The Mango Industry Recommendation for Preventive Controls Self-Assessment Tool

producing safe mangos

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Introduction

The regulations by the Food and Drug Administration (FDA) on current Good Manufacturing Practices (cGMP), hazard analysis, and risk-based preventive controls for human food are designed to promote safe food production.

This self-assessment tool presents the preventive controls for human food regulations as typical questions that will help you understand if your facility complies with the requirements of preventive controls for human food regulation and, if applicable, identify those areas that need improvement. However, by no means does this document have any legal value; it is a self-assessment tool for informative purposes only.

Instructions

Walk through your facility with this self-assessment in hand and answer the questions. If necessary, write down your comments in the space provided after each section.

There are no right or wrong answers; however, be aware of “no” and “not sure or some of the time” answers because you will need to take a closer look at these areas later and improve them in order to convert these answers into a yes.

Disclaimer

The National Mango Board (NMB), an instrument of the United States Department of Agriculture, commissioned this work in support of the mango industry. All efforts have been taken to ensure the accuracy and veracity of the information contained in this document. Nonetheless, the NMB and Food Safety Consulting & Training Solutions, LLC are not responsible, expressly or implied, for the ideas and recommendations contained in this document, as well as errors and omissions therein, and do not assume any legal responsibility for any loss or damage resulting from use of the information contained herein.

Subpart B: Current Good Manufacturing Practices

Questions	Answers and Comments
117.10 Personnel	
(a) Are persons with illness, open lesions, including boils, sores, or infected wounds, or any abnormal source of contamination prohibited from handling human food, food-contact surfaces, or food-packaging materials?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Are personnel wear 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Does personnel maintain adequate personal cleanliness?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Does personnel wash their hands thoroughly before starting work, after each absence from the work station, and at any other time when their hands may have become soiled or contaminated?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(4) Is jewelry and other objects that might fall into food, equipment, or containers, and hand jewelry that cannot be adequately sanitized, removed and/or prohibited when food is manipulated by hand? Is jewelry that cannot be removed covered by a material that can be maintained in an intact and sanitary condition?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(5) Are gloves used for food handling maintained in an intact, clean, and sanitary condition?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(6) Does personnel wear hairnets, headbands, caps, bear covers, or other hair restraints when appropriate?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(7) Are personal belongings and clothing stored in areas other than where food is exposed or where equipment or utensils are washed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(8) Are personnel prohibited from eating food, chewing gum, drinking beverages, or using tobacco in areas where food may be exposed and where equipment and utensils are washed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(9) Does personnel take 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 medicine applied to the skin)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.20 Plant and Grounds	
(a)(1) Do methods for grounds maintenance include 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Are the roads, yards, and parking lots maintained so that they do not constitute a source of contamination in areas where food is exposed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Are the areas that may contribute to food contamination by seepage, food-borne filth, or provide a breeding place for pests adequately drained?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4) Are the operating systems for waste treatment and disposal placed in an adequate manner, so that they do not constitute a source of contamination in areas where the food is exposed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(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 is exercised in the plant by inspection, extermination, and other means to exclude pests, dirt, and filth that may be source of food contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Does the plant have an adequate space for the placement of equipment and storage of materials as necessary for maintenance, sanitary operations, and the production of safe food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Does the plant permit the taking of adequate precautions to reduce the potential for allergen cross contact and contamination of food, food contact surfaces, or food packaging materials? Are the potentials for allergen cross contact and for contamination reduced by adequate food safety controls and operating practices or effective design?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Does the plant permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(4) Does the construction permit the adequate cleaning and repair of floors, walls and ceilings? Does the drip or condensate from fixtures, ducts, and pipes NOT contaminate food, food contact surfaces, or food packaging materials?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Do aisles or working spaces provided between equipment and walls have adequate space in which 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(5) Are areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned provided with adequate lighting?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(b)(6) Is there adequate ventilation to minimize dust, odor, and vapors in areas where they may cause allergen cross contact or contaminate food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(7) Are fans and other air blowing equipment located and operated in a manner that minimizes the potential for allergen cross contact and for contaminating food, food packaging materials, and food contact surfaces?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(8) Is there adequate screening or other protection against pests?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.35 Sanitary Operations	
(a) Are buildings, fixtures, and other physical facilities of the plant maintained in a clean and sanitary condition and adequate repair to prevent food from becoming adulterated?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Are cleaning compounds and sanitizing agents free from undesirable microorganisms, safe, and adequate under the conditions of use?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is the purchase of these substances under a letter of guarantee or certification or examination for contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are toxic cleaning compounds, sanitizing agents, and pesticide chemicals identified, held, and stored in a manner that protects against contamination of food, food contact surfaces, or food packaging materials?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Are toxic cleaning compounds, sanitizing agents, and pesticide chemicals identified, held, and stored in a manner that protects against contamination of food, food contact surfaces, or food packaging materials?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Are pests prohibited in every area of the food plant?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) If guard, guide, or pest-detecting dogs are used in some areas of a plant, is the presence of the dogs unlikely to result in contamination of food, food contact surfaces, or food packaging materials?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Are effective measures taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food by pests?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Are pesticides used only under precautions and restrictions that will protect against the contamination of food, food contact surfaces, and food packaging materials?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(1) Are food contact surfaces used for manufacturing/processing, packaging, or holding low moisture food in a clean, dry, sanitary condition before use?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
When the surfaces are wet cleaned, are they sanitized and dried thoroughly before use?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(2) In wet processing, are food contact surfaces cleaned and sanitized before their use and after any interruption during which the food contact surfaces may have become contaminated?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are equipment and utensils in a continuous production operation cleaned and sanitized as necessary?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(3) Are single service articles 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(e) Are non-food contact surfaces of equipment used in the operation of a food plant 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f) Are cleaned portable equipment and utensils stored in a location and manner that protects food contact surfaces from allergen cross contact and from contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.37 Sanitary Facilities and Controls	
(a) Is the water supply adequate for the operations intended and derived from an adequate source?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a) Is the water that contacts food, food contact surfaces, or food packaging materials safe and of adequate sanitary quality?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a) Is there running water at a suitable temperature and under pressure as needed 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Is plumbing of adequate size and design and adequately installed and maintained to:	
(b)(1) Carry adequate quantities of water to required locations throughout the plant?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Properly convey sewage and liquid disposable waste from the plant?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(5) Provide that there is no 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Is sewage disposed of into an adequate sewage system or disposed of through other adequate means?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d) Are there adequate and readily accessible toilet facilities for employees?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d) Are toilet facilities cleaned and not a potential source of contamination of food, food contact surfaces, or food packaging materials?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(e) Are handwashing facilities adequate, convenient, and furnished with running water at a suitable temperature?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f) Is rubbish and offal conveyed, stored, and disposed of to minimize the development of odor; the potential for waste becoming an attractant, harborage. or breeding place for pests. and to protect against contamination of food, food contact surfaces, food packaging materials, water supplies, and ground surfaces?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.40 Equipment and Utensils	
(a)(1) Are plant equipment and utensils designed and made from such material and workmanship as to be adequately cleanable and maintained to protect against allergen cross contact and contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Are the equipment and utensils designed, constructed, and used to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Is the equipment installed to facilitate its cleaning and maintenance and adjacent spaces?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4) Are food contact surfaces corrosion resistant when in contact with food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(5) Are food contact surfaces made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(6) Are food-contact surfaces maintained to protect food from allergen cross contact and from being contaminated by any source, including unlawful indirect food additives?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Are seams on food contact surfaces smoothly bonded or maintained so as to minimize the accumulation of food particles, dirt, and organic matter?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Is the equipment in areas where food is manufactured, processed, packaged, or held and that does not come into contact with food constructed in a way to keep it in a clean and sanitary condition?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d) Are holding, conveying, and manufacturing systems designed and constructed in a way that enables them to be maintained in an appropriate clean and sanitary condition?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(e) Is each freezer and cold storage compartment fitted with an indicating thermometer, temperature measuring device, or temperature recording device installed as to show the temperature accurately within the compartment?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f) Are the instruments and controls used for measuring, regulating, or recording the conditions that control or prevent the growth of undesirable microorganisms in food accurate and precise and adequately maintained and adequate in number for their designated uses?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(g) Is compressed air or other gases mechanically introduced into food or used to clean food contact surfaces or equipment treated in such way that food is not contaminated with unlawful indirect food additives?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

117.80 Processes and Controls	
(a)(1) Are the operations in the manufacturing, processing, packing, and holding of food conducted in accordance with adequate sanitation principles?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Are there appropriate quality control operations to ensure that food is suitable for human consumption and that food packaging materials are safe and suitable?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Is the sanitation of the plant under the supervision of one or more competent individuals assigned for this function?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4) Are actions taken to ensure that production procedures do not contribute to allergen cross contact and to contamination from any source?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(5) Where necessary, are testing procedures used to identify sanitation failures or possible allergen cross contact and food contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(6) Is contaminated food rejected or, if appropriate, treated or processed to eliminate the contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Are raw materials and other ingredients inspected and segregated or otherwise handled to ensure that they are clean and suitable for processing?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are raw materials and other ingredients stored under conditions that will protect them against allergen cross contact and contamination and minimize their deterioration?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are raw materials washed or cleaned as necessary to remove soil or other contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is water used for washing, rinsing, or conveying food, safe and of adequate sanitary quality?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is water reused only if it does not cause allergen cross contact or increase the level of contamination of the food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Do raw materials and other ingredients contain levels of microorganisms that do not render the food injurious to the health of humans?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Or Are raw materials and other ingredients pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(b)(3) Do raw materials and other ingredients comply with FDA regulations for poisonous or deleterious substances before they are incorporated into finished food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(4) Do raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material comply with applicable FDA regulations for natural or unavoidable defects?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(5) Are raw materials, other ingredients, and rework held in bulk or in containers designed and constructed so as to protect against allergen cross contact and against contamination and held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is the material scheduled for rework identified as such?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(6) Are frozen raw materials and frozen ingredients kept frozen?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is thawing done in a manner that prevents the raw materials and other ingredients from becoming adulterated?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(7) Are liquid or dry raw materials and other ingredients received and stored in bulk form held in a manner that protects against allergen cross-contact and against contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(8) Are raw materials and other ingredients that are food allergens and rework that contains food allergens identified and held in a manner that prevents allergen cross contact?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1) Are equipment, utensils, and food containers maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is the equipment taken apart for thorough cleaning, if necessary?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2) Are food manufacturing, processing, packing, and holding conducted under such conditions and controls as necessary to minimize the potential for the growth of microorganisms, allergen cross contact, contamination, and deterioration of food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(3) Is food that can support the rapid growth of undesirable microorganisms held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(4) Are measures (sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw) taken to destroy or prevent the growth of undesirable microorganisms, adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(5) Are work in process and rework handled in a manner that protects against allergen cross contact, contamination, and growth of undesirable microorganisms?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(c)(6) Are effective measures taken to protect finished food from allergen cross contact and from contamination by raw materials, other ingredients, or refuse?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is the handling of unprotected raw materials, other ingredients, or refuse done separately in a receiving, loading, or shipping area if it may result in allergen cross contact or contamination of food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is food transported by conveyor protected against allergen cross contact and against contamination as necessary?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(7) Are equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work in process, rework, or other food; constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross contact and against contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(8) Are adequate measures taken to protect against the inclusion of metal or other extraneous materials in food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(9) (i) Is adulterated food, raw materials, and other ingredients disposed of in a manner that protects against the contamination of other food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(ii) Is the adulterated food reconditioned using a method that has been proven to be effective or reconditioned, reexamined, and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(10) Are process steps performed so as to protect food against allergen cross contact and against contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is food protected from contaminants that may drip, drain, or be drawn into it?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(11) When required, is heat blanching affected 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is the growth and contamination by thermophilic microorganisms in blanchers minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(12) Are preparations that are held and used repeatedly over time, treated or maintained in such a manner that they are protected against allergen cross contact and against contamination and minimizing the potential for the growth of undesirable microorganisms?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(c)(13) Are operations such as filling, assembling, packaging, and others performed in such a way that the food is protected against allergen cross contact, contamination, and growth of undesirable microorganisms?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(14) Is the moisture level maintained at a safe level in food where aw is the principal control for preventing the growth of undesirable microorganisms?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(15) Is pH monitored and maintained at 4.6 or below in food where pH is the principal control for preventing the growth of undesirable microorganisms?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(16) Is the ice used in contact with food made from water that is safe and of adequate sanitary quality in accordance with §117.37(a) and used only if it has been manufactured in accordance with current good manufacturing practice, as outlined in this section?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.93 Warehousing and Distribution	
Is storage and transportation of food handled 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.95 Holding and Distribution of Human Food Byproducts for Use as Animal Food	
(a) Are human food byproducts held for distribution as animal food without additional manufacturing or processing by the human food processor held under conditions that will protect against contamination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(1) Are containers and equipment used to convey or hold human food byproducts for use as animal food before distribution, designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food byproducts for use as animal food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Are human food byproducts for use as animal food held for distribution in a way to protect against contamination from sources such as trash?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Are human food byproducts for use as animal food accurately identified during holding?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Is labeling that identifies the byproduct by the common or usual name, affixed to, or accompanied by human food byproducts for use as animal food used when distributed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) When the facility is responsible for transporting the human food byproducts or arranges a third party to transport the human food byproducts, are shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food byproducts examined prior to use?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.110 Defect Action Levels	
(a) Does the manufacturer, processor, packer, and holder of food utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Is the mixing of a food containing defects at levels that render that food adulterated with another lot of food prohibited?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

Subpart C: Hazard Analysis and Risk-Based Preventive Controls

Questions	Answers and Comments
117.126 Food Safety Plan	
(a)(1) Have you prepared and implemented a written food safety plan?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Is the safety plan prepared or overseen by a qualified individual?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Does the written food safety plan content include:	
(b)(1) Hazard analysis?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Preventive controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Supply-chain program?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(4) Recall plan?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(5) Procedures for monitoring the implementation of the preventive controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(6) Corrective actions procedures?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(7) Verification procedure?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Is the food safety plan a record subjected to the requirements of subpart F "Requirements Applying to Records That Must Be Established and Maintained"?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.130 Hazard Analysis	
(a)(1) Do you conduct a hazard analysis to identify and evaluate 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Is the hazard analysis written regardless of its outcome?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Does the hazard identification consider known or reasonably foreseeable hazards including biological, chemical, and physical hazards?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Does the hazard identification consider known or reasonably foreseeable hazards that may be present in food naturally, unintentionally introduced or intentionally introduced for purposes of economic gain?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1)(i) Does the hazard analysis include an evaluation of the hazards identified 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (1) (ii) Does the hazard evaluation 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 that would significantly minimize the pathogen?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Does the hazard evaluation consider the effect of:	
(c)(i) the formulation of food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(ii) the condition, function, and design of the facility and equipment?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(iii) raw materials and other ingredients?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(iv) transportation practices?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(v) manufacturing/processing procedures?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(vi) packaging and labeling?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(vii) storage and distribution?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(viii) intended or reasonably foreseeable use	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(c)(ix) sanitation, including employee hygiene	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(x) any other relevant factors, such as the temporal nature of some hazards?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.135 Preventive Controls	
(a)(1) Do you identify and implement preventive controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Have you identified and implemented preventive controls at critical control points (CCPs) and controls other than at CCPs that are also appropriate for food safety?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Are preventive controls written?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Do your preventive controls include, as appropriate to the facility and the food:	
(c) (1) process controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (2) food allergen controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (3) sanitation controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (4) supply-chain controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (5) recall plan?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (6) other controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1)(i) Do the process controls include procedures, practices, and processes to ensure the control of parameters associated with the control of the hazard during operations?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1)(ii) Do the process controls include procedures, practices, and processes to ensure the control of the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter controlled to significantly minimize or prevent a hazard requiring a process control?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2)(i) Is there a preventive control for food allergens that includes procedures, practices, and processes to ensure protection of food from allergen cross contact, including during storage, handling, and use?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2)(ii) Is there a preventive control for 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (3) Do 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Do sanitation controls include procedures, practices, and processes as appropriate to the facility and the food for:	
(c) (3)(i) Cleanliness of food contact surfaces including food contact surfaces of utensils and equipment?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (3)(ii) Prevention of allergen cross contact and cross contamination from unsanitary objects and from personnel to food, food packaging material, and other food contact surfaces and from raw product to processed product?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(6) If necessary, are there other preventive controls, including any other procedures, practices, and processes to satisfy the requirements of paragraph (a) of this section?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

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	
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 if you answer YES to any of the following circumstances:	
(a)(1) Do 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Do you rely on your customer, who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart, to ensure that the identified hazard will be significantly minimized or prevented?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
If not, procced to (a)(3), If YES:	
(a)(2)(i) Do you disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control identified hazard"?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2)(ii) Do you obtain from your customer an annual written assurance, subject to the requirements of §117.137, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Do 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
If not, procced to (a)(4), If YES:	
(a)(3)(i) Do you disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control identified hazard"?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3)(ii) Do you annually obtain from your customer a written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4) Do 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? If not, procced to (a)(5), If YES:	

(a)(4)(i) Do you disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control identified hazard"?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4)(ii)(A) Do you annually obtain from your customer written assurance, subjected to the requirements of §117.137, that your customer will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control identified hazard"? Or	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4)(ii)(B)(1) Do you annually obtain from your customer written assurance, subjected to the requirements of §117.137, and that your customer will only sell to another entity that agrees in writing it will follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart)? Or	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4)(ii)(B)(2) Do you annually obtain from your customer written assurance, subjected to the requirements of §117.137, and that your customer will only sell to another entity that agrees in writing it will obtain a similar written assurance from the entity's customer, subject to the requirements of §117.137, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(5) Have you have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute, and do you document the implementation of that system?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Do you document any circumstance, specified in paragraph (a) of this section that applies to you?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.137 Provision of Assurances Required Under §117.136(a)(2), (3), and (4)	
If a facility provides written assurance under §116.136(a)(2), (3) or (4):	
Does your facility act consistently with the assurance and document its actions taken to satisfy the written assurance?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.139 Recall Plan	
(a) Have you established a written recall plan for the food with a hazard requiring a preventive control?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Does the written recall plan include a procedure that describes the steps to directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Does the written recall plan include a procedure that describes the steps to notify the public about any hazard presented by the food when appropriate to protect public health?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Does the written recall plan include a procedure that describes the steps to conduct effectiveness checks to verify that the recall is carried out?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(4) Does the written recall plan include a procedure that describes the steps to appropriately dispose of recalled food, e.g., through reprocessing, reworking, destroying the food, or diverting to a use that does not present a safety concern?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.140 Preventive Control Management Components	
(a)(1) Are process, food allergen, sanitation, and other controls monitored in accordance with §117.145?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Do process, food allergen, sanitation, and other controls take into account corrective actions and corrections in accordance with §117.150?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Do process, food allergen, sanitation, and other controls take into account verification in accordance with §117.155?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Is the supply chain program established, subject to corrective actions and corrections, in accordance with §117.150?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Is the supply chain programestablished, subject to review records, in accordance with §117.165 (a)(4)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Is the supply chain program established subject to reanalysis in accordance with §117.170?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.145 Monitoring	
(a) Are written procedures established and implemented, including the frequency with which they are to be performed, for monitoring the preventive control?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Do you monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1) Do you document the monitoring of preventive controls in records that are subject to verification in accordance with §117.155(a)(2) and records review in accordance with §117.165(a)(4)(i)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (2)(ii) Are there exception records used in the operation?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.150 Corrective Actions and Corrections	
(a)(1)(i) Do you establish and implement written corrective action procedures for the presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a) (1)(ii) Do you establish and implement written corrective action procedures for the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a) (2)(i) Do corrective action procedures describe the steps to ensure that the appropriate action is taken to identify and correct a problem that has occurred with the implementation of a preventive control?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a) (2)(ii) Do corrective action procedures describe the steps to ensure that appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a) (2)(iii) Do corrective action procedures describe the steps to ensure that all affected food is evaluated for safety?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a) (2)(iv) 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, are there corrective action procedures that describe the steps to ensure that all affected food is prevented from entering into commerce?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
If your answer is YES of any of the next three questions, proceed to (b)(2), if not, proceed to (d):	
(b)(1)(i) Is there a preventive control not properly implemented and a corrective action procedure has not been established?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1)(ii) Has a preventive control, combination of preventive controls, or the food safety plan as a whole, been found ineffective?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1)(iii) Does a review of records in accordance with §117.165(a)(4) find 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2)(i) Do you take corrective actions 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2)(ii) Is the food safety plan reanalyzed when appropriate, in accordance with §117.170, to determine whether modification of the food safety plan is required?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

If your answer is YES to any of the next two questions, proceed to (d), if not, proceed to (a)(1):	
(c)(1) Do 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)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2) Do you take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly have an impact on product safety?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d) Are all corrective actions and, when appropriate, corrections 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).	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.155 Verification	
(a)(1) Do verification activities include a validation in accordance with §117.160?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Do the verification activities include verification that monitoring is being conducted as required by §117.140 and in accordance with §117.145?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Do the verification activities include a verification that appropriate decisions about corrective actions are being made as required by §117.140 and in accordance with §117.150?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4) Do the verification activities include a verification of implementation and effectiveness in accordance with §117.165?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(5) Do the verification activities include a reanalysis in accordance with §117.170?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Are the verification activities documented in records?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.160 Validation	
(a) Do you validate that the preventive controls identified and implemented 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Is the validation of the preventive controls performed by a qualified individual?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(i)(A) Is the validation of the preventive controls performed by a qualified individual prior to implementation of the food safety plan?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1)(i)(B)(1) Is the validation of the preventive controls done when necessary to demonstrate that control measures can be implemented as designed within 90 calendar days after production of the applicable food first begins?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Or **(b)(1)(i)(B)(2)** Is the validation of the preventive controls done 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(ii) Is the validation of the preventive controls done whenever a change to a control measure or combination of control measures could have an impact on whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) (iii) Is the validation of the preventive controls done whenever a reanalysis of the food safety plan reveals the need to do so?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Does the validation of the preventive controls include obtaining and evaluating scientific and technical evidence to determine whether the preventive controls, when properly implemented, will effectively control the hazards?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1) There is no need to validate other preventive controls that are part of the plan, if the preventive-controls-qualified individual prepares (or oversees the preparation) of a written justification that validation is not applicable based on 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. Food allergen controls in §117.135 (c)(2), sanitation controls in §117.135(c)(3), the recall plan in §117.139 and the supply-chain program in subpart G do not need validation.	

Notes

117.165 Verification of Implementation and Effectiveness	
(a)(1) Do you verify the preventive control for the calibration of process monitoring instruments and verification instruments or check them for accuracy?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Do you verify the preventive control for product testing for a pathogen (or appropriate indicator organism) or other hazard?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Do you verify the preventive control for 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4)(i) Do you review the records of monitoring and corrective actions within seven 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 seven working days?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4)(ii) Do you review the 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(5) Do you review the records of other activities appropriate for verification of implementation and effectiveness?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Do you establish and implement written procedures for 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Do you establish and implement written procedures for the product testing for pathogens or an appropriate indicator organism?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2)(i) Are procedures for product testing scientifically valid?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2)(ii) Do procedures for product testing identify testing microorganism(s) or other analyte(s)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2)(iii) Do procedures for product testing specify the procedures for identifying samples, including their relationship to specific lots of product?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2)(iv) Do procedures for product testing include the procedures for sampling, including the number of samples and the sampling frequency?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(b)(2)(v) Do the procedures for product testing identify the test(s) conducted, including the analytical method(s) used?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2)(vi) Do procedures for product testing identify the laboratory conducting the testing?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2)(vii) Do procedures for product testing include the corrective action procedures required by §117.150(a)(1)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3)(i) Are procedures for environmental monitoring scientifically valid?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3)(ii) Do procedures for environmental monitoring identify tested microorganism(s)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3)(iii) Do procedures for environmental monitoring identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring? Are the number and location of sampling sites adequate to determine whether preventive controls are effective?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time ☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3)(iv) Do procedures for environmental monitoring identify the timing and frequency for collecting and testing samples?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the timing and frequency for collecting and testing samples adequate to determine whether preventive controls are effective?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3)(v) Do the procedures for environmental monitoring identify the test(s) conducted, including the analytical method(s) used?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3)(vi) Do the procedures for environmental monitoring identify the laboratory conducting the testing?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3)(vii) Do the procedures for environmental monitoring include the corrective action procedures required by §117.150(a)(1)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.170 Reanalysis	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a) Do you conduct a reanalysis of the food safety plan as a whole at least once every three years?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Do you conduct a reanalysis of the food safety plan as a whole or the applicable portion of the food safety plan 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Do you conduct a reanalysis of the food safety plan as a whole or the applicable portion of the food safety plan whenever you become aware of new information about potential hazards associated with the food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Do you conduct a reanalysis of the food safety plan as a whole or the applicable portion of the food safety plan whenever appropriate after an unanticipated food safety problem in accordance with §117.150(b)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(4) Do you conduct a reanalysis of the food safety plan as a whole or the applicable portion of the food safety plan whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1) Do you complete the reanalysis required by a) and b) and validate, any additional preventive controls needed to address the hazard identified before any change in activities (including any change in preventive control) at the facility is operative?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2) Do you complete the reanalysis when necessary to demonstrate the control measures can be implemented as designed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2)(i) Do you complete the reanalysis within 90 calendar days after production of the applicable food first begins? Or	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2)(ii) Do you complete the reanalysis within a reasonable timeframe, provided that the preventive controls qualified individual prepares Or	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) (2)(ii) Oversees the preparation of a written justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d) Do you 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(e) Is the reanalysis performed by a preventive-controls-qualified individual?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f) Do you conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.180 Requirements Applicable to a Preventive Controls Qualified Individual and a Qualified Auditor	
(a)(1) Is the food safety plan done or overseen by one or more preventive-controls-qualified individuals?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Is the validation of preventive controls done or overseen by one or more preventive-controls-qualified individuals?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Is the written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food done or overseen by one or more preventive-controls-qualified individuals?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4) Is the determination that validation is not required done or overseen by one or more preventive-controls-qualified individuals?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(5) Is the review of records done or overseen by one or more preventive-controls-qualified individuals?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(6) Is the written justification for review of records of monitoring and corrective actions within a timeframe that exceeds seven working days done or overseen by one or more preventive controls qualified individuals?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(7) Is the reanalysis of the food safety plan done or overseen by one or more preventive controls qualified individuals?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(8) Is the determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the 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 done or overseen by one or more preventive controls qualified individuals?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Does a qualified auditor conduct an onsite audit?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1) Has the qualified individual 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 the 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.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2) Does the qualified auditor have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(d) Is the applicable training in the development and application of risk-based preventive controls documented in records, including the date of the training, the type of training, and the person(s) trained?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.190 Implementation Records Required for This Subpart	
(a)(1) Do you establish and maintain the records of documentation, as required by §117.136(b), of the basis for not establishing a preventive control in accordance to §117.136(a)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Do you establish and maintain the records that document the monitoring of preventive controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Do you establish and maintain the records that document corrective actions?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4) Do you establish and maintain the records that document verifications, including, as applicable, those related to validation, verification of monitoring, verification of corrective actions, calibration of process monitoring and verification instruments, product testing, environmental monitoring, records review and reanalysis?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(5) Do you establish and maintain the records that document the supply-chain program?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(6) Do you establish and maintain the records that document applicable training for the preventive controls qualified individual and the qualified auditor?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Are the records that you establish and maintain subject to the requirements of subpart F of this part?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

Subpart F: Requirements Applying to Records That Must Be Established and Maintained

117.301 Records Subject to the Requirements of this Subpart	
(a) Except as provided by paragraphs (b) and (c) of this section, all records required by this part are subject to all requirements of this subpart.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) The requirements of §117.310 apply only to the written food safety plan.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) The requirements of §117.305(b), (d), (e), and (f) do not apply to the records required by §117.201.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.305 General Requirements Applying to Records	
(a) Are the original records, true copies or electronic, kept?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Do the records contain the actual values and observations obtained during the monitoring and, as appropriate, during the verification activities?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Are the records accurate, indelible, and legible?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d) Are the records created concurrently with performance of the activity documented?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(e) Are the records detailed as necessary to provide history of work performed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f)(1) Do the records include the information adequate to identify the plant or facility (name and when necessary, the location)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f)(2) Do the records include the date and, when appropriate, the time of the activity documented?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f)(3) Do the records include the signature or initials of the person performing the activity?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f)(4) Do the records include, where appropriate, the identity of the product and the lot code?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.310 Additional Requirements Applying to the Food Safety Plan	
(a)(b) Is the food safety plan signed upon initial completion and upon any modification, by the owner, operator, or agent in charge of the facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.315 Requirements for Record Retention	
(a)(1) Are the records retained at the plant or facility for at least two years after the date they were prepared?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Are the records that a facility relies on during the three-year period preceding the applicable calendar year to support its status as a qualified facility retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Are the records that relate to the general adequacy of the equipment or processes being used by a facility retained for at least two years after their use is discontinued? Except for the food safety plan, the food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Can records that are stored offsite be retrieved and provided onsite within 24 hours of request for official review?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d) If the plant or facility is closed, is the food safety plan transferred to some other accessible location and returned to the plant or facility within 24 hours for official review upon request?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.320 Requirements for Official Review	
Are the records required by this part 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.325 Public Disclosure	
Records obtained by the FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.330 Use of Existing Records	
(a) Are the records supplemented as necessary to include all of the required information and satisfy the requirements of this subpart?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.335 Special Requirements Applicable to a Written Assurance	
(a) Does the written assurance contain effective date, printed names and signatures of authorized officials under section §117.136(a)(2), section §117.136(a)(3), section §117.136(a)(4), section §117.430(c)(2), section §117.430(d)(2), or section §117.430(e)(2)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Does the written assurance required under §117.136 (a)(2), (a)(3), and (a)(4) include the acknowledgment that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the written assurance?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Does the written assurance required under 117.136 a2, a3, and a4 include the provision that, if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

Subpart G: Supply-Chain Program

Questions	Answers and Comments
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, does the receiving facility 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Is the receiving facility an importer, in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, and have documentation of verification activities conducted under 1.506(e) of this chapter (assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) For food that is supplied for research or evaluation use, the requirements in this subpart do not apply if your answer is YES for the following questions:	
(a)(3)(i) Is the food not intended for retail sale and not sold or distributed to the public?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3)(ii) Is the food labeled with the statement “Food for research or evaluation use”?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3)(iii) Is the food 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3)(iv) Is the food 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Is the supply-chain program written?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Is the supply-chain-applied control applied by an entity other than the receiving facility’s supplier?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1) Does the receiving facility’s verify the supply-chain-applied control when a supply-chain-applied control is applied by an entity other than the receiving facility’s supplier?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2) Does the receiving facility verify the supply-chain applied control obtained documentation of an appropriate verification activity from another entity, review and assess the entity’s applicable documentation, and document said review and assessment?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.410 General Requirements Applicable to a Supply-Chain Program	
(a)(1) Does the supply-chain program use approved suppliers as required by §117.420?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(2) Does the supply-chain program determine appropriate supplier verification activities as required by §117.425?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3) Does the supply-chain program conduct the supplier verification activities as required by §117.430 and §117.435?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(4) Does the supply-chain program document supplier verification activities as required by §117.475?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(5) Does the supply-chain program verify 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 obtain documentation of an appropriate verification activity from another entity, review and assess that documentation and document the review and assessment as required by §117.475?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Do the supplier verification activities for raw materials and other ingredients include an onsite audit?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Do the supplier verification activities for raw materials and other ingredients include sampling and testing of the raw material or other ingredient?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Do the supplier verification activities for raw materials and other ingredients include review of the supplier's relevant food safety records?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(4) Do the supplier verification activities for raw materials and other ingredients include other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c) Does the supply-chain program provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented? (d)(1)(i) In approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, do you consider the hazard analysis of the food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(1)(ii) In approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, do you consider the entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(d)(1)(iii)(A) In approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, do you consider a supplier performance, including the supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(1)(iii)(B) In approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, do you consider a supplier performance, including the 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)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(1)(iii)(C) In approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, do you consider a supplier performance, including 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 the food, and responsiveness of the supplier in correcting problems?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(1)(iv) In approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, do you consider any other factors as appropriate and necessary?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(2) If your answer for the following questions is YES, considering supplier performance can be limited to the supplier's compliance history:	
(d)(2)(i) Is the supplier a qualified facility as defined by §117.3?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(2)(ii) Is the supplier 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(2)(iii) Is the supplier 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(e) In accordance with §117.150, if the receiving facility determines that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, does the receiving facility take and document prompt action?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.415 Responsibilities of the Receiving Facility	
(1) Does the receiving facility approve the suppliers?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(2) Except as provided by paragraphs (a)(3) and (a)(4), does the receiving facility determine and conduct appropriate supplier verification activities and satisfy all documentation requirements?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(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:	
(a)(3)(i) Are there established written procedures for receiving raw materials and other ingredients by the entity?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3)(ii) Is there a document that written procedures for receiving raw materials and other ingredients are being followed by the entity?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(a)(3)(iii) Does the entity determine, conduct, or both determine and conduct the appropriate supplier verification activities, with appropriate documentation?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(4) Does the supplier 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Are any of the following not accepted as a supplier verification activity:	
(b)(1) A determination by its supplier of the appropriate supplier verification activities for that supplier.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) An audit conducted by its supplier.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) A review by its supplier of that supplier's own relevant food safety records.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of §117.410(b)(4).	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(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.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.420 Using Approved Suppliers	
(a) Does the receiving facility approve suppliers in accordance with the requirements of §117.410(d)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Does the receiving facility document that approval, before receiving raw materials and other ingredients received from those suppliers?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1) Are the written procedures for receiving raw materials and other ingredients established and followed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(2) Do the written procedures for receiving raw materials and other ingredients 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)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(3) Are the written procedures for receiving raw materials and other ingredients documented?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.425 Determining Appropriate Supplier Verification Activities (including determining the frequency of conducting the activity)	
Are the appropriate supplier verification activities (including the frequency of conducting the activity) determined in accordance with the requirements of §117.410(d)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.430 Conducting Supplier Verification Activities for Raw Materials and Other Ingredients	
(b)(1)(i) Is the appropriate supplier verification activity an onsite audit of the supplier?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b)(1)(ii) Is the audit conducted before using the raw material or other ingredient from the supplier and at least annually thereafter?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1)(i) Does the receiving facility obtain written assurance that the supplier is a qualified facility as defined by §117.3 before first approving the supplier for an applicable calendar year?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1)(ii) Does the receiving facility obtain written assurance that the supplier is a qualified facility, as defined by §117.3 on an annual basis thereafter, by December 31 of each calendar year for the following calendar year?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2) Does the receiving facility obtain written assurance, at least every two 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2)(i) Does the written assurance include a brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2)(ii) Does the written assurance include a statement that the facility is in compliance with state, local, county, tribal, or other applicable nonfederal food safety laws, including relevant laws and regulations of foreign countries?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(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:	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(1)(i) Does the receiving facility obtain 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 before first approving the supplier for an applicable calendar year?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(d)(1)(ii) Does the receiving facility obtain 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, on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(d)(2) Does the receiving facility obtain written assurance, at least every two years, that the farm 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 comparable or has determined to be equivalent to that of the United States?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(e)(1)(i) Does the receiving facility obtain 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 before first approving the supplier for an applicable calendar year?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(e)(1)(ii) Does the receiving facility obtain 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 on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(e)(2) Does the receiving facility obtain written assurance, at least every two 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 comparable or has determined to be equivalent to that of the United States?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(f) There are no financial conflicts of interests that influence the results of the verification activities listed in §117.410(b), and payment is not be related to the results of the activity?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.435 Onsite Audit	
(a) Is the onsite audit of a supplier performed by a qualified auditor?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Does the onsite audit consider if the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations and include a review of the supplier's written plan?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
If your answer is YES to any of the next questions, you do not need an onsite audit.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1)(i) Do you have the written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by the FDA, by representatives of other federal agencies or by representatives of state, local, tribal, or territorial agencies?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1)(i) Do you have 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(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: Is the food that is the subject of the onsite audit within the scope of the official recognition or equivalence determination, and the foreign supplier in, and under the regulatory oversight of, such country?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

117.475 Records Documenting the Supply-chain Program	
(a) Are the records documenting the supply-chain program subjected to the requirements of subpart F of this part?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(b) Has the receiving facility reviewed the records listed in paragraph (c) of this section in accordance with §117.165(a)(4)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(1) Has the receiving facility documented the written supply-chain program record?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(2) Has the receiving facility documented a record of the documentation that it is an importer 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(3) Is the documentation of the approval of a supplier documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(4) Are the written procedures for receiving raw materials and other ingredients documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(5) Is the documentation demonstrating use of the written procedures for receiving raw materials and other ingredients documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(6) Is the documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(7) Is the documentation of the conduct of an onsite audit documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(7)(i) Does this documentation include the name of the supplier subject to the onsite audit?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(7)(ii) Does this documentation include documentation of audit procedures?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(7)(iii) Does this documentation include dates when the audit was conducted?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(7)(iv) Does this documentation include conclusions of the audit?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(7)(v) Does this documentation include corrective actions taken in response to significant deficiencies identified during the audit?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(7)(vi) Does this documentation include the documentation that the audit was conducted by a qualified auditor?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(c)(8) Is the documentation of sampling and testing conducted as a supplier verification activity documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(8)(i) Does this documentation activity include the identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(8)(ii) Does this documentation include the identification of the test(s) conducted, including the analytical method(s) used?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(8)(iii) Does this documentation include the date(s) on which the test(s) were conducted and the date of the report?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(8)(iv) Does this documentation include the results of the testing?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(8)(v) Does this documentation include corrective actions taken in response to detection of hazards?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(8)(vi) Does this documentation include information identifying the laboratory conducting the testing?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(9) Is the documentation of the review of the supplier's relevant food safety records documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(9)(i) Does this documentation include the name of the supplier whose records were reviewed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(9)(ii) Does this documentation include the date(s) of review?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(9)(iii) Does this documentation include the general nature of the records reviewed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(9)(iv) Does this documentation include the conclusions of the review?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(9)(v) Does this documentation include the corrective actions taken in response to significant deficiencies identified during the review?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(10) Is the documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(11) Does the 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 documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(c)(12) For a supplier that is a qualified facility:	
(c)(12)(i) Is 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, documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(12)(ii) Is 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, documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(13) The receiving facility must document 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.	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(13)(i) Is the written assurance that the 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, documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(13)(i) Is the written assurance that the farm 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 comparable or has determined to be equivalent to that of the United States, documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(14) The receiving facility must document 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:	
(c)(14)(i) Is 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, documented in a record for the receiving facility?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(14)(ii) Is 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, documented in a record for the receiving facility?)	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(15) Does the receiving facility document 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 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

(c)(16) Does the receiving facility document actions taken with respect to supplier non-conformance, in a record?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(17) Does the receiving facility document the verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier, in a record?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(18)(i) Does the receiving facility document the applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(18)(ii) Does the receiving facility document the 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(18)(iii) Does the receiving facility document the applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(18)(iv) Does the receiving facility document applicable documentation from its supplier of the results of sampling and testing conducted by the supplier? Does the receiving facility document applicable documentation from its supplier of the results of an audit conducted by a third-party qualified auditor in accordance with §§117.430(f) and 117.435?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
(c)(18)(v) Does the receiving facility document 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?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

Recordkeeping Procedures

Accurate recordkeeping is an essential part of a successful preventive controls program. These questions will help give you an idea of your compliance related to the records that are required under the Preventive Controls for Human Food Regulation. These questions focus on implementation records; this type of records document the actual implementation of the Food Safety Plan and demonstrate that you did what you were supposed to do.

Subpart F: General Requirements for Records

Are records kept as originals or true copies? (or in an electronic format)	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Do the records include the actual values or observations?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are records recorded in a permanent manner? (e.g., not recorded in pencil) Is the information recorded at the same time the activity is being performed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Do the records include enough detail to provide a history of the work performed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Computerized Records	
Are there electronic or computerized records?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the electronic records equivalent to paper records?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the electronic signatures equivalent to traditional handwritten signatures?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the electronic records authentic, accurate, and protected from unauthorized changes?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are electronic records reviewed by management with adequate frequency to ensure the facility's food safety plan is being followed?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are electronic records available for review and copying by public health authorities if necessary?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is the electronic recordkeeping system validated?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Owner/ Agent in Charge Must Be Informed	
Is the food safety plan signed and dated by the owner, operator, or agent in charge of the facility, when the food safety plan is completed and any time there is a modification?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Basic Information on Records	
Do the records include:	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Name of the facility,	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Facility location,	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Date,	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Time that the activity was documented,	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Actual measurements or observations made,	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Product identification, if applies (e.g., lot code, time, date)	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Initials or signatures of individuals performing monitoring and verification activities,	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Signatures of individuals performing reviewing and data of reviewed activities?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Notes

Subpart F: Implementation Record Requirements

	Answers and Comments
Implementation Records	
Food safety plan implementation records demonstrate that the activities described in your plan were carried out.	
Is there a monitoring record for preventive controls?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is there a corrective actions record?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is there a verification activities record for....	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
validation record?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
monitoring?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
monitoring and corrective action?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
monitoring and verification instruments?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
product testing?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
environmental monitoring?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
records reviews?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
reanalysis?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is there a supply-chain record?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is there a training record?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Monitoring Records	
Used to document that food safety hazards have been controlled by preventive controls.	
Do the monitoring records have an identifier? (title or number)	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Do the monitoring records have the signature or initials of the individual reviewing the record and date of the review?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the monitoring records signed and dated by the reviewer after these activities?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Corrective Action Records

These records describe the deviation that triggered corrective action.

Do the records include.....	
the product identification (e.g., lot code) and, if apply, volume on hold?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
a description of deviation from parameters?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
actions taken to prevent recurrence?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
if relevant, results of the evaluation or testing of product?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
the final disposition of product?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
corrective action verification?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
the name and signature of the person responsible for the corrective action(s)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
the name and signature of the person reviewing the corrective action(s) report?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
the signature or initials of the individual reviewing the record and date of the review?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the corrective actions records signed and dated by the reviewer after these activities?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

Verification Records

Records of verification activities must be kept to demonstrate that the food safety plan has been implemented properly, monitoring measurements or observations are accurate and reliable, and the food safety system is working as intended.

As appropriate for the food and food safety system, is there a verification record for.....	
validation studies?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
verification of monitoring and corrective action record?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

accuracy checks and calibration of process-monitoring instruments?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
product testing?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
environmental monitoring?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
supply-chain program verification?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
reanalysis?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
audit records to verifying supplier compliance with food safety equirements?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
results from third-party audits or regulatory agency inspections?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Validation Records, when applicable	
Validation provides evidence that the parameters and preventive controls in the food safety plan will control relevant hazards.	
Are the preventive controls (and the parameters and values or critical limits at CCPs) adequate to significantly minimize or prevent food safety concerns?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is there new information the facility should consider regarding the safety of their products such as emerging hazards?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Does lack of customer or consumer complaints (when you have a system to collect them) suggest that there is history of a food safety concern?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Product Testing and Environmental Monitoring Records	
Apply to microbiological and chemical analysis specified as verification activities in the food safety plan.	
Is there a record for the laboratory conducting the test?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Do the record include.....	
sample identification (lot number, date of sampling),	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
location of sampling (finished product, n process, environmental sample site)	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
date of test	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

target microorganism or chemical,	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
methods used,	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
results of the test per unit volume (g, ml, presence/absence)?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Employee Training Record	
Records could be kept in individual personnel files and summarized for easy access.	
Does the record include.....	
form title?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
employee name?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
hire date?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
the name, location and date completed of the training course?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Record Retention and Availability	
Are the records retained for at least two years from the date of its record?	
Are the records that relate to the general adequacy of the equipment or processes being used kept at the facility for at least two years after their use is discontinued?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Is the food safety plan retained onsite? (Electronic records are considered onsite if they are accessible from onsite.)	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the off-site stored records readily available within 24 hours when requested for official review?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the records associated with the food safety plan available to FDA regulatory personnel?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time
Are the records organized and accessible?	☐ Yes ☐ No ☐ N/A ☐ Not sure or some of the time

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The Mango Industry Recommendation for Preventive Controls Self-Assessment Tool