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**THE FOLLOWING RULES ARE PROPOSED TO BE RESCINDED.**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