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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.