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**901:3-5-01 Criteria and definitions for processing acidified foods in hermetically sealed containers.**

(A) Food processing establishments processing acidified foods in hermetically sealed containers shall comply with Chapter 901:3-5 of the Administrative Code and [the applicable provisions of Chapter ~~901:3-1~~ 901:3-17](#) of the Administrative Code.

(B) Definitions.

As used in Chapter 901:3-5 of the Administrative Code:

- (1) "Acid foods" means foods that have a natural pH of 4.6 or below.
- (2) "Acidified foods";
  - (a) Means low-acid foods that have a water activity ( $a_w$ ) greater than 0.85 and have a finished equilibrium pH of 4.6 or below to which acids or acid foods are added.
  - (b) Does not include carbonated beverages, jams, jellies, preserves, acid foods such as standardized and nonstandardized food dressings and condiment sauces that contain small amounts of low-acid food and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, or foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage of this chapter.
- (3) "Lot" means the food product produced during a period indicated by a specific code.
- (4) "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.
- (5) "pH" is the symbol for the negative logarithm of the hydrogen ion concentration which is a measure of degree of acidity or alkalinity of a solution.
- (6) "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 processing authority.
- (7) " $A_w$ " means water activity which 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.

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**901:3-6-02 Food.**

- (A) Food shall be obtained from sources that comply with law.
- (B) Food shall be labeled as specified in law, and shall be honestly presented in a way that does not mislead or misinform the consumer.
- (C) Eggs shall be clean and sound.
- (D) Ice used as a cooling medium shall be made from water that complies with rule 901:3-6-06 of the Administrative Code.
- (E) All food products shall be safe, unadulterated, and honestly presented. Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food.
- (F) Food shall be protected from contamination.
- (G) Eggs shall be maintained at an ambient air temperature of forty-five degrees Fahrenheit or less.
- (H) Poultry and non-amenable meats shall be maintained frozen or at an internal temperature of forty-one degrees Fahrenheit or less.
- (I) Food that is unsafe, adulterated, or not honestly presented shall be discarded.
- (J) Except for whole and intact raw agricultural products, foods shall not be displayed or stored on the ground.
- (K) Cider and other juices manufactured on site of a farm market shall be processed in accordance with the good manufacturing practices established in Chapter ~~901:3-1~~ [901:3-17](#) of the Administrative Code.

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## 901:3-7-01 Criteria and definitions for fish and fishery products.

- (A) Food processing establishments processing fish and fishery products shall comply with ~~Chapters~~ [Chapter 901:3-7](#) and [the applicable provisions of Chapter 901:3-1-901:3-17](#) of the Administrative Code. The rules in this part do not apply to:
- (1) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
  - (2) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
  - (3) The operation of a retail food establishment or food service operation as defined in Chapter 3717. of the Revised Code.

### (B) Definitions.

As used in Chapter 901:3-7 of the Administrative Code:

- (1) "Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.
- (2) "Corrective action plan" means a plan that describes the steps to be taken and assigns responsibility for those steps as they pertain to a particular deviation from the HACCP plan.
- (3) "Critical control point" means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.
- (4) "Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.
- (5) "Fish" means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life and the roe of such animals, including but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin and all mollusks, where such animal life is intended for human consumption. Fish does not include birds or mammals.
- (6) "Fishery product" means any human food product in which fish is a characterizing ingredient.
- (7) "Food safety hazard" means any biological, chemical, or physical property determined through experience, illness data, scientific reports, or other information, that may cause a food to be unsafe for human consumption.
- (8) "Food processing establishment" has the same meaning as used in section 3715.021 of the Revised Code.
- (9) "HACCP" means hazard analysis and critical control point.
- (10) "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.
- (11) "Preventive measure" means physical, chemical, or other factors that can be used to control an identified

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food safety hazard.

- (12) "Process-monitoring instrument" means an instrument or device used to indicate conditions during processing at a critical control point.
- (13) "Processing of fish or fishery products" means handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding of fish or fishery products.
- (14) "Processor" means any person engaged in commercial, custom, or institutional processing of fish or fishery products. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests.
- (15) "Scombroid toxin-forming species" means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.
- (16) "Shellfish control authority" means a federal, state, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.
- (17) "Shellstock" means raw, in-shell molluscan shellfish.
- (18) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.
- (19) "Smoked or smoke-flavored fishery products" means the finished food prepared by:
  - (a) Treating fish with salt (sodium chloride), and
  - (b) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.
- (20) "Tag" means a record of harvesting information attached to a container of shellstock by the harvester or processor.

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## **901:3-7-07 Sanitation control procedures.**

### (A) Sanitation monitoring.

Each processor shall monitor the sanitary conditions and practices during processing. Each processor shall correct in a timely manner any sanitary conditions and practices that are not met to ensure, at a minimum, conformance with those sanitary conditions and practices specified in Chapter ~~901:3-17~~[901:3-17](#) of the Administrative Code that are both applicable to the plant and the food being processed and relate to the following:

- (1) Safety of the water that comes into contact with food or food contact surfaces or is used in the manufacture of ice;
- (2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
- (3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
- (4) Maintenance of hand washing, hand sanitizing, and toilet facilities;
- (5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
- (6) Proper labeling, storage, and use of toxic compounds;
- (7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
- (8) Exclusion of pests from the food plant.

### (B) Sanitation control records.

Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (A) of this rule. These records are subject to the requirements of rule 901:3-7-05 of the Administrative Code.

## **901:3-23-01 Criteria and definitions for juice products.**

- (A) Except for as specified in paragraph (B) of this rule, all food processing establishments processing juice, including juice products to be used as an ingredient, shall comply with Chapter 901:3-23 and [the applicable provisions found in](#) Chapter ~~901:3-17~~[901:3-17](#) of the Administrative Code.
- (B) Entities which produce juice that has not undergone a five log reduction are exempt from the rules of this chapter provided that they are either:
- (1) A food processing establishment that is also a licensed food service operation or retail food establishment who moves juice, including juice products, to a separate food service operation or retail food establishment which is licensed under the same name; or

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(2) A registered farm market that moves their product to a registered farmers market.

(C) Definitions.

As used in Chapter 901:3-23 of the Administrative Code:

- (1) "Cleaned" means washed with water of adequate sanitary quality.
- (2) "Control" means to prevent, eliminate, or reduce.
- (3) "Control measure" means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.
- (4) "Corrective action plan" means a plan that describes the steps to be taken and assigns responsibility for those steps as they pertain to a particular deviation from the HACCP plan.
- (5) "Critical control point" means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.
- (6) "Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
- (7) "Culled" means the separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with rule 901:3-23-09 of the Administrative Code, culled means undamaged, tree-picked fruit that is U.S. department of agriculture choice or higher quality.
- (8) "Food hazard" means any biological, chemical, or physical property that is reasonably likely to cause illness or injury in the absence of its control.
- (9) "HACCP" means hazard analysis and critical control point.
- (10) "Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.
- (11) "mL" means milliliter.
- (12) "Monitor" means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.
- (13) "Processing" means activities that are directly related to the production of juice products. Processing does not include harvesting, picking, or transporting raw agricultural ingredients of juice products without otherwise engaging in processing.
- (14) "Processor" means any person engaged in commercial, custom, or institutional processing of juice products. A processor includes any person engaged in the processing of juice products that are to be used in market or consumer tests.
- (15) "Shelf-stable product" means a product that is hermetically sealed in accordance with Chapter 901:3-3 of the Administrative Code and when stored at room temperature should not demonstrate any microbial growth.

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- (16) "Validation" means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.
- (17) "Verification" means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

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**901:3-23-02 Sanitation standard operating procedures.**

(A) Sanitation controls.

Each processor shall have and implement a sanitation standard operating procedure that addresses sanitation conditions and practices before, during, and after processing. The sanitation standard operating procedure shall address:

- (1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;
- (2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
- (3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;
- (4) Maintenance of hand washing, hand sanitizing, and toilet facilities;
- (5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
- (6) Proper labeling, storage, and use of toxic compounds;
- (7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
- (8) Exclusion of pests from the food plant.

(B) Monitoring.

The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified Chapter ~~901:3-1~~[901:3-17](#) of the Administrative Code that are appropriate both to the plant and to the food being processed. Each processor shall correct, in a timely manner, those conditions and practices that are not met.

(C) Records.

Each processor shall maintain sanitation standard operating procedure records that, at a minimum, document the monitoring and corrections prescribed by paragraph (B) of this rule. These records are subject to the recordkeeping requirements of rule 901:3-23-07 of the Administrative Code.

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## 901:3-23-09 Process controls and verification.

- (A) In order to meet the requirements of rules 901:3-23-01 to 901:3-23-09 of the Administrative Code, processors of juice products shall include in their hazard analysis and critical control point plans control measures that will consistently produce, at a minimum, a five-log reduction of the pertinent microorganism, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions. For the purposes of this rule, the "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice. The following juice processors are exempt from this paragraph:
- (1) A juice processor that is subject to the requirements of Chapter 901:3-3 of the Administrative Code and Chapter 901:3-5 of the Administrative Code; and
  - (2) A juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by rule 901:3-23-03 of the Administrative Code.
- (B) All juice processors shall meet the requirements of paragraph (A) of this rule through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning as defined in rule 901:3-23-01 (C)(1) and (C)(7) of the Administrative Code and the reduction is accomplished within a single production facility.
- (C) All juice processors shall meet the requirements of paragraphs (A) and (B) of this rule and perform final product packaging within a single production facility operating under [the applicable provisions found in Chapter ~~901:3-~~901:3-17](#) of the Administrative Code. Processors claiming an exemption under paragraph (A)(1) or (A)(2) of this rule shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under [the applicable provisions found in Chapter ~~901:3-~~901:3-17](#) of the Administrative Code.
- (D) Each juice processor that relies on treatments that do not come into direct contact with all parts of the juice to achieve the requirements of this rule shall analyze the finished product for biotype I Escherichia coli at an approved laboratory at the following frequency and sample sizes:
- (1) One twenty mL sample (consisting of two ten mL subsamples) for each one-thousand gallons of juice produced shall be sampled each production day. If less than one thousand gallons of juice is produced per day, the sample must be taken for each one-thousand gallons produced but not less than once every five working days that the facility is producing that juice. Each subsample shall be taken by randomly selecting a package of juice ready for distribution to consumers.
  - (2) If the facility is producing more than one type of juice covered by this rule, processors shall take subsamples according to paragraph (D)(1) of this rule for each of the covered juice products produced.
  - (3) Processors shall analyze each subsample for the presence of E. coli by a method designed to detect the presence or absence of E. coli in a twenty mL sample of juice (consisting of two ten mL subsamples).
  - (4) If either ten mL subsample is positive for E. coli, the twenty mL sample is recorded as positive and the processor shall:
    - (a) Review monitoring records for the control measures to attain the five-log reduction standard and

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correct those conditions and practices that are not met.

- (b) If the review of monitoring records or the additional testing indicates that the five-log reduction standard was not achieved, the processor shall take corrective action as set forth in rule 901:3-23-05 of the Administrative Code.
- (5) If two samples in a series of seven tests are positive for E. coli, the control measures to attain the five-log reduction standard shall be deemed to be inadequate and the processor shall immediately:
  - (a) Use an alternative process or processes that achieve the five-log reduction after the juice has been expressed until corrective actions are completed;
  - (b) Perform a review of the monitoring records for control measures to attain the five-log reduction standard. The review shall be sufficiently extensive to determine if there are trends towards loss of control:
    - (i) If the conditions and practices are not being met, correct those that do not conform to the HACCP plan; or
    - (ii) If the conditions and practices are being met, the processor shall validate the HACCP plan in relation to the five-log reduction standard.
  - (c) Take corrective action as set forth in rule 901:3-23-05 of the Administrative Code.

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**901:3-62-01 Criteria and definitions for processing bottled water.**

(A) Food processing establishments processing and bottling drinking water shall comply with Chapter 901:3-62 and the applicable provisions of Chapter ~~901:3-17~~[901:3-17](#) of the Administrative Code.

(B) Definitions.

As used in Chapter 901:3-62 of the Administrative Code:

(1) "Approved source" means:

- (a) A public water system, as defined in division (A) of section 6109.01 of the Revised Code, with a current license issued by the director of the EPA under authority of section 6109.21 of the Revised Code;
- (b) A private water system, as defined in division (A) of section 3701.344 of the Revised Code, for which a permit has been issued under authority of paragraph (C) of rule 3701-28-03 of the Administrative Code and which is operating in compliance with the requirements of Chapter 3701. of the Revised Code and the rules adopted thereunder;
- (c) A source of water which is not required by law to be licensed either as a public water system; or to be operated as a private water system in compliance with the requirements of Chapter 3701. of the Revised Code, but for which:
  - (i) A written opinion from either a geologist or hydrologist has been obtained stating that the location and geological characteristics of the source do not expose water from the source to contamination by a chemical, biological and radiological pollutants injurious to human health, and
  - (ii) An analysis of the water from the source, done by a United States environmental protection agency certified laboratory, a state EPA laboratory or a state certified laboratory, has been obtained verifying that the water from the source meets the chemical, biological and radiological quality requirements for bottled water and bottled water packaged in the United States contained in 21 CFR 165.110(b) (2011).

(2) "Board of health" means a board of health of a city or general health district or the authority having the duties of a board of health under Chapter 3709. of the Revised Code.

(3) "Bottled water" means all water, that is intended for human consumption, including artesian water, mineral water, purified water, sparkling bottled water, and spring water, and that is sealed in bottles, packages, or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents. Floride may be optionally added within the limitations established in 21 C.F.R. Part 165.110 (b)(4)(ii) (2011).

(4) "C.F.R." means Code of Federal Regulations.

(5) "Director" means the director of the Ohio department of agriculture.

(6) "E.P.A." means the Ohio environmental protection agency.

(7) "Lot" means a collection of primary containers or unit packages of the same size, type, and style produced

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under conditions as nearly uniform as possible and designated by a common container code or marking.

- (8) "Multi-service containers" means containers intended for use more than one time.
- (9) "Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, and packaging of bottled 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.
- (10) "Operations water" means water that is delivered under pressure to a plant for container washing, hand washing, plant and equipment cleanup and for other sanitary purposes.
- (11) "ppm" means parts per million.
- (12) "Primary container" means the immediate container in which the product water is packaged.
- (13) "Product water" means processed water used by a plant for bottled water.
- (14) "Shipping case" means a container in which one or more primary containers of the product are held.
- (15) "Single-service container" means a container intended for one time usage only.
- (16) "TDS" means total dissolved solids.
- (17) "Unit package" means a standard commercial package of bottled water, which may consist of one or more containers.

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**THE FOLLOWING RULES ARE PROPOSED TO BE RESCINDED.**

**901:3-1-01 Criteria and definitions for good manufacturing practices; labeling and standards of identity.**

(A) All food processing establishments, including processors of intoxicating beverages, shall comply with the applicable good manufacturing practices, standards of identity, and labeling requirements in Chapter 901:3-1 of the Administrative Code to determine that the food has been manufactured under such conditions that renders it safe and unadulterated; and not misbranded.

(B) Definitions.

As used in Chapter 901:3-1 of the Administrative Code:

- (1) "Acid foods or acidified foods" means foods that have an equilibrium pH of 4.6 or below.
- (2) "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (3) "Adulterated" means adulterated as defined in Chapter 3715. of the Revised Code.
- (4) "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.
- (5) "Blanching" means a prepackaging heat treatment of foodstuffs, except for tree nuts and peanuts, 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.
- (6) "Critical control point" means a point, step or procedure in a food process where there is a high probability that improper control may result in an unacceptable health hazard or contribute to filth in the final food or decomposition of the final food.
- (7) "Defect action level" means the maximum levels for defects in foods produced under current good manufacturing practices.
- (8) "Food" means food as defined in Chapter 3715. of the Revised Code.
- (9) "Food-contact surface" means:
  - (a) A surface of equipment or a utensil with which food normally comes into contact; or
  - (b) A surface of equipment or a utensil from which food may drain, drip, or splash into a food, or onto a surface normally in contact with food.
- (10) "Intoxicating beverage" means intoxicating liquor, liquor, low alcohol beverages, wine, beer, and cider, as defined in section 4301.01 of the Revised Code.
- (11) "Lot" means the food produced during a period of time indicated by a specific code.
- (12) "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

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that are of public health significance, that subject food to decomposition, indicate food is contaminated with filth, or otherwise may cause food to be adulterated.

- (13) "Pest" means any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
- (14) "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of food.
- (15) "Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.
- (16) "Rework" means clean, unadulterated food intended for consumption 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.
- (17) "Safe moisture level" means 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 data is available that demonstrate that the food at or below the given  $a_w$  will not support the growth of undesirable microorganisms.
- (18) "Sanitize" means the application of cumulative heat or chemical to food contact surfaces 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.
- (19) " $a_w$ " means water activity which 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.
- (20) "pH" is the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

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## **901:3-1-02 Personnel.**

### (A) Disease control.

Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness that is transmitted through food, 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 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 protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

- (1) Wearing outer garments suitable to the operation that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
- (2) Maintaining personal cleanliness.
- (3) Washing hands in an acceptable 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. A hand sanitizer may be used to supplement hand washing.
- (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry. If such hand jewelry cannot be removed, it may be covered by an acceptable 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.
- (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 eating food, chewing gum, drinking beverages, or using tobacco to areas other than where food may be exposed or where equipment or utensils are washed.
- (9) Taking any other necessary precautions to protect food, food-contact surfaces, or food-packaging materials from contamination by microorganisms or foreign substances such as, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

### (C) Education and training.

Food handlers and supervisors shall receive appropriate training in proper food handling techniques and food protection principles.

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(D) Supervision.

Responsibility for assuring compliance by all personnel with all requirements of this chapter shall be assigned to supervisory personnel.

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## **901:3-1-03 Plant and grounds.**

### **(A) Grounds.**

The grounds surrounding 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 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) 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 a manner so that they do not constitute a source of contamination in areas where food is exposed.

### **(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 be designed and constructed:

- (1) To 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) To 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 sanitation standard operating procedures 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) To permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:
  - (a) Using protective coverings.
  - (b) Controlling areas over and around the vessels to eliminate harborage areas for pests.
  - (c) Checking on a regular basis for pests and pest infestation.
  - (d) Skimming the fermentation vessels, as necessary.
- (4) In such a manner that floors, walls, and ceilings may be effectively 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 unobstructed and of sufficient width to permit employees to

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perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

- (5) To provide at least twenty foot-candles of light, thirty inches above the floor, where food is stored; at least twenty foot-candles of light, thirty inches above the floor, in hand-washing areas, dressing and locker rooms, and toilet rooms; and fifty foot-candles of light at a surface where food is examined or processed, and where equipment or utensils are cleaned.
- (6) To 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.
- (7) To 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.
- (8) To provide, where necessary, effective screening or other protection against pests.

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## **901:3-1-04 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. 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) Toxic materials.

- (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be safe and effective under the conditions of use. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:
  - (a) Those required to maintain clean and sanitary conditions;
  - (b) Those necessary for use in laboratory testing procedures;
  - (c) Those necessary for plant and equipment maintenance and operation; and
  - (d) 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.

### (C) Animal and pest control.

No animals or pests shall be allowed in any area of a food plant. Guard dogs or support animals may be allowed in some areas of a plant if the presence of the dogs or support animals 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. A restricted use pesticide shall be applied in accordance with Chapter 921. of the Revised Code and the rules adopted thereunder.

### (D) Sanitation of food-contact surfaces.

All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned 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, 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.

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- (3) Sanitizing agents shall be effective 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 effective cleaning and sanitizing treatment.

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**901:3-1-06      Equipment and utensils.**

- (A) All plant equipment and utensils shall be so designed and of such material and workmanship as to be easily cleanable, and shall be properly maintained.
- (B) 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.
- (C) Food-contact surfaces shall be corrosion resistant and maintained to protect food from being contaminated. 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.
- (D) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter.
- (E) 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.
- (F) 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.
- (G) 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.
- (H) 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 maintained, and adequate in number for their designated uses.
- (I) Food temperature measuring devices that are scaled only in Fahrenheit shall be accurate to plus or minus two degrees Fahrenheit; or if scaled only in Celsius or dually scaled in Celsius and Fahrenheit shall be accurate to plus or minus one degree Celsius in the intended range of use.
- (J) Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure accuracy.
- (K) 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.

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**901:3-1-07 Controls.**

- (A) All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with plant sanitation standard operating procedures that conform to this chapter.
- (B) Quality control operations shall be employed to ensure that food is safe and food-packaging materials are safe and suitable.
- (C) Overall sanitation and quality control of the plant shall be under the supervision of one or more individuals assigned responsibility for this function.
- (D) The operator shall 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.
- (E) All food that has become contaminated to the extent that it is adulterated shall be rejected, or, if permissible, treated, or processed to eliminate the contamination.

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**901:3-1-08 Raw materials and other ingredients.**

- (A) 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.
- (B) Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.
- (C) 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. 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.
- (D) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with defect 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.
- (E) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable 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.
- (F) 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. Material scheduled for rework shall be clearly identified for that purpose.
- (G) 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.
- (H) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

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**901:3-1-09 Manufacturing operations.**

- (A) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing. Equipment shall be disassembled as necessary to allow access for thorough cleaning.
- (B) 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.
- (C) 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 and as applicable:
  - (1) Maintaining refrigerated foods at forty-five degrees Fahrenheit or below as appropriate for the particular food involved.
  - (2) Maintaining frozen foods in a frozen state.
  - (3) Maintaining hot foods at one hundred forty degrees Fahrenheit or above.
  - (4) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.
- (D) 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 effective under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.
- (E) Work-in-process shall be handled in a manner that protects against contamination.
- (F) 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.
- (G) 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.
- (H) Effective measures, such as using sieves, traps, magnets, electronic metal detectors, or other suitable effective means shall be taken to protect against the inclusion of metal or other extraneous material in food.
- (I) Food, raw materials, and other ingredients that are adulterated 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 before being incorporated into other food.
- (J) 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.

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- (K) Heat blanching, when required in the preparation of food, shall 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.
- (L) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination.
- (M) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination.
- (N) Food including 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 by any effective means including employment of one or more of the following practices: monitoring the  $a_w$  of the food, controlling the soluble solids-water ratio in finished food, and/or 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.
- (O) Food including 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 by any effective means including employment of one or more of the following practices: monitoring the pH of raw materials, food in process, and finished food and/or controlling the amount of acid or acidified food added to low-acid food.
- (P) 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 chapter.
- (Q) Unless there is no reasonable possibility for the contamination of the food intended for human consumption, food manufacturing areas and equipment used for manufacturing food intended for human consumption shall not be used to manufacture food grade animal feed or inedible products,
- (R) 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, regardless of the defect level of the final food.

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**901:3-1-10      Warehousing and distribution.**

Storage and transportation of 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.