AUDIT STANDARDS COMPARISON TO THE FDA PREVENTIVE CONTROLS FOR HUMAN FOOD RULE

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Subpart A—General Provisions				
§117.4 Qualifications of individuals who manufacture, process, pack, or hold food.				
(b) Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must: (1) Be a qualified individual as that term is defined in §117.3—i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and (2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.				
(c) *Additional qualifications of supervisory personnel.* Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.				

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§117.9 Records required for this subpart. (a) Records that document training required by §117.4(b)(2) must be established and maintained. (b) The records that must be established and maintained are subject to the requirements of subpart F of this part.				
Subpart B—Current Good Manufacturing Practice				
§ 117.10 Personnel.				
The management of the establishment must take 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, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable				

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cover). Personnel must be instructed to report such health conditions to their supervisors.				
(b) *Cleanliness*. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:				
(1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.				
(2) Maintaining adequate personal cleanliness.				
(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing 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				

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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.				
(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 allergen cross-contact and against contamination of food, food-contact surfaces, or food packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).				
§ 117.20 Plant and grounds.				

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(a) *Grounds*. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:				
(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.				
(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.				
(3) 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.				
(5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to				

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exclude pests, dirt, and filth that may be a source of food contamination.				
(b) *Plant construction and design*. The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:				
(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.				
(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.				

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(3) Permit the taking of adequate precautions to protect food in installed outdoor bulk 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 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, food-contact surfaces, or food-packaging materials with clothing or personal contact.				
(5) Provide adequate lighting in handwashing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and				

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provide shatter-resistant 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.				
(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.				
(7) Provide, where necessary, adequate screening or other protection against pests.				
§ 117.35 Sanitary operations.				
(a) *General maintenance*. Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.				

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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 must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of 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 must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.				
(c) *Pest control*. Pests must not be allowed in any area of a food plant. Guard, guide, or pest-				

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detecting 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-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant 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, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.				
(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.				
(2) In wet processing, when cleaning is necessary to protect against allergen cross-				

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contact or the introduction of microorganisms into food, all food- contact surfaces must 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 must be cleaned and sanitized as necessary.				
(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.				
(e*) Sanitation of non-food-contact surfaces*. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.				
(f) *Storage and handling of cleaned portable equipment and utensils*. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces				

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from allergen cross-contact and from contamination.				
§ 117.37 Sanitary facilities and controls.				
Each plant must be equipped with adequate sanitary facilities and accommodations including: (a) *Water supply*. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must 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.				
(b) *Plumbing*. Plumbing must be of adequate size and design and adequately installed and maintained to: (1) Carry adequate 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.				

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(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.				
(c) *Sewage disposal*. Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.				
(d) *Toilet facilities*. Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.				
(e) *Hand-washing facilities*. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.				

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(f) *Rubbish and offal disposal*. Rubbish and any offal must 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, food-packaging materials, water supplies, and ground surfaces.				
§ 117.40 Equipment and utensils.				
(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.				
(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.				
(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.				
(4) Food-contact surfaces must be corrosion-resistant when in contact with food.				
(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand				

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the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.				
(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.				
(b) Seams on food-contact surfaces must 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 and allergen cross-contact.				
(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.				
(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.				
(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be				

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fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately within the compartment.				
(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 must be accurate and precise 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 must be treated in such a way that food is not contaminated with unlawful indirect food additives.				
§ 117.80 Processes and controls.				
(a) *General*. (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.				
(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.				

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(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.				
(4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.				
(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.				
(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.				
(b) *Raw materials and other ingredients*. (1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing,				

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or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.				
(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.				
(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.				
(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.				
(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen				

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cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.				
(6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.				
(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.				
(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.				
(c) *Manufacturing operations*. (1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.				
(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to				

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minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.				
(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.				
(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.				
(5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.				
(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that				

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handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.				
(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.				
(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.				
(9) Food, raw materials, and other ingredients that are adulterated: (i) Must be disposed of in a manner that protects against the contamination of other food; or (ii) If the adulterated food is capable of being reconditioned, it must be: (A) Reconditioned (if appropriate) using a method that has been proven to be effective; or (B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal				

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Food, Drug, and Cosmetic Act before being incorporated into other food.				
(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.				
(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must 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. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.				
(12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.				
(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.				
(14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.				
(15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.				
(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.				
§117.93 Warehousing and distribution.				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.				
§117.95 Holding and distribution of human food by-products for use as animal food.				
(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in §507.12 of this chapter, must be held under conditions that will protect against contamination, including the following: (1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food; (2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(3) During holding, human food by-products for use as animal food must be accurately identified. (b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed. (c) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.				
§ 117.110 Defect action levels.				
(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible. (b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at http://www.fda.gov/pchfrule and at http://www.fda.gov.				
Subpart C—Hazard Analysis and Risk-Based Preventive Controls				
§ 117.126 Food safety plan.				
(a) *Requirement for a food safety plan*. (1) You must prepare, or have prepared, and implement a written food safety plan. (2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.				
(b) *Contents of a food safety plan*. The written food safety plan must include: (1) The written hazard analysis as required by § 117.130(a)(2); (2) The written preventive controls as required by § 117.135(b); (3) The written supply-chain program as required by subpart G of this part; (4) The written recall plan as required by § 117.139(a); and (5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(6) The written corrective action procedures as required by § 117.150(a)(1); and (7) The written verification procedures as required by § 117.165(b).				
(c) *Records*. The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.				
§ 117.130 Hazard analysis.				
(a) *Requirement for a hazard analysis.* (1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. (2) The hazard analysis must be written regardless of its outcome.				
(b) *Hazard identification*. The hazard identification must consider: (1) Known or reasonably foreseeable hazards that include: (i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens; (ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and (iii) Physical hazards (such as stones, glass, and metal fragments); and (2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons: (i) The hazard occurs naturally; (ii) The hazard may be unintentionally introduced; or (iii) The hazard may be intentionally introduced for purposes of economic gain.				
(c) *Hazard evaluation*. (1)(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. (ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a				

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formulation lethal to the pathogen) that would significantly minimize the pathogen. 2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer: (i) The formulation of the food; (ii) The condition, function, and design of the facility and equipment; (iii) Raw materials and other ingredients; (iv) Transportation practices; (v) Manufacturing/ processing procedures; (vi) Packaging activities and labeling activities; (vii) Storage and distribution; (viii) Intended or reasonably foreseeable use; (ix) Sanitation, including employee hygiene; and (x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).				
§ 117.135 Preventive controls.				
(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
403(w) of the Federal Food, Drug, and Cosmetic Act. (2) Preventive controls required by paragraph (a)(1) of this section include: (i) Controls at critical control points (CCPs), if there are any CCPs; and (ii) Controls, other than those at CCPs, that are also appropriate for food safety.				
(b) Preventive controls must be written.				
(c) Preventive controls include, as appropriate to the facility and the food: (1) *Process controls*. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (i) Parameters associated with the control of the hazard; and (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(2) *Food allergen controls*. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for: (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and				
(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.				
(3) *Sanitation controls*. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:				
(i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;				
(ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
material, and other food-contact surfaces and from raw product to processed product.				
(4) *Supply-chain controls*. Supply-chain controls include the supply-chain program as required by subpart G of this part.				
(5) *Recall plan*. Recall plan as required by § 117.139.				
(6) *Other controls*. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.				
§ 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/ processing facility is not required to implement a preventive control.				
(a) *Circumstances*. If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:				
(1) You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control.				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart C to ensure that the identified hazard will be significantly minimized or prevented and you: (i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and				
(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and you:				
(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is ''not processed to control [identified hazard]''; and				
(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:				
(i) Disclose in documents accompanying the food, in accordance with the practice of the				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
trade, that the food is ''not processed to control [identified hazard]''; and				
(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product you distribute and you document the implementation of that system.				
(b) Records. You must document any circumstance, specified in paragraph (a) of this section, that applies to you, including: (1) A determination, in accordance with paragraph (a) of this section, that the type of food could not be consumed without application of an appropriate control;				
(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food product you distribute.				
§ 117.139 Recall plan.				
For food with a hazard requiring a preventive control: (a) You must establish a written recall plan for the food. (b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food; (2) Notify the public about any hazard presented by the food when appropriate to protect public health; (3) Conduct effectiveness checks to verify that the recall is carried out; and (4) Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.				
§ 117.140 Preventive control management components.				
(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:				
(1) Monitoring in accordance with § 117.145;				
(2) Corrective actions and corrections in accordance with § 117.150; and				
(3) Verification in accordance with § 117.155.				
(b) The supply-chain program established in subpart G of this part is subject to the following				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient: (1) Corrective actions and corrections in accordance with § 117.150, taking into account the nature of any supplier non-conformance; (2) Review of records in accordance with § 117.165(a)(4); and (3) Reanalysis in accordance with § 117.170. (c) The recall plan established in §117.139 is not subject to the requirements of paragraph (a) of this section.				
§ 117.145 Monitoring.				
As appropriate to the nature of the preventive control and its role in the facility's food safety system: (a) *Written procedures*. You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and.				
(b) *Monitoring*. You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.				
(c) *Records*. (1) Requirement to document monitoring. You must document the monitoring				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
of preventive controls in accordance with this section in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 17.165(a)(4)(i). (2) *Exception records*. (i) Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control. (ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.				
§ 117.150 Corrective actions and corrections.				
(a) *Corrective action procedures*. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section: (1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate: (i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
conducted in accordance with § 117.165(a)(2); and (ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).				
(2) The corrective action procedures must describe the steps to be taken to ensure that: (i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (iii) All affected food is evaluated for safety; and (iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.				
(b) *Corrective action in the event of an unanticipated food safety problem.* (1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply:				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(i) A preventive control is not properly implemented and a corrective action procedure has not been established; (ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or (iii) A review of records in accordance with §117.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.				
(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must: (i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and (ii) When appropriate, reanalyze the food safety plan in accordance with §117.170 to determine whether modification of the food safety plan is required.				

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(c) *Corrections.* You do not need to comply with the requirements of paragraphs (a) and (b) of this section if: (1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in §117.135(c)(2)(i) or the sanitation controls in §117.135(c)(3)(i) or (ii); or (2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.				
(d) *Records.* All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with §117.155(a)(3) and records review in accordance with §117.165(a)(4)(i).				
§117.155 Verification.				
(a) *Verification activities.* Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system: (1) Validation in accordance with §117.160. (2) Verification that monitoring is being conducted as required by §117.140 (and in accordance with §117.145).				

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(3) Verification that appropriate decisions about corrective actions are being made as required by §117.140 (and in accordance with §117.150). (4) Verification of implementation and effectiveness in accordance with §117.165; and (5) Reanalysis in accordance with §117.170. (b) *Documentation.* All verification activities conducted in accordance with this section must be documented in records.				
§117.160 Validation.				
(a) You must validate that the preventive controls identified and implemented in accordance with §117.135 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system. (b) The validation of the preventive controls: (1) Must be performed (or overseen) by a preventive controls qualified individual: (i)(A) Prior to implementation of the food safety plan; or (B) When necessary to demonstrate the control measures can be implemented as designed: (*1*) Within 90 calendar days after production of the applicable food first begins; or (*2*) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a				**Note:** You do not need to validate:(1) The food allergen controls in §117.135(c)(2); (2) The sanitation controls in §117.135(c)(3); (3) The recall plan in §117.139; (4) The supply-chain program in subpart G of this part; and (5) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on

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written justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins; (ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and (iii) Whenever a reanalysis of the food safety plan reveals the need to do so;				factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.
(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards; and				
§ 117.165 Verification of implementation and effectiveness.				
(a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:				

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(1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);				
(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;				
(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and				
(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions: (i) Records of monitoring and corrective action records within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days; and				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(ii) Records of calibration, testing (e.g., product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and				
(5) Other activities appropriate for verification of implementation and effectiveness.				
(b) *Written procedures*. As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities: (1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section.				
(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must: (i) Be scientifically valid; (ii) Identify the test microorganism(s) or other analyte(s); (iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(iv) Include the procedures for sampling, including the number of samples and the sampling frequency; (v) Identify the test(s) conducted, including the analytical method(s) used; (vi) Identify the laboratory conducting the testing; and (vii) Include the corrective action procedures required by § 117.150(a)(1).				
(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must: (i) Be scientifically valid; (ii) Identify the test microorganism(s); (iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective; (iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective; (v) Identify the test(s) conducted, including the analytical method(s) used;				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(vi) Identify the laboratory conducting the testing; and (vii) Include the corrective action procedures required by § 117.150(a)(1).				
§ 117.170 Reanalysis.				
(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years;				
(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan: (1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard; (2) Whenever you become aware of new information about potential hazards associated with the food; (3) Whenever appropriate after an unanticipated food safety problem in accordance with § 117.150(b); and (4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.				
(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified: (1) Before any change in activities (including any change in preventive control) at the facility is operative; or				
(2) When necessary to demonstrate the control measures can be implemented as designed: (i) Within 90 calendar days after production of the applicable food first begins; or (ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90-calendar days after production of the applicable food first begins.				
(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or document the basis for the conclusion that no revisions are needed.				
(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.				
§ 117.180 Requirements applicable to a preventive controls qualified individual and a qualified auditor.				
(a) One or more preventive controls qualified individuals must do or oversee the following: (1) Preparation of the food safety plan (§ 117.126(a)(2)); (2) Validation of the preventive controls (§ 117.160(b)(1)); (3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food; (4) Determination that validation is not required (§ 117.160(c)(5)); (5) Review of records (§ 117.165(a)(4)); (6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days; (7) Reanalysis of the food safety plan (§ 117.170(d)); and (8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.				
(b) A qualified auditor must conduct an onsite audit (§ 117.435(a)).				
(c)(1) To be a preventive controls qualified individual, the individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.				
(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.				
(d) All applicable training in the development and application of risk-based preventive controls				

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must be documented in records, including the date of the training, the type of training, and the person(s) trained.				
§ 117.190 Implementation records required for this subpart.				
(a) You must establish and maintain the following records documenting implementation of the food safety plan:				**Note:** This section does not establish any new records requirements, it is simply a list for convenience, **Also, note:** (b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.
(1) Documentation, as required by §117.136(b), of the basis for not establishing a preventive control in accordance with § 117.136(a);				
(2) Records that document the monitoring of preventive controls;				
(3) Records that document corrective actions;				
(4) Records that document verification, including, as applicable, those related to: (i) Validation; (ii) Verification of monitoring; (iii) Verification of corrective actions;				

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(iv) Calibration of process monitoring and verification instruments; (v) Product testing; (vi) Environmental monitoring; (vii) Records review; and (viii) Reanalysis;				
(5) Records that document the supply-chain program; and				
(6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.				
§ 117.206 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged food.				
(a) If a facility that is solely engaged in the storage of unexposed packaged food stores any such refrigerated packaged food that requires time/ temperature control to significantly minimize or prevent the growth of, or toxin production by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:				
(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, pathogens;				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(2) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;				
(3) If there is a loss of temperature control that may impact the safety of such refrigerated packaged food, take appropriate corrective actions to: (i) Correct the problem and reduce the likelihood that the problem will recur; (ii) Evaluate all affected food for safety; and (iii) Prevent the food from entering commerce, if you cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;				
(4) Verify that temperature controls are consistently implemented by: (i) Calibrating temperature monitoring and recording devices (or checking them for accuracy); (ii) Reviewing records of calibration within a reasonable time after the records are created; and (iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7 working days after the records are created or within a reasonable timeframe, provided that				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days;				
(5) Establish and maintain the following records: (i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged food;				
(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged food; and				
(iii) Records documenting verification activities.				
(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.				
Subpart F—Requirements Applying to Records That Must Be Established and Maintained				
§ 117.305 General requirements applying to records.				
Records must: (a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies,				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;				
(b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;				
(c) Be accurate, indelible, and legible;				
(d) Be created concurrently with performance of the activity documented;				
(e) Be as detailed as necessary to provide history of work performed; and				
(f) Include: (1) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility); (2) The date and, when appropriate, the time of the activity documented; (3) The signature or initials of the person performing the activity; and (4) Where appropriate, the identity of the product and the lot code, if any.				
§ 117.310 Additional requirements applying to the food safety plan.				
The owner, operator, or agent in charge of the facility must sign and date the food safety plan: (a) Upon initial completion; and (b) Upon any modification.				
§ 117.315 Requirements for record retention.				

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(a)(1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.				
(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.				
(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.155(b)));				
(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.				
§ 117.320 Requirements for official review.				
All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.				
Subpart G—Supply-Chain Program				
§ 117.405 Requirement to establish and implement a supply-chain program.				
(a)(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.				
(2) A receiving facility that is an importer, is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides				

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assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.				
(3) The requirements in this subpart do not apply to food that is supplied for research or evaluation use, provided that such food: (i) Is not intended for retail sale and is not sold or distributed to the public; (ii) Is labeled with the statement ‘‘Food for research or evaluation use’’; (iii) Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and (iv) Is accompanied with documents, in accordance with the practice of the trade, stating that the food will be used for research or evaluation purposes and cannot be sold or distributed to the public.				
(b) The supply-chain program must be written.				
(c) When a supply-chain-applied control is applied by an entity other than the receiving facility’s supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
covered by part 112 of this chapter)), because growing, harvesting, and packing activities are under different management), the receiving facility must: (1) Verify the supply-chain-applied control; or (2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.				
§ 117.410 General requirements applicable to a supply-chain program.				
(a) The supply-chain program must include: (1) Using approved suppliers as required by § 117.420;				
(2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 117.425;				
(3) Conducting supplier verification activities as required by §§ 117.430 and 117.435;				
(4) Documenting supplier verification activities as required by § 117.475; and				
(5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 117.475, or obtaining documentation of an appropriate				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 117.475.				
(b) The following are appropriate supplier verification activities for raw materials and other ingredients: (1) Onsite audits; (2) Sampling and testing of the raw material or other ingredient; (3) Review of the supplier's relevant food safety records; and (4) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.				
(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.				
(d)(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered: (i) The hazard analysis of the food, including the nature of the hazard controlled before receipt of				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
the raw material or other ingredient, applicable to the raw material and other ingredients; (ii) The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;				
(iii) Supplier performance, including: (A) The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;				
(B) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of food and other FDA compliance actions related to food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and (C) The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of				

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the food, and responsiveness of the supplier in correcting problems; and (iv) Any other factors as appropriate and necessary, such as storage and transportation practices.				
(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is: (i) A qualified facility as defined by § 117.3; (ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or (iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens.				
(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or other ingredients from the supplier do not cause food that is				

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manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.				
§ 117.415 Responsibilities of the receiving facility.				
(a)(1) The receiving facility must approve suppliers.				
(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.				
(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment: (i) Establish written procedures for receiving raw materials and other ingredients by the entity; (ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and (iii) Determine, conduct, or both determine and conduct the appropriate supplier verification activities, with appropriate documentation.				

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(4) The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.				
(b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity: (1) A determination by its supplier of the appropriate supplier verification activities for that supplier; (2) An audit conducted by its supplier; (3) A review by its supplier of that supplier's own relevant food safety records; or (4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 117.410(b)(4).				
(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435.				

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§ 117.420 Using approved suppliers.				
(a) Approval of suppliers. The receiving facility must approve suppliers in accordance with the requirements of § 117.410(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers;				
(b) Written procedures for receiving raw materials and other ingredients. (1) Written procedures for receiving raw materials and other ingredients must be established and followed;				
(2) The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use); and				
(3) Use of the written procedures for receiving raw materials and other ingredients must be documented.				
§ 117.425 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).				

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Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 117.410(d).				
§ 117.430 Conducting supplier verification activities for raw materials and other ingredients.				
(a) Except as provided by paragraph (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 117.410(b), as determined under § 117.410(d), must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter.				
(b)(1) Except as provided by paragraph (b)(2) of this section, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans: (i) The appropriate supplier verification activity is an onsite audit of the supplier; and (ii) The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter. (2) The requirements of paragraph (b)(1) of this section do not apply if there is a written				

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PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.				
(c) If a supplier is a qualified facility as defined by § 117.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility: (1) Obtains written assurance that the supplier is a qualified facility as defined by § 117.3: (i) Before first approving the supplier for an applicable calendar year; and (ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and				
(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).				
The written assurance must include either: (i) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or				

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(ii) A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.				
(d) If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility: (1) Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5: (i) Before first approving the supplier for an applicable calendar year; and (ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and				
(2) Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act				

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(or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).				
(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility: (1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens: (i) Before first approving the supplier for an applicable calendar year; and (ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and (2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as				

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comparable or has determined to be equivalent to that of the United States).				
(f) There must not be any financial conflicts of interests that influence the results of the verification activities listed in § 117.410(b) and payment must not be related to the results of the activity.				
§ 117.435 Onsite audit.				
(a) An onsite audit of a supplier must be performed by a qualified auditor.				
(b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).				
(c)(1) The following may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:				

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(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or (ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.				
(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.				
(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not				

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subject to the requirements in those regulations.				
§ 117.475 Records documenting the supply-chain program.				
(a) The records documenting the supply-chain program are subject to the requirements of subpart F of this part.				
(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 117.165(a)(4).				
(c) The receiving facility must document the following in records as applicable to its supply-chain program: (1) The written supply-chain program;				
(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification activities conducted under § 1.506(e) of this chapter;				
(3) Documentation of the approval of a supplier;				
(4) Written procedures for receiving raw materials and other ingredients;				
(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;				

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(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;				
(7) Documentation of the conduct of an onsite audit. This documentation must include: (i) The name of the supplier subject to the onsite audit; (ii) Documentation of audit procedures; (iii) The dates the audit was conducted; (iv) The conclusions of the audit; (v) Corrective actions taken in response to significant deficiencies identified during the audit; and (vi) Documentation that the audit was conducted by a qualified auditor;				
(8) Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include: (i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested; (ii) Identification of the test(s) conducted, including the analytical method(s) used; (iii) The date(s) on which the test(s) were conducted and the date of the report; (iv) The results of the testing; (v) Corrective actions taken in response to detection of hazards; and				

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(vi) Information identifying the laboratory conducting the testing;				
(9) Documentation of the review of the supplier's relevant food safety records. This documentation must include: (i) The name of the supplier whose records were reviewed; (ii) The date(s) of review; (iii) The general nature of the records reviewed; (iv) The conclusions of the review; and (v) Corrective actions taken in response to significant deficiencies identified during the review;				
(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;				
(11) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans;				

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(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility: (i) The written assurance that the supplier is a qualified facility as defined by § 117.3, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);				
(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter: (i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the farm acknowledges that its food is subject to section				

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402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);				
(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens: (i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);				
(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA,				

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by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;				
(16) Documentation of actions taken with respect to supplier nonconformance;				
(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and				
(18) When applicable, documentation of the receiving facility's review and assessment of: (i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed; (ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients; (iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;				

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(iv) Applicable documentation, from its supplier, of: (A) The results of sampling and testing conducted by the supplier; or (B) The results of an audit conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435; and (v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.				