check it with freshly prepared 0.025 molar phosphate solution prepared as outlined in the AOAC, 13th Ed. (1980), section 50.007(e), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii) of this section. Expanded scale pH meters may be checked with pH 3.0 or pH 5.0 standard buffers. Buffers and instruments can be further checked by comparison with values obtained with a second properly standardized instrument.

(v) Indicating electrodes may be checked for proper operation by first using an acid buffer and then a base buffer. First standardize the electrodes using a pH 4.0 buffer at or near 25 °C. Standardization control should be adjusted so that the meter reads exactly 4.0. Electrodes should be rinsed with water, then blotted and immersed in a pH 9.18 borax buffer prepared as outlined in the AOAC, 13th Ed. (1980), section 50.007(f), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii) of this section. The pH reading should be within  $\pm 0.3$  units of the 9.18 value.

(vi) The pH meter can be tested for proper operation by shorting the glass and reference electrode inputs, thereby reducing the voltage to zero. In some meters this shorting is done by switching the instrument to standby, and in other instruments by use of a shorting strap. With the instrument shorted out, standardization control should be turned from one extreme to another. This operation should produce a deflection greater than  $\pm 1.5$  pH unit from center scale.



(5) *Determining pH on samples.*

(i) Adjust the temperature of the sample to room temperature (25 °C), and set the temperature compensator control to the observed temperature. With some expanded scale instruments, the sample temperature must be the same as the temperature of the buffer solution used for the standardization.

(ii) Rinse and blot the electrodes. Immerse the electrodes in the sample and take the pH reading, allowing 1 minute for the meter to stabilize. Rinse and blot the electrodes and repeat on a fresh portion of sample. Oil and grease from the samples may coat the electrodes; therefore, it is advisable to clean and standardize the instrument frequently. When oily samples cause fouling problems, it may become necessary to rinse the electrodes with ethyl ether.

(iii) Determine two pH values on the well-mixed sample. These readings should agree with one another to indicate that the sample is homogeneous. Report values to the nearest 0.05 pH unit.

(6) *Preparation of samples.* Some food products may consist of a mixture of liquid and solid components that differ in acidity. Other food products may be semisolid in character. The following are examples of preparation procedures for pH testing for each of these categories:

(i) *Liquid and solid component mixtures.* Drain the contents of the container for 2 minutes on a U.S. standard No. 8 sieve (preferably stainless steel) inclined at a 17- to 20-degree angle. Record weight of the liquid and solid portions and retain each portion separately.

(a) If the liquid contains sufficient oil to cause electrode fouling, separate the layers with a separatory funnel and retain the aqueous layer. The oil layer may be discarded. Adjust the temperature of the aqueous layer to 25 °C and determine its pH.

(b) Remove the drained solids from the sieve, blend to a uniform paste, adjust the temperature of the paste to 25 °C and determine its pH.

(c) Mix aliquots of solid and liquid fractions in the same ratio as found in the original container and blend to a uniform consistency. Adjust the temperature of the blend to 25 °C and determine the equilibrated pH. Alternatively, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25 °C, and determine the equilibrated pH.

(ii) *Marinated oil products.* Separate the oil from the solid product. Blend the solid in a blender to a paste consistency; it may become necessary to add a small amount of distilled water to some samples to facilitate the blending. A small amount of added water will not alter the pH of most food products, but caution must be exercised concerning poorly buffered foods. No more than 20 milliliters of distilled water should be added to each 100 grams of product. Determine the pH by immersing electrodes in the prepared paste after adjusting the temperature to 25 °C.

(iii) *Semisolid products.* Food products of a semisolid consistency, such as puddings, potato salad, etc., may be blended to a paste consistency, and the pH may be determined on the prepared paste. If more fluidity is required, 10 to 20 milliliters of distilled water may be added to 100 grams of product. Adjust the temperature of the prepared paste to 25 °C and determine its pH.

(iv) *Special product mixtures.* For special product mixtures such as antipasto, pour off the oil, blend the remaining product to a paste, and determine the pH of the blended paste. If more

fluidity is required, add 10 to 20 milliliters of distilled water to each 100 grams of product and blend. Adjust the temperature of the prepared paste to 25 °C and determine its pH.

(7) *Process pH determination.* Obtain sample portions of material for pH determination.

(i) For process liquids, adjust the temperature of the liquid to 25 °C and determine the pH by immersing the electrodes in the liquid.

(ii) Drain solid materials on a sieve and blend to a workable paste. Adjust the temperature of the prepared paste to 25 °C and determine its pH.

(iii) If enough solid materials are available to make a paste, blend representative aliquots of liquid and solid materials to a workable paste. Adjust the temperature of the prepared paste to 25 °C and determine the equilibrated pH. Alternatively, blend the entire contents of the container to a uniform paste, adjust the temperature of the paste to 25 °C, and determine the equilibrated pH.

(b) *Colorimetric methods for the determination of pH.*

This method may be used in lieu of the potentiometric method if the pH is 4.0 or lower.

(1) *Principle.* The colorimetric method for pH involves the use of indicator dyes in solutions that gradually change color over limited pH ranges. An indicator that has the greatest color change at approximately the pH of the sample being tested is selected. The pH is determined by the color of the indicator when exposed to the sample under test.

(2) *Indicator solutions.* Most indicator solutions are prepared as a 0.04 percent solution of the indicator dye in alcohol. In testing, a few drops of indicator solution are added to 10-milliliter portions of the sample solution. Colors should be compared using a bright background. Approximate determinations can be made on white porcelain spot plates, the test colors being compared thereon with a set of color standards. More accurate colorimetric tests can be made using a comparator block fitted with sets of tubes of standard indicator solutions of known pH.

(3) *Indicator paper.* A paper tape treated with indicator dye is dipped into the sample solution. Depending upon the pH of the solution, the tape will change color and an approximate pH can be determined by comparison with a standard color chart. (c) *Titrateable acidity.* Acceptable methods for determining titrateable acidity are described in the AOAC, 13th Ed. (1980), section 22.060, under "Titrateable Acidity—Official Final Action," for "Indicator Method," and section 22.061 for "Glass Electrode Method—Official Final Action," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii) of this section. The procedure for preparing and standardizing the sodium hydroxide solution is described in the AOAC, 13th Ed. (1980), sections 50.032-50.035, under "Sodium Hydroxide—Official Final Action" by the "Standard Potassium Hydroxide Phthalate Method," which is also incorporated by reference and available as set forth in paragraph (a)(4)(ii) of this section.

#### **§114.100 Records.**

(a) Records shall be maintained of examinations of raw materials, packaging materials, and finished products, and of suppliers' guarantees or certifications that verify compliance with Food and Drug Administration regulations and guidance documents or action levels.

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(b) Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, shall be maintained and shall contain sufficient additional information such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production.

(c) All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified; these departures shall be recorded and made the subject of a separate file (or log identifying the appropriate data) delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.

(d) Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

(e) Copies of all records provided for in paragraphs (b), (c), and (d) of this section shall be retained at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture.

**Code of Federal Regulations**

**PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER**

**§129.1 Current good manufacturing practice.**

The applicable criteria in part 110 of this chapter, as well as the criteria in §§ 129.20, 129.35, 129.37, 129.40, and 129.80 shall apply in determining whether the facilities, methods, practices, and controls used in the processing, bottling, holding, and shipping of bottled drinking water are in conformance with or are operated or administered in conformity with good manufacturing practice to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions.

**§129.3 Definitions.**

For the purposes of this part, the following definitions apply:

(a) *Approved source* when used in reference to a plant's product water or operations water means a source of water and the water therefrom, whether it be from a spring, artesian well, drilled well, municipal water supply, or any other source, that has been inspected and the water sampled, analyzed, and found to be of a safe and sanitary quality according to applicable laws and regulations of State and local government agencies having jurisdiction. The presence in the plant of current certificates or notifications of approval from the government agency or agencies having jurisdiction constitutes approval of the source and the water supply.

(b) *Bottled drinking water* means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

(c) *Lot* means a collection of primary containers or unit packages of the same size, type, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.

(d) *Multiservice containers* means containers intended for use more than one time.

(e) *Nontoxic materials* means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled drinking water, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the water.

(f) *Operations water* means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.

(g) *Primary container* means the immediate container in which the product water is packaged.

(h) *Product water* means processed water used by a plant for bottled drinking water.

(i) *Shall and should*. "Shall" refers to mandatory requirements and "should" refers to recommended or advisory procedures or equipment.

(j) *Shipping case* means a container in which one or more primary containers of the product are held.

(k) *Single-service container* means a container intended for one time usage only. (l) *Unit package* means a standard commercial package of bottled drinking water, which may consist of one or more containers.

**§129.20 Plant construction and design.**

(a) The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

(b) If processing operations are conducted in other than a sealed system under pressure, adequate protection shall be provided to preclude contamination of the water and the system.

(c) Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas.

(d) The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room.

(e) Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

**§129.35 Sanitary facilities.**

Each plant shall provide adequate sanitary facilities including, but not limited to, the following:

(a) *Product water and operations water—*

(1) *Product water.* The product water supply for each plant shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(2) *Operations water.* If different from the product water supply, the operations water supply shall be obtained from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(3) *Product water and operations water from approved sources.*

(i) Samples of source water from each source in use by the plant are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for total coliform at least once each week. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli*. This sampling is in addition to any performed by government agencies having jurisdiction. Source water found to contain *E. coli* is not considered water of a safe, sanitary quality as required for

use in bottled water by paragraph (a)(1) of this section. Before a bottler can use source water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its reoccurrence. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative. Records of approval of the source water by government agencies having jurisdiction, records of sampling and analyses for which the plant is responsible, and records describing corrective measures taken in response to a finding of *E. coli* are to be maintained on file at the plant.

(ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in § 165.110(b) of this chapter.

(iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency (EPA) and State-certified laboratories).

*(4) Source water testing exemptions.*

(i) Firms that use a public water system for source water may substitute public water system testing results, or certificates showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants (40 CFR parts 141 and 143), for the testing requirements of § 129.35(a)(3).

(ii) Firms that do not use a public water system as the source of their water may reduce the frequency of their testing of that source, as well as the number of chemical contaminants for which they test the source water, if they can document that such reduction is consistent with a State-issued waiver under EPA regulations (40 CFR parts 141 and 143).

(iii) Firms that do not use a public water system as the source of their water and whose source water has not been treated with a chlorine-based disinfectant or ozone do not have to test their source water for the residual disinfectants and DBP's listed in § 165.110(b)(4)(iii)(H) of this chapter. Firms that do not use a public water system as the source of their water but whose source water has been treated with a chlorine-based disinfectant or ozone must test their source water for the residual disinfectants and the DBP's listed in § 165.110(b)(4)(iii)(H) that are likely to result from such treatment.

(iv) The finished bottled water must comply with bottled water quality standards (§ 165.110(b) of this chapter) and section 402(a)(1) and (a)(3) of the Federal Food, Drug, and Cosmetic Act dealing with adulterated foods.

*(b) Air under pressure.*

Whenever air under pressure is directed at product water or a product water-contact surface, it shall be free of oil, dust, rust, excessive moisture, and extraneous materials; shall not affect the bacteriological quality of the water; and should not adversely affect the flavor, color, or odor of the water.

*(c) Locker and lunchrooms.*

When employee locker and lunchrooms are provided, they shall be separate from plant operations and storage areas and shall be equipped with self-closing doors. The rooms shall be

maintained in a clean and sanitary condition and refuse containers should be provided. Packaging or wrapping material or other processing supplies shall not be stored in locker or lunchrooms.

**§ 129.37 Sanitary operations.**

(a) The product water-contact surfaces of all multiservice containers, utensils, pipes, and equipment used in the transportation, processing, handling, and storage of product water shall be clean and adequately sanitized. All product water-contact surfaces shall be inspected by plant personnel as often as necessary to maintain the sanitary condition of such surfaces and to assure they are kept free of scale, evidence of oxidation, and other residue. The presence of any unsanitary condition, scale, residue, or oxidation shall be immediately remedied by adequate cleaning and sanitizing of that product water-contact surface prior to use.

(b) After cleaning, all multiservice containers, utensils, and disassembled piping and equipment shall be transported and stored in such a manner as to assure drainage and shall be protected from contamination.

(c) Single-service containers and caps or seals shall be purchased and stored in sanitary closures and kept clean therein in a clean, dry place until used. Prior to use they shall be examined, and as necessary, washed, rinsed, and sanitized and shall be handled in a sanitary manner.

(d) Filling, capping, closing, sealing, and packaging of containers shall be done in a sanitary manner so as to preclude contamination of the bottled drinking water.

**§ 129.40 Equipment and procedures.**

(a) *Suitability.*

(1) All plant equipment and utensils shall be suitable for their intended use. This includes all collection and storage tanks, piping, fittings, connections, bottle washers, fillers, cappers, and other equipment which may be used to store, handle, process, package, or transport product water.

(2) All product water contact surfaces shall be constructed of nontoxic and nonabsorbant material which can be adequately cleaned and sanitized and is in compliance with section 409 of the act.

(b) *Design.* Storage tanks shall be of the type that can be closed to exclude all foreign matter and shall be adequately vented.

**§ 129.80 Processes and controls.**

(a) *Treatment of product water.*

All treatment of product water by distillation, ion-exchanging, filtration, ultraviolet treatment, reverse osmosis, carbonation, mineral addition, or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in accordance with section 409 of the Federal Food, Drug, and Cosmetic Act. All such processes shall be performed in and by equipment and with substances which will not adulterate the bottled product. A record of the type and date of physical inspections of such equipment, conditions found, and the performance

and effectiveness of such equipment shall be maintained by the plant. Product water samples shall be taken after processing and prior to bottling by the plant and analyzed as often as is necessary to assure uniformity and effectiveness of the processes performed by the plant. The methods of analysis shall be those approved by the government agency or agencies having jurisdiction.

(b) *Containers.*

(1) Multiservice primary containers shall be adequately cleaned, sanitized, and inspected just prior to being filled, capped, and sealed. Containers found to be unsanitary or defective by the inspection shall be reprocessed or discarded. All multiservice primary containers shall be washed, rinsed, and sanitized by mechanical washers or by any other method giving adequate sanitary results. Mechanical washers shall be inspected as often as is necessary to assure adequate performance. Records of physical maintenance, inspections and conditions found, and performance of the mechanical washer shall be maintained by the plant.

(2) Multiservice shipping cases shall be maintained in such condition as to assure they will not contaminate the primary container or the product water. Adequate dry or wet cleaning procedures shall be performed as often as necessary to maintain the cases in satisfactory condition.

(c) *Cleaning and sanitizing solutions.*

Cleaning and sanitizing solutions utilized by the plant shall be sampled and tested by the plant as often as is necessary to assure adequate performance in the cleaning and sanitizing operations. Records of these tests shall be maintained by the plant.

(d) *Sanitizing operations.*

Sanitizing operations, including those performed by chemical means or by any other means such as circulation of live steam or hot water, shall be adequate to effect sanitization of the intended product water-contact surfaces and any other critical area. The plant should maintain a record of the intensity of the sanitizing agent and the time duration that the agent was in contact with the surface being sanitized. The following times and intensities shall be considered a minimum:

(1) Steam in enclosed system: At least 170 °F for at least 15 minutes or at least 200 °F for at least 5 minutes.

(2) Hot water in enclosed system: At least 170 °F for at least 15 minutes or at least 200 °F for at least 5 minutes.

(3) Chemical sanitizers shall be equivalent in bactericidal action to a 2-minute exposure of 50 parts per million of available chlorine at 57 °F when used as an immersion or circulating solution. Chemical sanitizers applied as a spray or fog shall have as a minimum 100 parts per million of available chlorine at 57 °F or its equivalent in bactericidal action.

(4) 0.1 part per million ozone water solution in an enclosed system for at least 5 minutes.

(5) When containers are sanitized using a substance other than one provided for in § 178.1010 of this chapter, such substance shall be removed from the surface of the container by a rinsing procedure. The final rinse, prior to filling the container with product water, shall be performed with a disinfected water rinse free of pathogenic bacteria or by an additional sanitizing procedure equivalent in bactericidal action to that required in paragraph (d)(3) of this section.



*(e) Unit package production code.*

Each unit package from a batch or segment of a continuous production run of bottled drinking water shall be identified by a production code. The production code shall identify a particular batch or segment of a continuous production run and the day produced. The plant shall record and maintain information as to the kind of product, volume produced, date produced, lot code used, and the distribution of the finished product to wholesale and retail outlets.

*(f) Filling, capping, or sealing.*

During the process of filling, capping or sealing either single-service or multiservice containers, the performance of the filler, capper or sealer shall be monitored and the filled containers visually or electronically inspected to assure they are sound, properly capped or sealed, and coded and labeled. Containers which are not satisfactory shall be reprocessed or rejected. Only nontoxic containers and closures shall be used. All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each 3 months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. The procedure and apparatus for these bacteriological tests shall be in conformance with those recognized by the government agency or agencies having jurisdiction. Tests shall be performed either by qualified plant personnel or a competent commercial laboratory.

*(g) Compliance procedures.*

A quality standard for bottled drinking water is established in § 165.110(b) of this chapter. To assure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

(1) For bacteriological purposes, take and analyze at least once a week for total coliform a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample shall consist of primary containers of product or unit packages of product. If any coliform organisms are detected, follow-up testing must be conducted to determine whether any of the coliform organisms are *E. coli*.

(2) For chemical, physical, and radiological purposes, take and analyze at least annually a representative sample from a batch or segment of a continuous production run for each type of bottled drinking water produced during a day's production. The representative sample(s) consists of primary containers of product of unit packages of product.

(3) Analyze such samples by methods approved by the government agency or agencies having jurisdiction. The plant shall maintain records of date of sampling, type of product sampled, production code, and results of the analysis.

*(h) Record retention.*

All records required by §§ 129.1, 129.20, 129.35, 129.37, 129.40, and 129.80 shall be maintained at the plant for not less than 2 years. Plants shall also retain, on file at the plant, current certificates or notifications of approval issued by the government agency or agencies approving the plant's source and supply of product water and operations water. All required documents shall be available for official review at reasonable times.