

Document: Proposed Rule

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**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

Proposed Rule
LSA Document #01-7

DIGEST

Adds 410 IAC 7-21 to safeguard public health and assure that food provided to consumers is safe, unadulterated, and honestly presented. The rule will establish minimum sanitary standards for the operation of wholesale food establishments, which include manufacturers, processors, repackagers, and distributors of food, excluding meat and poultry processors regulated under IC 15-2.1-24; dairy processors, regulated under IC 15-2.1-22, IC 15-2.1-23, and 345 IAC 8; and shell egg plants regulated under 370 IAC 1-10-1 and IC 16-42-11. Effective 120 days after filing with the secretary of state.

410 IAC 7-21

SECTION 1. 410 IAC 7-21 IS ADDED TO READ AS FOLLOWS:

Rule 21. Wholesale Food Establishment Sanitation Requirements

410 IAC 7-21-1 Applicability

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 1. The definitions in this rule apply throughout this rule. (*Indiana State Department of Health; 410 IAC 7-21-1*)

410 IAC 7-21-2 “Acid foods” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 2. “Acid foods” means foods that have a natural pH of 4.6 or below. (*Indiana State Department of Health; 410 IAC 7-21-2*)

410 IAC 7-21-3 “Acidified foods” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 3. (a) “Acidified foods” means low-acid foods to which acid or acid food is added; these foods include, but are not limited to:

- (1) beans;
- (2) cucumbers;
- (3) cabbage;
- (4) artichokes;
- (5) cauliflower;
- (6) puddings;
- (7) peppers;
- (8) tropical fruits; and
- (9) fish;

singly or in any combination. They have a water activity (a_w) greater than eighty-five hundredths (0.85) and have a finished equilibrium pH of 4.6 or below. These foods may be called pickled, such as “pickled cauliflower”.

(b) Excluded from the definition of acidified foods are:

- (1) carbonated beverages;**
- (2) jams;**
- (3) jellies;**
- (4) preserves; and**
- (5) acid foods;**

(including such foods 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, and foods that are stored, distributed, and retailed under refrigeration. (Indiana State Department of Health; 410 IAC 7-21-3)

410 IAC 7-21-4 “Adequate” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 4. “Adequate” means that which is needed to accomplish the intended purpose in keeping with good public health practice. (Indiana State Department of Health; 410 IAC 7-21-4)

410 IAC 7-21-5 “Adulterated” defined

Authority: IC 16-42-5-5

Affected: IC 16-42

Sec. 5. “Adulterated” has the meaning set forth under IC 16-42-1 through IC 16-42-4. (Indiana State Department of Health; 410 IAC 7-21-5)

410 IAC 7-21-6 “Allergen” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 6. “Allergen” means foods that are commonly known to cause serious allergenic responses, including, but not limited to, the following:

- (1) Milk.**
- (2) Eggs.**
- (3) Fish.**
- (4) Crustacea.**
- (5) Mollusks.**
- (6) Tree nuts.**
- (7) Wheat.**
- (8) Legumes, particularly peanuts and soybeans.**

(Indiana State Department of Health; 410 IAC 7-21-6)

410 IAC 7-21-7 “Batter” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 7. “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. (Indiana State Department of Health; 410 IAC 7-21-7)

410 IAC 7-21-8 “Blanching” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 8. “Blanching”, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to affect other

physical or biochemical changes in the food. *(Indiana State Department of Health; 410 IAC 7-21-8)*

410 IAC 7-21-9 “Bottled drinking water” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 9. “Bottled drinking water” means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water. *(Indiana State Department of Health; 410 IAC 7-21-9)*

410 IAC 7-21-10 “CFR” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 10. “CFR” means the Code of Federal Regulations. *(Indiana State Department of Health; 410 IAC 7-21-10)*

410 IAC 7-21-11 “CIP system” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 11. “CIP” means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning. The term does not include the cleaning of equipment, such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system. *(Indiana State Department of Health; 410 IAC 7-21-11)*

410 IAC 7-21-12 “Critical control point” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 12. “Critical control point” means a point or procedure in a specific food process where loss of control may result in an unacceptable health risk. *(Indiana State Department of Health; 410 IAC 7-21-12)*

410 IAC 7-21-13 “Department” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 13. “Department” means the Indiana state department of health or its authorized representative. *(Indiana State Department of Health; 410 IAC 7-21-13)*

410 IAC 7-21-14 “Drinking water” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 14. “Drinking water” means water that meets the requirements of 327 IAC 8. The term is traditionally known as potable water. The term includes water, except where the term used connotes that the water is not potable, such as boiler water, mop water, wastewater, and nondrinking water. *(Indiana State Department of Health; 410 IAC 7-21-14)*

410 IAC 7-21-15 “Food” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 15. “Food” means the following:

(1) All articles used for food, drink, confectionery, or condiment whether simple, mixed, or compound.

(2) All substances or ingredients used in the preparation of the items described in subdivision (1).

(Indiana State Department of Health; 410 IAC 7-21-15)

410 IAC 7-21-16 “Food-contact surface” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 16. “Food-contact surface” means a surface of equipment or a utensil:

(1) with which food normally comes into contact; or

(2) from which food may drain, drip, or splash into a food, or onto a surface normally in contact with food.

(Indiana State Department of Health; 410 IAC 7-21-16)

410 IAC 7-21-17 “Food employee” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 17. “Food employee” means an individual working with food, food equipment or utensils, or food-contact surfaces.

(Indiana State Department of Health; 410 IAC 7-21-17)

410 IAC 7-21-18 “HACCP plan” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 18. “HACCP plan” means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods.

(Indiana State Department of Health; 410 IAC 7-21-18)

410 IAC 7-21-19 “Lot” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 19. “Lot” means the food produced during a period of time indicated by a specific code. *(Indiana State Department of Health; 410 IAC 7-21-19)*

410 IAC 7-21-20 “Low-acid food” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 20. “Low-acid food” means any food, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than eighty-five hundredths (0.85). *(Indiana State Department of Health; 410 IAC 7-21-20)*

410 IAC 7-21-21 “Microorganisms” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 21. “Microorganisms” means yeasts, molds, bacteria, protozoa, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance and those of nonpublic health significance that result in food spoilage or that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. “Microbial” is used in some instances instead of using an adjectival phrase containing the word microorganism. *(Indiana State Department of Health; 410 IAC 7-21-21)*

410 IAC 7-21-22 “Pest” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 22. “Pest” refers to any objectionable animals or insects, including, but not limited to, the following:

(1) Birds.

(2) Rodents.

(3) Flies.

(4) Larvae.

(Indiana State Department of Health; 410 IAC 7-21-22)

410 IAC 7-21-23 “pH” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 23. “pH” means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between zero (0) and seven (7) indicate acidity, and values between seven (7) and fourteen (14) indicate alkalinity. The value for pure distilled water is seven (7), which is considered neutral. *(Indiana State Department of Health; 410 IAC 7-21-23)*

410 IAC 7-21-24 “Plant” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 24. “Plant” means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, holding, or storing of human food. *(Indiana State Department of Health; 410 IAC 7-21-24)*

410 IAC 7-21-25 “Potentially hazardous food” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 25. (a) “Potentially hazardous food” means a natural or synthetic food and requires temperature control because it is in a form capable of supporting any of the following:

- (1) The rapid and progressive growth of infectious or toxigenic microorganisms.**
- (2) The growth and toxin production of *Clostridium botulinum*.**
- (3) In raw shell eggs, the growth of *Salmonella enteritidis*.**

(b) The term includes the following:

- (1) A food of animal origin that is raw or heat-treated.**
- (2) A food of plant origin that is heat-treated or consists of raw seed sprouts.**
- (3) Cut melons.**
- (4) Garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under subsection (a).**

(c) The term does not include any of the following:

- (1) An air-cooled hard-boiled egg with shell intact.**
- (2) A food with a water activity (a_w) value of eighty-five hundredths (0.85) or less.**
- (3) A food with a pH level of four and six-tenths (4.6) or below when measured at seventy-five (75) degrees Fahrenheit.**
- (4) A food, in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution.**
- (5) A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *Salmonella enteritidis* in eggs or *Clostridium botulinum* cannot occur, such as a food that:
 - (A) has an a_w and a pH that are above the levels specified under subdivisions (2) and (3); and**
 - (B) may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms.****
- (6) A food that may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness, but that does not support the growth of microorganisms as specified under subsection (a).**

(Indiana State Department of Health; 410 IAC 7-21-25)

410 IAC 7-21-26 “Public health significance” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 26. “Public health significance” means:

(1) the potential for causing diseases with symptoms, such as, but not limited to:

- (A) diarrhea;**
- (B) fever;**
- (C) jaundice;**
- (D) vomiting or sore throat with fever; or**
- (E) boils; or**

(2) for diseases such as, but not limited to:

- (A) Salmonella spp.;**
- (B) Shigella spp.;**
- (C) Escherichia coli 0157:H7; or**
- (D) Hepatitis A virus associated with foodborne or waterborne transmission that are reportable according to 410 IAC 1-2.3.**

(Indiana State Department of Health; 410 IAC 7-21-26)

410 IAC 7-21-27 “Quality control operation” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-2-2; IC 16-42-5

Sec. 27. “Quality control operation” means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated as defined under IC 16-42-2-2. *(Indiana State Department of Health; 410 IAC 7-21-27)*

410 IAC 7-21-28 “Reduced oxygen packaging” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 28. (a) “Reduced oxygen packaging” means the following:

(1) The reduction of the amount of oxygen in a package by:

- (A) removing oxygen;**
- (B) displacing oxygen and replacing it with another gas or combination of gases; or**
- (C) otherwise controlling the oxygen content to a level below that normally found in the surrounding twenty-one percent (21%) oxygen atmosphere.**

(2) A process as specified in subdivision one (1) that involves a food for which Clostridium botulinum is identified as a microbiological hazard in the final packaged form.

(b) The term includes the following:

(1) Vacuum packaging in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package, such as sous vide.

(2) Modified atmosphere packaging in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes any of the following:

- (A) Reduction in the proportion of oxygen.**
- (B) Total replacement of oxygen.**
- (C) An increase in the proportion of other gases, such as carbon dioxide or nitrogen.**

(3) Controlled atmosphere packaging in which the atmosphere of a package of food is modified so that, until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained as such by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(Indiana State Department of Health; 410 IAC 7-21-28)

410 IAC 7-21-29 “Restricted use pesticide” defined

Authority: IC 16-42-5-5

Affected: IC 15-3-3.5-2; IC 16-42-5

Sec. 29. “Restricted use pesticide” has the same meaning as defined in IC 15-3-3.5-2(27). *(Indiana State Department of Health;*

410 IAC 7-21-29)

410 IAC 7-21-30 “Rework” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 30. “Rework” means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. (Indiana State Department of Health; 410 IAC 7-21-30)

410 IAC 7-21-31 “Sanitization” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 31. “Sanitization” means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five (5) logs, which is equal to a ninety-nine and nine hundred ninety-nine thousandths percent (99.999%) reduction of representative disease-causing microorganisms of public health significance. (Indiana State Department of Health; 410 IAC 7-21-31)

410 IAC 7-21-32 “Scheduled process” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 32. “Scheduled process” means the process selected by a processor as adequate for use under food manufacturing conditions to achieve and maintain a food that will not permit the growth of microorganisms having a public health significance. The term includes control of pH and other critical factors equivalent to the process established by a competent processing authority. (Indiana State Department of Health; 410 IAC 7-21-32)

410 IAC 7-21-33 “Water activity” defined

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 33. “Water activity” indicated by the symbol a_w means water activity that is a measure of the free moisture in a food and the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature. (Indiana State Department of Health; 410 IAC 7-21-33)

410 IAC 7-21-34 “Wholesale food establishment” defined

Authority: IC 16-42-5-5

Affected: IC 15-2.1; IC 16-42

Sec. 34. (a) “Wholesale food establishment” means any establishment within Indiana that manufactures, packages, stores, repackages, or transports human food products for distribution to another entity for resale or redistribution.

(b) The term does not include the following:

(1) A residential kitchen in a private home.

(2) Bed and breakfast establishments subject to 410 IAC 7-15.5.

(3) An establishment engaged solely in the harvesting, storage, or distribution of one (1) or more raw agricultural commodities, that is not ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(4) Meat and poultry processing plants subject to IC 15-2.1-24; dairy processing plants subject to IC 15-2.1-22, IC 15-2.1-23 and 345 IAC 8; or shell egg plants subject to 370 IAC 1-10-1 and IC 16-42-11.

(5) Any establishments as defined in 410 IAC 7-20-70, except when engaged in activities under subsection (a) or when producing acidified foods in hermetically sealed containers.

(Indiana State Department of Health; 410 IAC 7-21-34)

410 IAC 7-21-35 Personnel health

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 35. (a) The plant management shall take all reasonable measures and precautions to ensure compliance with the following:

(1) Any person who, by medical examination or supervisory observation, is shown to have, or appears to have:

(A) an illness;

(B) an open lesion, including:

(i) boils;

(ii) sores; or

(iii) infected wounds; or

(C) 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 or restricted from any operations, which may result in contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to supervisory personnel.

(2) An exclusion shall be applied if a food employee is diagnosed with an illness due to Salmonella spp., Shigella spp., Escherichia coli O157:H7, or Hepatitis A virus. A food employee shall be restricted from working with exposed food, food-contact surfaces, clean equipment, and utensils or food-packaging materials if the food employee:

(A) has a symptom caused by illness, infection, or other source that is associated with an acute gastrointestinal illness, such as, diarrhea, fever, vomiting, jaundice, or sore throat with fever;

(B) has a lesion containing pus, such as a boil or infected wound that is open or draining and is:

(i) on the hands or wrists unless an impermeable cover, such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;

(ii) on exposed portions of the arms unless the lesion is protected by an impermeable cover; or

(iii) on the other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage; or

(C) is not experiencing a symptom of acute gastroenteritis as specified in this subdivision, but has a stool that yields a specimen culture that is positive for Salmonella spp., Shigella spp., or Escherichia coli O157:H7.

(3) An exclusion may be removed when supervisory personnel obtains from the excluded person written medical documentation from a physician, a nurse practitioner, or a physician assistant that the excluded person may work in an unrestricted capacity.

(4) A restriction may be removed by supervisory personnel when the restricted person:

(A) is free of the symptoms of illness specified in subdivision (2) and no foodborne illness occurs that may have been caused by the restricted person;

(B) is suspected of causing foodborne illness but:

(i) is free of the symptoms specified under subdivision (2)(A); and

(ii) provides written medical documentation from a physician, a nurse practitioner, or a physician assistant stating that the restricted person is free of the infectious agent that is suspected of causing the person's symptoms or causing foodborne illness; or

(C) provides written medical documentation from a physician, a nurse practitioner, or a physician assistant stating that the symptoms experienced result from a chronic noninfectious condition, such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis.

(b) The department may issue an order of restriction or exclusion to a wholesale food establishment without prior warning, notice of a hearing, or a hearing if the order states the following:

(1) The reasons for the restriction or exclusion that is ordered.

(2) The evidence that the wholesale food establishment shall provide in order to demonstrate that the reasons for the restriction or exclusion has been eliminated.

(3) That a suspected food employee or the wholesale food establishment may request an appeal hearing by submitting a timely request as provided in law.

(4) The name and address of the department's representative to whom a request for an appeal hearing may be made.

(Indiana State Department of Health; 410 IAC 7-21-35)

410 IAC 7-21-36 Personnel hygienic practices

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 36. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to good hygienic practices while on duty. The methods for maintaining good hygiene include, but are not limited to, the following:

- (1) Wearing clean outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.**
- (2) Maintaining adequate personal cleanliness, including:**
 - (A) keeping fingernails clean and neatly trimmed; and**
 - (B) not wearing fingernail polish or artificial fingernails;****while working with exposed food.**
- (3) Washing hands thoroughly in an adequate hand washing facility as follows:**
 - (A) Before starting work.**
 - (B) After each absence from the work station.**
 - (C) After touching bare human body parts other than clean hands and clean, exposed portions of arms.**
 - (D) After using the toilet room.**
 - (E) After caring for or handling service animals or aquatic animals.**
 - (F) After coughing, sneezing, or using a handkerchief or disposable tissue.**
 - (G) After drinking, unless the handling of the container allows for no direct contamination, and after eating or using tobacco.**
 - (H) After handling soiled surfaces, equipment, or utensils.**
 - (I) During food preparation, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks.**
 - (J) When switching between working with raw food and working with ready-to-eat food.**
 - (K) Directly before touching ready-to-eat food or food-contact surfaces.**
 - (L) At any other time when the hands may have become soiled or contaminated.**
- (4) Wearing no jewelry while preparing food. If hand jewelry cannot be removed or if approval is given by supervisory personnel for the wearing of a wedding band, it may be covered by an impermeable cover, such as a glove, that can be maintained in an intact, clean, and sanitary condition and that protects against contamination.**
- (5) Maintaining gloves in an intact, clean, and sanitary condition if they are used in direct contact with food. The gloves shall be made of an impermeable material.**
- (6) Wearing hair restraints, such as nets, hats, beard restraints, and clothing that covers body hair, which are designed and worn effectively to keep hair from contacting exposed food, clean food-contact equipment and utensils.**
- (7) Storing employees' food and personal belongings in a designated location separate from food processing, storage, and packaging areas.**
- (8) Confining the following to areas other than where food and food processing equipment may be exposed or where equipment or utensils are washed and stored:**
 - (A) eating food;**
 - (B) chewing gum;**
 - (C) drinking beverages; or**
 - (D) using tobacco.**
- (9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances, including, but not limited to, the following:**
 - (A) Perspiration.**
 - (B) Hair.**
 - (C) Cosmetics.**
 - (D) Tobacco.**
 - (E) Chemicals.**
 - (F) Medicines applied to the skin.**

(Indiana State Department of Health; 410 IAC 7-21-36)

410 IAC 7-21-37 Personnel training

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 37. (a) Personnel responsible for identifying sanitation failures or food contamination shall have an educational background or experience, or a combination thereof, to provide a level of competency necessary for production of unadulterated, honestly presented, safe food. Food employees and supervisory personnel involved in food processing shall receive appropriate training in proper food-handling techniques, foodborne illness prevention, and food protection principles and be informed of the danger of poor personal hygiene and insanitary practices.

(b) Competent supervisory personnel shall be clearly assigned responsibility for assuring compliance by all food employees engaged in food processing with all requirements. Supervisory personnel shall hold a certification or be trained at a minimum on the following areas of knowledge as are applicable to the operations conducted at the wholesale food establishment:

- (1) The relationship between the prevention of foodborne disease and the personal hygiene of a food employee.
- (2) Responsibility of supervisory personnel for preventing the transmission of foodborne disease by a food employee who has an illness or medical condition that may cause foodborne disease.
- (3) Symptoms associated with the diseases that are transmissible through food.
- (4) Required food temperatures and times for safe cooking, cooling and reheating of potentially hazardous foods and refrigerated storage temperatures include those for meat, poultry, eggs, and fish.
- (5) The relationship between the prevention of foodborne illness and the management and control of the following:
 - (A) Cross-contamination.
 - (B) Hand contact with ready-to-eat foods.
 - (C) Hand washing.
 - (D) Maintaining the wholesale food establishment in a clean condition and in good repair.
- (6) The correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment.
- (7) Poisonous or toxic materials identification and the procedures necessary to ensure that they are safely stored, dispensed, used and disposed of according to law.
- (8) Knowledge of important processing points in the operation from purchasing through sale or service.
- (9) The principles and details of a HACCP plan, if used, or if required by federal or state law, or if an agreement between the department and the firm exists.
- (10) Water sources identification and measures taken to ensure that it remains protected from contamination, such as providing protection from backflow and precluding the creation of cross-connections.

(Indiana State Department of Health; 410 IAC 7-21-37)

410 IAC 7-21-38 Physical facilities and grounds

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 38. (a) 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 adequate maintenance of grounds include, but are not limited to, the following:

- (1) Properly storing or removing unnecessary equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the physical facility that may constitute an attractant, breeding place, or harborage for pests.
- (2) Maintaining roads and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
- (3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
- (4) Operating systems for waste treatment and removal of liquid and solid waste at such a frequency that the waste does not constitute a source of contamination in areas where food is exposed.
- (5) Constructing, if needed, an outdoor storage surface of nonabsorbent material, such as concrete or asphalt that shall be smooth, durable, and sloped to drain for refuse, recyclables, and returnables. Refuse, recyclables, and returnables shall be handled by:
 - (A) storing them in receptacles or waste handling units so that they are inaccessible to insects and rodents.
 - (B) keeping receptacles and waste handling units for refuse, recyclables, and returnables covered with tight-fitting lids or doors; and
 - (C) locating receptacles and waste handling equipment at a distance from the building that minimizes the entrance of pests and other vermin.

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

(c) Physical facilities shall be adequate in size, construction, and design to facilitate maintenance and sanitary operations for food manufacturing purposes. Methods for maintaining a sanitary operation include, but are not limited to, the following:

(1) Providing sufficient space for placement of equipment and storage of materials.

(2) Taking 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 shall be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one (1) or more of the following means:

(A) Location.

(B) Time.

(C) Partition.

(D) Air flow.

(E) Enclosed systems.

(F) Other effective means.

(3) Locating areas designated for employees to eat, drink, and use tobacco so that food and equipment are protected from contamination.

(4) Prohibiting a person from living or sleeping in a room used for food-handling or in a room opening directly into a wholesale food establishment. If living or sleeping quarters are located on the premises, such as those provided for security personnel, it shall be separated from rooms and areas used for wholesale food establishment operations by complete partitioning and solid self-closing doors.

(5) Protecting food in outdoors bulk fermentation vessels by any effective means, including, but not limited to, the following:

(A) Using protective coverings.

(B) Controlling areas over and around the vessels to eliminate harborage for pests.

(C) Checking on a regular basis for pests and pest infestation.

(D) Skimming the fermentation vessels, when necessary.

(6) Constructing facility in such a manner that:

(A) floors, walls, and ceilings may be adequately cleaned and maintained in good repair;

(B) drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and

(C) aisles or working spaces are provided between equipment and walls and food products and walls and are adequately unobstructed and have adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(7) Providing sufficient lighting in hand washing areas, dressing and locker rooms, toilet rooms, and all areas where food is examined, processed, or stored and where equipment or utensils, are cleaned. Light bulbs shall be protected in the following manner:

(A) Shielded, coated, or otherwise shatter-resistant in areas suspended over exposed food in any step of preparation and over clean equipment, utensils, and linens.

(B) Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages if:

(i) the integrity of the packages cannot be affected by broken glass falling onto them; and

(ii) the packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

(8) Providing 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. To comply:

(A) intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials; and

(B) ventilation systems may not create a public health hazard or nuisance or unlawful discharge, if vented to the outside.

(9) Protecting outer openings against the entry of insects, rodents, or other vermin by:

(A) filling or closing holes and other gaps along floor, walls, and ceilings;

(B) closed, tight-fitting windows;

(C) solid, self-closing, and tight-fitting doors, except emergency exit and dock doors do not need to be self-closing; and

(D) using screening, air curtains, or other effective means, when appropriate.

(Indiana State Department of Health; 410 IAC 7-21-38)

410 IAC 7-21-39 Sanitary operations; general maintenance

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 39. (a) The plant shall be:

- (1) maintained in a sanitary condition; and**
- (2) 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) Food-contact surfaces, utensils, and equipment shall be cleaned as frequently as necessary to protect against contamination of food by performing the following:

- (1) Food-contact surfaces of equipment and utensils used for manufacturing or holding low moisture food shall be in a dry, clean, and sanitary condition at the time of use. When the food-contact surfaces are wet cleaned, they shall be sanitized and thoroughly dried before subsequent use.**
- (2) In wet processing, when cleaning is performed to protect against the introduction of microorganisms into food, food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated.**
- (3) Where equipment and utensils are used in a continuous production operation, food-contact surfaces of the equipment shall be cleaned and sanitized as necessary to prevent contamination.**
- (4) Nonfood-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.**
- (5) Single-service articles, such as utensils intended for one-time use, paper cups, and paper towels, should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.**
- (6) Cleaned and sanitized portable equipment with food-contact surfaces and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination.**
- (7) 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 sanitized.**
- (8) Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010.**

(Indiana State Department of Health; 410 IAC 7-21-39)

410 IAC 7-21-40 Toxic and poisonous substances; pest control

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 40. (a) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by an effective means, including, but not limited to, purchase of substances under a supplier's guarantee or certification, or examination of the substances for contamination.

(b) Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

- (1) Chemicals required for maintaining clean and sanitary conditions.**
- (2) Chemicals necessary for use in laboratory testing procedures.**
- (3) Chemicals necessary for plant and equipment maintenance and operation.**
- (4) Chemicals necessary for use in the plant's operations.**

(c) 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. Poisonous or toxic materials shall be stored and transported according to the following:

- (1) Separating the poisonous or toxic materials by spacing or partitioning.**

(2) Locating the poisonous or toxic materials in an area that is not above food, equipment, linens, or food-contact surfaces.

(d) Poisonous or toxic materials shall be applied and used according to all relevant regulations promulgated by other federal, state, and local government agencies and according to the following:

(1) Manufacturers' use directions on the label.

(2) The conditions of certification for use of the pest control materials.

(3) Applied in a manner that does not constitute a hazard to personnel or does not contaminate by drip, drain, fog, splash, or spray any food, equipment, utensils, linens, or other food-contact surface. For pesticide use, this is achieved by:

(A) removing the items;

(B) covering the items with impermeable covers; or

(C) taking other appropriate preventive action and cleaning and sanitizing equipment, utensils, and food-contact surfaces after application.

(4) Chemicals used to wash or peel whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315.

(5) Chemicals used as boiler water additives shall meet the requirements as specified in 21 CFR 173.310.

(6) A restricted use pesticide shall be applied only by an applicator certified according to 312 IAC 18-3-14 or a person under the direct supervision of a certified applicator.

(e) Pests shall not be allowed in any area of a wholesale food establishment. 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 protect against the contamination of food, food-contact surfaces, and food-packaging materials, such as the following:

(1) Rodent bait shall be contained in a covered, tamper-resistant bait station.

(2) Toxic tracking powder pesticide may not be used in wholesale food establishments.

(f) Guard dogs and service animals may be allowed in some areas of a plant if the presence of the animals cannot result in contamination of food, food-contact surfaces, or food-packaging materials. (*Indiana State Department of Health; 410 IAC 7-21-40*)

410 IAC 7-21-41 Plumbing and sewage systems

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 41. Each facility shall be equipped with effective plumbing and sewage facilities and adequate accommodations, including, but not limited to, the following:

(1) The water supply shall be sufficient for the operations intended and shall be derived from an approved source. Drinking water and water used for food processing operations shall meet bacteriological and chemical quality standards specified in 327 IAC 8-2. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(2) If a food processing plant obtains water from a water system not subject to 327 IAC 8-2 for its operations the operator shall sample the water at least annually for bacterial analysis by a certified laboratory, maintain records of analyses of sample results for three (3) years, and provide such records to the department upon request.

(3) A plumbing system shall be of sufficient size and shall be designed, constructed, installed, and maintained according to the applicable Indiana plumbing code, 675 IAC 16-1.3, to do the following:

(A) Carry sufficient quantities of water to required locations throughout the facility.

(B) Properly convey sewage and liquid disposable waste from the facility.

(C) Avoid constituting a source of contamination to food, water supplies, equipment, and utensils or creating an unsanitary condition.

(D) Provide sufficient floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(E) Prevent backflow or backsiphonage from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing. This shall be accomplished by the following:

(i) Installing a backflow or backsiphonage prevention device on a water supply system which meets the standards in 675 IAC 16-1.3 for construction, installation, maintenance, inspection and testing for that specific application and type

of approved device.

(ii) Using an air gap, if necessary, between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment. It shall be at least twice the diameter of the water supply inlet and may not be less than one (1) inch.

It shall be a minimum of two (2) pipe diameters of the pipe or six (6) inches, whichever is the lesser.

(4) Sewage disposal shall be conveyed into an approved sanitary sewerage system or other system, including the use of sewage transport vehicles, pumps, hoses, and connections that are constructed, maintained, and operated according to law. (*Indiana State Department of Health; 410 IAC 7-21-41*)

410 IAC 7-21-42 Sanitary facilities and controls

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 42. (a) Each facility shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement shall be accomplished by, but not limited to, the following:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against contamination such as double doors or positive airflow systems.

(b) Each facility shall provide its employees with hand washing facilities that are adequate, readily accessible, and convenient. Compliance with this requirement shall be accomplished by providing the following:

(1) Hand washing facilities at each location in the plant where good sanitary practices require employees to wash their hands. Each hand washing facility shall be:

(A) furnished with hot and cold running water tempered by means of a mixing valve or combination faucet; and

(B) capable of reaching a minimum water temperature of eighty-five (85) degrees Fahrenheit within sixty (60) seconds.

(2) Effective hand-cleaning preparations.

(3) Sanitary towel service, paper towels, or suitable drying devices.

(4) Devices or fixtures, such as water control valves, designed and constructed to protect against recontamination of clean hands.

(5) Signs directing food employees handling unprotected food, unprotected food-packaging materials, and food-contact surfaces to wash and, where appropriate, sanitize their hands. These signs should be posted in the processing room and in all other areas where employees handle food, food-packaging materials, or food-contact surfaces. If necessary, the signs should be multilingual.

(c) Receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect-resistant, rodent-resistant, leakproof, nonabsorbent, and maintained in good repair.

(d) Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces. (*Indiana State Department of Health; 410 IAC 7-21-42*)

410 IAC 7-21-43 Equipment and utensils

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 43. (a) All processing equipment and utensils shall be so designed and of such material and workmanship as to be effectively cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment shall be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including

unlawful indirect food additives by the following means:

- (1) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.
- (2) 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 maintained in a clean condition.
- (3) 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.

(b) Each freezer and refrigeration unit, including transportation vehicles, used to store, hold, or transport food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately within the compartment and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation. The operator shall do the following:

- (1) Record the temperature shown by each measuring device installed in the unit, with the date on which the temperature reading was taken. Temperature shall be monitored and recorded at least weekly.
- (2) Retain and have available for inspection the temperature records for the last six (6) months.

(c) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, sufficient in number for their designated uses, and calibrated at the frequency recommended by the manufacturer of the device. The ambient air temperature measuring devices that are scaled in Fahrenheit shall be accurate to plus or minus three (3) degrees Fahrenheit in the intended range of use.

(d) The amount of food stored in a refrigerator or frozen food storage unit shall not exceed the designed capacity of that unit.

(e) 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. (*Indiana State Department of Health; 410 IAC 7-21-43*)

410 IAC 7-21-44 Raw materials; production and process controls

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 44. (a) All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with current sanitation principles as follows:

- (1) Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.
- (2) Overall sanitation of the plant shall be under the supervision of one (1) or more competent individuals assigned responsibility for this function.
- (3) All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source by adhering to the following:
 - (A) Chemical, microbial, or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination.
 - (B) 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.

(b) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ensure that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration by the following:

- (1) Washing or cleaning raw materials as necessary to remove soil or other contamination.
- (2) Using water for washing, rinsing, or conveying food that is safe and meets the quality standards specified in 327 IAC 8-2.
- (3) Reusing water for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.
- (4) Inspecting on receipt containers and carriers of raw materials to ensure that their condition has not contributed to the

contamination or deterioration of food.

(c) Raw materials and other ingredients shall not contain levels of microorganisms that may produce foodborne illness or other disease in humans. If the potential for high levels of disease-causing microorganisms is present, food shall be pasteurized or otherwise treated during manufacturing operations so that the food no longer contains levels that would cause the product to be adulterated. Compliance with this requirement may be verified by any effective means, such as with a HACCP plan or 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 current state and federal regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by:

- (1) purchasing raw materials and other ingredients under a supplier's guarantee or certification; or
- (2) verifying 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 state and federal regulations, guidelines, and defect action levels for natural or unavoidable defects, as specified in 21 CFR 110.110, if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, such as:

- (1) purchasing the materials under a supplier's guarantee or certification; or
- (2) examination of these materials for contamination.

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

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

(h) 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.

(i) Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170 through 21 CFR 180 relating to food additives generally recognized as safe, or prior sanctioned substances that exceed amounts specified in 21 CFR 181, 21 CFR 182, 21 CFR 184, and 21 CFR 186. (*Indiana State Department of Health; 410 IAC 7-21-44*)

410 IAC 7-21-45 Manufacturing operations

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 45. (a) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing and when necessary the following:

- (1) Equipment shall be taken apart for thorough cleaning and sanitizing.
- (2) A CIP system may be used when the design of the equipment requires the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution.

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

(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. Compliance with this subsection shall be accomplished by an effective means, including, but not limited to, the following:

- (1) Maintaining cold, potentially hazardous foods at forty-one (41) degrees Fahrenheit or below. Exceptions to this requirement are when the receiving and storage temperatures are specified in another law, such as laws governing milk, molluscan shellfish, and shell eggs. These foods may be received and stored at the temperature specified in law.
- (2) Maintaining hot, potentially hazardous foods at one hundred forty (140) degrees Fahrenheit or above.
- (3) Heat treating acid or acidified foods to destroy mesophilic micro-organisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(d) Frozen foods shall be maintained in a frozen state and should be stored at zero (0) degrees Fahrenheit or below. Frozen foods shall not be refrozen after having been thawed unless the products are to be further processed by the processor, as necessary to control microbial growth.

(e) Frozen foods during transportation shall remain frozen and should be at zero (0) degrees Fahrenheit or below. Refrigerated foods during transportation shall be at forty-one (41) degrees Fahrenheit or below unless law governing their distribution applies, such as temperature requirements for shell eggs.

(f) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH, or controlling a_w that is taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be effective under the conditions of manufacturing, handling, and distribution to prevent food from being adulterated.

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

(h) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, including potential food allergens, or refuse in the following manner:

- (1) When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in receiving, loading, or shipping areas if that handling could result in contaminated food.
- (2) Food transported by conveyor shall be protected against contamination as necessary.

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

(j) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this subsection shall be accomplished by using sieves, traps, magnets, and electronic metal detectors, or other effective means. If lubricants are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces, they shall meet the requirements specified in 21 CFR 178.3570.

(k) 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.

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

(m) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delays. Thermophilic growth and contamination in blanchers should be minimized by the use of effective operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and meet the quality standards specified in 327 IAC 8-2.

(n) Batters, breadings, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. If the products are potentially hazardous they shall be held at forty-one (41) degrees Fahrenheit or below or at one hundred forty (140) degrees Fahrenheit or above. Compliance with this subsection shall be accomplished by an effective means, including one (1) or more of the following:

- (1) Using ingredients free of contamination.
- (2) Employing adequate heat processes where applicable.
- (3) Using adequate time and temperature controls.
- (4) Providing effective physical protection of food or equipment from contaminants that may drip, drain, or be drawn into them.
- (5) Rapid cooling to a storage temperature of forty-one (41) degrees Fahrenheit or below.
- (6) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(o) Filling, assembling, packaging, and other operations shall be performed in a way that the food is protected against contamination. Compliance with this subsection shall be accomplished by the following:

- (1) Using a quality control operation in which the critical control points are identified and controlled during manufacturing, if applicable.
- (2) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
- (3) Using materials for food containers and food-packaging materials that are safe and intended for food use.
- (4) Providing effective physical protection from contamination, particularly airborne contamination.
- (5) Using sanitary handling procedures.

(p) Food, such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level of eighty-five hundredths (0.85) or less. Compliance with this subsection shall be accomplished by any effective means, including the employment of one (1) or more of the following practices:

- (1) Monitoring the a_w of food.
- (2) Controlling the soluble solids/water ratio in finished food.
- (3) Protecting finished food from moisture pick-up 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.

(q) When ice is used as an ingredient or in contact with food, it shall be made from water that is safe and meets the quality standards specified in 327 IAC 8-2. It shall be used only if it has been manufactured in accordance with this rule.

(r) Bottled drinking water, manufactured, used, or sold, shall meet the requirements of 21 CFR 129 and 21 CFR 165.

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

(t) The operator of a wholesale food establishment that manufactures ready-to-eat, potentially hazardous foods shall report to the department the results of any microbiological test or other laboratory analysis, which shows a likelihood that any ready-to-eat food produced by that operator contains pathogenic organisms, undeclared allergens, or other health hazards. The operator shall report to the department within twenty-four (24) hours after receiving positive test results. The operator may report orally, electronically, or in writing, except as specified in the following:

- (1) A wholesale food establishment operator is not required to report test results if the following conditions apply:
 - (A) A product code or production date identifies the ready-to-eat food lot number.
 - (B) The wholesale food establishment operator has not sold or distributed any of the food represented by the product code or production lot number as specified under clause (A).
- (2) The department shall be notified in a timely manner if the wholesale food establishment initiates a recall and if positive testing results in the disposition of products.

(Indiana State Department of Health; 410 IAC 7-21-45)

410 IAC 7-21-46 Reduced oxygen packaging

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 46. (a) A wholesale food establishment that packages food using a reduced oxygen packaging method, with *Clostridium botulinum* identified as a microbiological hazard in the final packaged form, shall ensure that there are at least two (2) barriers in place to control the growth and toxin formation of *Clostridium botulinum*. These controls may include refrigeration, pH, and water activity.

(b) An establishment that packages food using a reduced oxygen packaging method, with *Clostridium botulinum* identified as a microbiological hazard in the final packaged form, shall have a HACCP plan that does the following:

(1) Contains a flow diagram by specific food or category type identifying critical control points and providing information on the following:

(A) Ingredients, materials, and equipment used in the preparation of that food.

(B) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

(2) Contains a statement of standard operating procedures for the plan that clearly identifies the following:

(A) Each critical control point.

(B) The critical limits for each critical control point.

(C) The method and frequency for monitoring and controlling each critical control point by the food employee designated by supervisory personnel.

(D) The method and frequency for supervision to routinely verify that the food employee is following standard operating procedures and monitoring critical control points.

(E) Action to be taken by supervision if the critical limits for each critical control point is not met.

(F) Records to be maintained by supervision to demonstrate that the HACCP plan is properly operated and managed.

(3) Identifies the food to be packaged.

(4) Limits the food packaged to a food that does not support the growth of *Clostridium botulinum* because it meets with one (1) of the following criteria:

(A) Has an a_w of ninety-one hundredths (0.91) or less.

(B) Has a pH of four and six-tenths (4.6) or less.

(C) Is a meat or poultry product cured at a food processing plant regulated by the United States Department of Agriculture and is received in an intact package.

(D) Is a food with a high level of competing organisms, such as raw meat or raw poultry.

(5) Specifies methods for maintaining food at forty-one (41) degrees Fahrenheit or below.

(6) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(A) maintain the food at forty-one (41) degrees Fahrenheit or below; and

(B) discard the food if within fourteen (14) calendar days of its packaging it is not sold for consumption.

(7) Limits the shelf life to no more than fourteen (14) calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first.

(8) Includes operational procedures that:

(A) prohibit contacting food with bare hands;

(B) identify a designated area and the method by which:

(i) physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination; and

(ii) access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation; and

(C) delineate cleaning and sanitization procedures for food-contact surfaces.

(9) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(A) concepts required for a safe operation;

(B) equipment and facilities; and

(C) procedures specified under subdivisions (2) and (8).

(Indiana State Department of Health; 410 IAC 7-21-46)

410 IAC 7-21-47 Acidified foods

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 47. A wholesale food establishment that processes acidified foods shall employ appropriate quality control procedures

to ensure that finished foods do not present a health hazard as follows:

- (1) All operators of processing and packaging systems shall be under the operating supervision of a person who has:
 - (A) attended a school giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification; and
 - (B) been identified by that school as having satisfactorily completed the prescribed course of instruction.

A United States Food and Drug Administration (FDA) sponsored Better Processing Control School is an approved school. Other equivalent schools approved by the department may be attended. The department shall consider students who have satisfactorily completed required portions of the school to be in compliance with the requirement of this subdivision.

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

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

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

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

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

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

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

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

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

- (6) pH meters shall be standardized to get an accurate pH measurement. The directions for standardization and storage supplied by the manufacturer of the equipment shall be followed.

- (7) Each container or product shall be marked with an identifying code permanently visible to the naked eye. If the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, as long as the label is securely affixed to the product container. The required identification shall specify in code the wholesale food establishment where the product was packed, the product contained therein, and the year, day, and period during which it was packed. The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Codes may be changed periodically on one (1) of the following bases:

- (A) Intervals of four (4) to five (5) hours.

- (B) Personnel shift changes.

- (C) Batches, as long as the containers constituting the batch do not represent those processed during more than one (1) personnel shift.

- (8) A qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods shall establish the scheduled process and be considered a processing authority. A written document or published paper prepared by experts in acidified food processing, such as the "Ball Canning Book," may qualify. Any modifications to a process listed in a document or paper shall be substantiated by a qualified person and that person shall be listed as the processing authority. Copies of the scheduled process shall be kept at the facility.

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

- (A) Fully reprocess that portion of the food by a process established by a competent processing authority as effective to

ensure a safe product.

(B) Thermally process the food as a low-acid food under 21 CFR 113.

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

(10) Records shall be maintained of examinations of raw materials, packaging materials, and finished products and of suppliers' guarantees or certifications that verify compliance with this rule.

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

(12) Records shall be kept of all departures from scheduled processes having a possible bearing on public health or the safety of the food. The records shall delineate the action taken and the final disposition of the product involved.

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

(14) If a processor makes an electronic record of pH by connection of the pH meter to a computer or by manually keying the pH values into a computer as the primary record, then that record is subject to 21 CFR 11.

(15) Copies of all records provided for in subdivisions (10) through (14) shall be retained at the processing plant or other reasonable, accessible location for a period of three (3) years from the date of manufacture.

(Indiana State Department of Health; 410 IAC 7-21-47)

410 IAC 7-21-48 Warehousing and distribution

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 48. Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. Potentially hazardous foods shall be transported at the temperatures as specified in section 45(c)(1) of this rule and sections 45(d) through 45(e) of this rule. *(Indiana State Department of Health; 410 IAC 7-21-48)*

410 IAC 7-21-49 Accurate representation of packaged food using standards of identity, honest presentation of food, and food labels

Authority: IC 16-42-5-5

Affected: IC 16-42; IC 16-42-2

Sec. 49. (a) Packaged food shall comply with standard of identity requirements in 21 CFR 130 through 21 CFR 169.

(b) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

(c) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of the food.

(d) Food packaged or stored in a wholesale food establishment shall be labeled as specified in law, including the following:

(1) IC 16-42-1.

(2) IC 16-42-2.

(3) 410 IAC 7-5.

(4) 21 CFR 101.

(e) Label information shall include the following:

(1) The common name of the food or, absent a common name, an adequately descriptive identity statement.

(2) If made from two (2) or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food.

(3) An accurate declaration of the quantity of contents as required in 410 IAC 12-1.

(4) The name and place of business of the manufacturer, packer, or distributor.

(Indiana State Department of Health; 410 IAC 7-21-49)

410 IAC 7-21-50 Public health protection; access; reporting imminent health hazards

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 50. (a) The department shall uniformly apply this rule to all wholesale food establishments in a reasonable manner that promotes its underlying purpose of safeguarding public health and ensuring that food is safe, not misbranded, unadulterated, and honestly presented when offered to the consumer.

(b) Facilities and equipment that were installed prior to the effective date of this rule, that do not fully meet all of the design and fabrication requirements, shall be deemed acceptable in that wholesale food establishment if it is in good repair, capable of being maintained in a sanitary condition, and the food-contact surfaces are nontoxic.

(c) After the department presents official credentials and expresses an intent to inspect, investigate, or collect food samples, the supervisory personnel shall allow the department access to the establishment during the establishment's hours of operation and other reasonable times. Information and records to which the department is entitled according to law and are specified in this rule shall be provided upon request.

(d) A wholesale food establishment shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist because of an emergency, such as:

(1) a fire;

(2) a flood;

(3) an extended interruption of electrical or water service;

(4) a sewage backup;

(5) a misuse of poisonous or toxic materials;

(6) an onset of an apparent foodborne illness outbreak;

(7) a gross unsanitary occurrence or condition; or

(8) other circumstance that may endanger public health.

(e) Operation need not be discontinued in an area of a wholesale food establishment that is unaffected by the imminent health hazard.

(f) If operations are discontinued as specified under this subsection or otherwise according to law, the wholesale food establishment shall obtain approval from the department before resuming operations. *(Indiana State Department of Health; 410 IAC 7-21-50)*

410 IAC 7-21-51 Registration of a wholesale food establishment

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 51. (a) A wholesale food establishment that maintains a place of business in Indiana shall file with the department, on forms to be furnished by the department, a written statement of the name and address of the owner, the name of the business, the character of the business, and the business address of each place of business in Indiana.

(b) A new wholesale food establishment shall not be established in Indiana until the place of business has been registered as provided in this subsection. The department shall be notified of intent to operate at least thirty (30) days prior to beginning operations.

(c) If ownership of a registered place of business changes, the new owner shall register the place of business before operating the same.

(d) If the name of the business or the address of a registered place of business changes, the owner shall register the change.
(Indiana State Department of Health; 410 IAC 7-21-51)

410 IAC 7-21-52 Incorporation by reference

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 52. (a) The following are hereby incorporated by reference:

- (1) 21 CFR 11 (April 1, 2000 Edition).**
- (2) 21 CFR 110.110 (April 1, 2000 Edition).**
- (3) 21 CFR 101 (April 1, 2000 Edition).**
- (4) 21 CFR 113 (April 1, 2000 Edition).**
- (5) 21 CFR 129 (April 1, 2000 Edition).**
- (6) 21 CFR 130 through 21 CFR 169 (April 1, 2000 Edition).**
- (7) 21 CFR 170 through 21 CFR 180 (April 1, 2000 Edition).**
- (8) 21 CFR 181 through 21 CFR 182, 21 CFR 184, and 21 CFR 186 (April 1, 2000 Edition).**
- (9) 21 CFR 173.310 (April 1, 2000 Edition).**
- (10) 21 CFR 173.315 (April 1, 2000 Edition).**
- (11) 21 CFR 178.1010 (April 1, 2000 Edition).**
- (12) 21 CFR 178.3570 (April 1, 2000 Edition).**

(b) Federal rules, which have been incorporated by reference, do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. *(Indiana State Department of Health; 410 IAC 7-21-52)*

SECTION 2. SECTION 1 of this document takes effect 120 days after filing with the secretary of state.

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on July 10, 2001 at 2:00 p.m., at the Indiana State Department of Health, 2 North Meridian Street, Rice Auditorium, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on proposed new rules to safeguard public health and assure that food provided to consumers is safe, unadulterated, and honestly presented, and to establish minimum sanitary standards for the operation of wholesale food establishments, which include manufacturers, processors, repackagers, and distributors of food, excluding meat and poultry processors regulated under IC 15-2.1-24; dairy processors, regulated under IC 15-2.1-22, IC 15-2.1-23, and 345 IAC 8; and shell egg plants regulated under 370 IAC 1-10-1 and IC 16-42-11. Copies of these rules are now on file at the Indiana State Department of Health, 2 North Meridian Street, 5th Floor and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Gregory A. Wilson, M.D.
State Health Commissioner
Indiana State Department of Health