AMERICAN MEAT INSTITUTE

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Kimberly K. Rice

FSIS Docket Clerk
Food Safety and Inspection Service, USDA
Room 102
Cotton Annex Building
300 12th Street, SW
Washington, DC 20250-3700

Re: Docket No. 00-14N Announcement of and Request for Comment Regarding Industry Petition on Hazard Analysis and Critical Control Point (HACCP) Inspection

To whom it may concern:

The American Meat Institute (AMI) is the national organization representing the interests of meat and poultry slaughterers and processors and their suppliers throughout North America. AMI's members produce the majority of meat and poultry products manufactured in the United States and as the leader of the industry coalition that submitted the Industry Petition on Hazard Analysis and Critical Control Point (HACCP) Inspection (the petition), we are very interested in commenting on the above captioned notice.

Our comments are brief and concise because the issues raised by the petition should be fully explored and the Food Safety and Inspection Service (FSIS or the agency) should hold a technical conference specifically to address the issues raised in the petition and subsequent agency questions. Below is a brief summary of the issues raised in the petition:

- The HACCP rule was written and has been interpreted too narrowly, preventing FSIS from considering elements of other plant programs, such as Sanitation Standard Operating Procedures (SSOPs) and Good Manufacturing Practices (GMPs), when evaluating the adequacy of a plant's HACCP plan. Consequently, the agency has been focusing on hazards rather than the risk presented by the hazard and mandating additional CCPs that are unnecessary or counterproductive within the context of these other in-plant food safety control systems.

Accordingly, the rule should be amended to account for these other programs.

- The definition and interpretation of a food safety hazard should be amended to reflect a more precise definition adopted by the National Advisory Committee on Microbiological Criteria for Foods to prevent the inclusion of non-significant hazards in a HACCP plan.

- The rule does not adequately address when a product is within an establishment's control, thereby permitting FSIS to conclude that a potentially adulterated product has entered commerce when, for example, it has simply left a facility's loading dock, even if it remains in a tractor-trailer on a plant's property. The rule should be amended to establish when product is shipped.

- The provision regarding inadequate HACCP plans should be amended to eliminate "produced" from § 417.6(e). Such a change would allow a plant to take appropriate corrective action on adulterated product, prior to shipment, in a manner consistent with its HACCP plan.

The following are our responses to the questions raised by the agency in the *Federal Register* Notice.

The industry petition relies mainly on the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) document and does not provide any data or examples to support its request. Is there any information that would support taking any of the actions requested in the petition?

The purpose of the petition is to bring the agency's philosophical approach and interpretation of the final Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems (the rule) back to the NACMCF document, in its entirety. The agency relied upon this document in both the proposed and final rules. Furthermore, it is the only document, outside current regulations, that the agency relies upon in its technical advice to industry and, more importantly, in its current HACCP In-depth Verification initiative. However, there are many peer reviewed scientific articles regarding HACCP that are available to the public and the agency through the National Agricultural Library and a sample list of those articles is attached (Attachment 1).

In addition, Table 1 *HACCP Definitions Side-by-Side* (Table 1), Table 2 *HACCP Principles Side-by-Side* (Table 2), and Table 3 *HACCP General Procedures Side-by-Side*

(Table 3) provided by the agency in the July 25, 2000, *Federal Register* Notice (the extension) reopening the comment period, offer further support for the actions requested in the petition. The NACMCF document is the most in-depth of the four documents in the tables. However, it is the document on which the other three (9 CFR 417, 21 CFR 123, and Codex Alimentarius Commission and the FAO/WHO Food Standards Programme, annex to CAC/RCP 1-1969, Rev. 3) are based. In addition, the NACMCF document (the only non-regulatory document in the tables) has significantly more detail and was designed to provide guidance in developing and integrating HACCP plans in food manufacturing facilities.

Would amending 9 CFR 417.2(a) in the manner suggested in the petition result in regulations that provide the level of public health protection required by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA)?

The requested change in 417.2(a) will bring the agency's philosophical approach and interpretation of the rule closer to the NACMCF document that the agency continues to rely on. Further, the requested change more clearly defines the expectations of the hazard analysis process and the use of risk analysis that the agency and the international scientific community are using to determine the level of protection needed to ensure public health. The rule, and the agency's interpretation of it, do not take into account the risk and severity factors related to hazards that are so fundamental to the hazard analysis process. This shortcoming is demonstrated in Table 2.

The requested change will focus the scope of HACCP plans to those hazards that are likely to pose a risk and severity that will cause illness and injury to the intended consumer of the product covered by the HACCP plan. The focus provided by the change will more clearly enhance the public health protection required by the FMIA and PPIA.

Should FSIS consider regulatory modifications that would acknowledge the prerequisite programs concept of the NACMCF?

Regulatory modification to acknowledge prerequisite programs is unnecessary. The current rule, and other regulations discussed below, provide the agency access to prerequisite programs. Section 9 CFR 417.5(a)(1) ("..written hazard analysis prescribed in 417.2(a) of this part, **including all supporting documentation**;" (emphasis added)) currently provides the agency access to documents and information used in an establishment's hazard analysis development process. Therefore, additional regulations are not necessary.

Moreover, prerequisite programs or GMPs are programs that are not specific to a single operation but typically cover an entire establishment. For example, a program

regarding room temperature control of processing and storage areas is generally not product specific but an overall operating program for an establishment. However, cook temperature for a ready-to-eat product is specific to a product and process. Therefore, room temperature control for processing and storage would be considered a prerequisite or GMP while cook temperature would be more apt to be included in a HACCP plan.

Furthermore, the relationship between prerequisite programs and their supporting relationship to HACCP programs is recognized internationally as evidenced by the Codex Alimentarius *Recommended International Code of Practice General Principles of Food Hygiene* (the Codex document), which the agency referenced portions of in Tables 1, 2 and 3. The Codex document clearly indicates that there is a relationship between "necessary hygiene conditions" and HACCP. These "necessary hygiene conditions" referenced are things such as plant and equipment layout and design, water supply, sewage, personal hygiene, air quality and ventilation, lighting, storage, etc.

Do FDA regulations, such as the GMP regulations, offer an approach that FSIS should consider? How would such an approach fit within the HACCP concept? How would FSIS implement such an approach?

Based on information provided by FSIS in the extension notice, the FDA GMP regulations are very similar, if not the same, as existing FSIS regulations. The bulk of the FDA GMP regulations are covered under the FSIS revised sanitation performance standards that were implemented in January 2000. Other FDA GMP requirements are covered throughout the FSIS regulations in specific sections relating to specific products. A table comparing the two sets of regulations is attached (Attachment 2).

What will be the effects of making FSIS and FDA HACCP regulatory requirements dissimilar?

FSIS and FDA currently have dissimilar regulatory requirements as demonstrated in Tables 1, 2 and 3. In addition, in those areas where the regulations are exactly the same, the interpretation is completely different, especially relating to the issues raised in the petition. This conclusion is evidenced by the extensive information found on the FDA website under HACCP regarding prerequisite programs. Throughout all of the information regarding current regulatory and pilot projects, FDA acknowledges the use of prerequisite programs. Furthermore, the enforcement of the regulations is different. HACCP is mandatory for all meat and poultry products regulated by FSIS. However, only seafood and unpasteurized juice have mandatory FDA HACCP regulations. In addition, if an FSIS regulated establishment does not have a HACCP plan in place they can not produce products, however FDA regulated establishments are allowed to continue to operate without HACCP plans.

Should the changes suggested in the industry petition be considered in light of the views expressed on HACCP by Codex and by other countries?

Information provided in Tables 1-3 show that the NACMCF document and Codex views are more closely related than the current FSIS regulations and the Codex views. Furthermore, the Codex document in its entirety recognizes the use of prerequisite programs and the hazard analysis process as spelled out by the NACMCF document. Therefore, the changes should be considered to bring FSIS closer to the Codex views on HACCP.

These comments are preliminary answers to questions raised by the agency. AMI strongly recommends that FSIS hold a technical conference to discuss the issues raised in the petition and further explore answers to the questions raised in the Notice. AMI appreciates the opportunity to submit these comments and looks forward to further discussion with the agency.

Respectfully submitted,

Kimberly K. Rice

Attachments

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FDA Regulations	FSIS Regulations
§ 110.3 Definitions. The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply: (a) Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below. (b) Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice. (c) Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods. (d) Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food. (e) Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food. (f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients. (g) Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations.	**§ 301.2 Definitions.** **§ 381.1 Definitions.** Cover definitions under the FSIS regulations and are specific to those operations and processes regulated by FSIS.

Attachment 1

Bernard, D.T.;Cole, W.R.;Gombas, D.E.;Pierson, M.;Savage, R.; et al, "Developing HACCP plans: overview of examples for teaching," Dairy, Food and Environmental Sanitation,

Notermans, S.;Gallhoff, G.;Zwietering, M.H.;Mead, G.C., "Identification of critical control points in the HACCP system with a quantitative effect on the safety of food products," Food Microbiology, 1995 v.12, p. 93-98

Riddle, C., "The role of HACCP/GMPs in safer processing of ground meat," Activities report of the R & D Associates. Research and Development Associates for Military Food and Packaging Systems. 1997/1998. v. 49/50 (2/1) ,p. 311-312.

Sperber, William H., "Modern HACCP system; the hazard analysis and critical control point system is a preventive and dynamic system which can significantly improve the safety of our food supply," Food Technology, 1991(June).

Sperber, William H.;Stevenson, K.E.;Bernard, D.T.;Deibel, K.E.; et al, "Role of prerequisite programs in managing a HACCP system," Dairy, Food and Environmental Sanitation, 1998 v. 18(7)

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''Food-contact surfaces" includes utensils and food-contact surfaces of equipment. (h) Lot means the food produced during a period of time indicated by a specific code. (i) Microorganisms means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term ''undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective ''microbial" instead of using an adjectival phrase containing the word microorganism. (j) Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae. (k) Plant means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food. (l) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act. (m) Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. (n) Safe-moisture level is a level of moisture low enough to prevent the	

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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 (Aw). An Aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given Aw will not support the growth of undesirable microorganisms. (o) Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer. (p) Shall is used to state mandatory requirements. (q) Should is used to state recommended or advisory procedures or identify recommended equipment. (r) Water activity (Aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.	
§ 110.5 Current Good Manufacturing Practice. (a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been	

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rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264). (b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.	
§ 110.10 Personnel. The plant management shall take all reasonable measures and precautions to ensure the following: (a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.	**§Sec. 416.5 Employee hygiene.** (c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination must be excluded from any operations which could result in product adulteration until the condition is corrected.
§ 110.10 Personnel. (b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.	**§Sec. 416.5 Employee hygiene.** (a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product **§Sec. 416.5 Employee hygiene.** (b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at

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(2) Maintaining adequate personal cleanliness. (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. (4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials. (5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material. (6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints. (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed. (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco. (9) Taking any other necessary precautions to protect against	the start of each working day and garments must be changed during the day as often as necessary to prevent contamination or adulteration of product

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contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.	
§ 110.10 Personnel. (c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.	FSIS regulations have only two parts that require education or training. The first is 307.7 and the other is 417.
§ 110.10 Personnel. (d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.	
§ 110.19 Exclusions. (a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more ''raw agricultural commodities,'' as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public. (b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.	**§ 303.1 Exemptions** **§ 381.10 Exemptions for Specified Operations** **§ 381.11 Exemptions based on religious dietary laws.** **§ 381.12 Effect of religious dietary laws exemptions on other persons.** **§ 381.13 Suspension or termination of exemptions.** **§ 381.14 Inspection concerning purportedly exempted operations.** **§ 381.15 Exemption from definition of "poultry product" of certain human food products containing poultry.** All of these sections cover exemptions/exclusions under the FSIS regulations.

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§ 110.20 Plant and Grounds. (a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to: (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.	**§Sec. 416.2 Establishment grounds and facilities.** (a) Grounds and pest control. The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS personnel. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product.
(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.	
(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.	
(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's Control and not maintained in the manner described in paragraph (a)(1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.	
(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall: (1) Provide sufficient space for such placement of equipment and storage	**§Sec. 416.2 Establishment grounds and facilities.** (b)(1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in

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of materials as is necessary for the maintenance of sanitary operations and the production of safe food.	product adulteration or the creation of insanitary conditions.
(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, air flow, enclosed systems, or other effective means.	**§Sec. 416.2 Establishment grounds and facilities.** (b)(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.
(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including: (i) Using protective coverings. (ii) Controlling areas over and around the vessels to eliminate harborages for pests. (iii) Checking on a regular basis for pests and pest infestation. (iv) Skimming the fermentation vessels, as necessary.	
(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.	**§Sec. 416.2 Establishment grounds and facilities.** (b)(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product.

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(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.	**§Sec. 416.2 Establishment grounds and facilities.** (c)Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.
(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.	**§Sec. 416.2 Establishment grounds and facilities.** (d)Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.
(7) Provide, where necessary, adequate screening or other protection against pests.	**§Sec. 416.2 Establishment grounds and facilities.** (b)(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.
§ 110.35 Sanitary Operations. (a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.	**§Sec. 416.4 Sanitary operations.** (a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions or the adulteration of product. (b)Non-food-contact surfaces of facilities, equipment, and

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(b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed: (i) Those required to maintain clean and sanitary conditions; (ii) Those necessary for use in laboratory testing procedures; (iii) Those necessary for plant and equipment maintenance and operation; and (iv) Those necessary for use in the plant's operations. (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed. (c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-	utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions or the adulteration of product (c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection personnel for review (d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

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contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials. (d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food. (1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use. (2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary. (3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food. (4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that	

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protects against contamination of food or food-contact surfaces. (5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment. (e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.	
§ 110.37 Sanitary Facilities and Controls. Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to: (a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.	**§Sec. 416.2 Establishment grounds and facilities.** (g) (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR Part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply, that has been renewed at least semi-annually. (2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product

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	may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product. (3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse water which has come into contact with raw product may not be used on ready-to-eat product. (4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section. (5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

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	(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions
(b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to: (1) Carry sufficient quantities of water to required locations throughout the plant. (2) Properly convey sewage and liquid disposable waste from the plant. (3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition. (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor. (5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.	(e)Plumbing systems must be installed and maintained to: (1) Carry sufficient quantities of water to required locations throughout the establishment; (2) Properly convey sewage and liquid disposable waste from the establishment; (3) Prevent adulteration of product, water supplies, equipment, or utensils, and maintain sanitary conditions throughout the establishment; (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; (5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and (6) Prevent the backup of sewer gases.
(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.	(f) Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the

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	letter of approval from that authority upon request.
(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by: (1) Maintaining the facilities in a sanitary condition. (2) Keeping the facilities in good repair at all times. (3) Providing self-closing doors. (4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).	(h)(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product. (h) (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.
(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing: (1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands. (2) Effective hand-cleaning and sanitizing preparations. (3) Sanitary towel service or suitable drying devices. (4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands. (5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact	

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surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces. (6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.	(h)(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product
(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.	**§Sec. 416.3 Equipment and utensils.** (c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.
§ 110.40 Equipment and Utensils. (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.	**§Sec. 416.3 Equipment and utensils.** (a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product. (b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS personnel from inspecting the equipment or utensils to determine whether they are in sanitary condition.

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(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms. (c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition. (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition. (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation. (f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses. (g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.	

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§ 110.80 Processes and Controls. All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination. (a) Raw materials and other ingredients. (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.	§ 416. 11-416.17 Sanitation Standard Operating Procedures as well as other sections of the FSIS regulations specific to individual products cover the rest of the intent of the rest of the FDA Requirements.

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(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification. (3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, 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 purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins. (4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination. (5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be	

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identified as such. (6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act. (7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination. (b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning. (2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, Aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food. (3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any	

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effective means, including: (i) Maintaining refrigerated foods at 45 deg.F (7.2 deg.C) or below as appropriate for the particular food involved. (ii) Maintaining frozen foods in a frozen state. (iii) Maintaining hot foods at 140 deg. F (60 deg. C) or above. (iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures. (4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling Aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act. (5) Work-in-process shall be handled in a manner that protects against contamination. (6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary. (7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled,	

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and maintained during manufacturing or storage in a manner that protects against contamination. (8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means. (9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food. (10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step. (11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the	

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blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality. (12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following: (i) Using ingredients free of contamination. (ii) Employing adequate heat processes where applicable. (iii) Using adequate time and temperature controls. (iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them. (v) Cooling to an adequate temperature during manufacturing. (vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms. (13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including: (i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing. (ii) Adequate cleaning and sanitizing of all food-contact surfaces and food	

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containers. (iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter. (iv) Providing physical protection from contamination, particularly airborne contamination. (v) Using sanitary handling procedures. (14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of Aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices: (i) Monitoring the Aw of food. (ii) Controlling the soluble solids-water ratio in finished food. (iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the Aw of the food does not increase to an unsafe level. (15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:	

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(i) Monitoring the pH of raw materials, food in process, and finished food. (ii) Controlling the amount of acid or acidified food added to low-acid food. (16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part. (17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.	
§ 110.93 Warehousing and Distribution. Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.	
§ 110.110 Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard. (a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action. (b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.	

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(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible. (d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food. (e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.	