DEPARTMENT OF
Food Science and
Human Nutrition

FSMA Human Food Audit Checklist

Iowa State University Extension and Outreach
Department of Food Science and Human Nutrition

The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. FSMA is the largest change in food safety law since the Food, Drug, and Cosmetic Act was first passed in 1938. FSMA seeks to 1) Prevent foodborne illness; 2) Improve inspection, compliance, and response; 3) Improve safety of imported foods and; 4) Improve miscellaneous provisions and enhance partnerships.

This Checklist focuses on manufacturers of human food. It will help you organize your materials and assess your current food safety preparedness. The Checklist is NOT itself a plan; it is only an assessment tool to assist in the development of your own plan. This Checklist has four main parts: 1) Hazard Analysis and Risk-Based Preventive Controls (21 CFR Part 117 Subpart C); 2) Current Good Manufacturing Practices (21 CFR Part 117 Subpart B); 3) Sanitary Transportation of Human and Animal Food (21 CFR Part 1 Subpart O); and 4) Registration of Food Facilities (21 CFR Part 1 Subpart H). It is recommended to do one part at a time and collect/list documentation in each part as you go. If the answer to a question is no, put no; then this will be an area to improve. This checklist is for your use only; it is not a regulatory compliance program.

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We welcome input and suggestions. It may be possible to tailor versions of the Checklist to specific industries. This Checklist does not make distinctions among industries in the application of preventive controls. However, the Current Good Manufacturers Practices and Preventive Controls for Human Food (CGMP & PC) rule does describe several exemptions from the rule, or certain provisions of the rule, including exemptions based on size of business, activities conducted, and types of products. All the provisions apply to all non-exempt industries and facilities regulated by FDA.

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Hazard Analysis and Risk-based Preventive Controls

Hazard Analysis and Risk-Based Preventive Controls Checklist Part 1 – §117.180(c)(1)

	Preventive Controls Qualified Individual	Yes	No	N/A	Documents
1.1	Identify a preventive controls qualified individual with food safety training and/or education.				
	Hint: A preventive controls qualified individual has job experience in the development and application of a food safety system or has successfully finished training in the development and application of risk-based preventive controls at least equivalent to the standardized curriculum recognized as adequate by FDA. Currently, the standardized curriculum recognized as adequate by FDA is that offered by the Food Safety Preventive Controls Alliance. The preventive controls qualified individual does not have to be an employee of the company.				
1.2	Documentation of training of the preventive controls qualified individual.				
	Hint: Records of training completed by preventive controls qualified individuals should include the date, type of training, the people trained, if applicable.				
1.3	You may wish to establish a food safety team.				
	Hint: A multifaceted team with a variety of expertise that can contribute to food safety risk assessment. This can help bring expertise from various areas of operation as well as provide a well-informed group to help develop and implement the food safety plan.				

Comments:

A preventive controls qualified individual must do or oversee: the preparation of the food safety plan, validation of the preventive controls, review of records, reanalysis of the food safety plan, and if necessary, the determination that validation is not required.

Definitions (§117.3):

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

FDA means the Food and Drug Administration.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Preventive controls qualified individual (PCQI) means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Hazard Analysis and Risk-Based Preventive Controls Part 2 – §117.126

	Contents of a Food Safety Plan Overview	Yes	No	N/A	Documents
2.1	Food Safety Plan includes a hazard analysis.				
	Hint: Identify and evaluate all known or foreseeable hazards for each food manufactured, processed, packed, or held at the facility.				
2.2	Food Safety Plan must include preventive controls if the hazard analysis concludes there is/are a hazard(s) requiring preventive controls.				
	Hint: Identify and implement preventive controls to provide assurance that hazards requiring a preventive control appropriate to the food being processed would be significantly minimized or prevented. The food safety plan may also include documentation as to why a critical control point is not a preventive control.				
2.3	Food Safety Plan may include supply-chain program.				
	Hint: Establish a program to accept or reject raw materials and other ingredients for which hazard(s) requiring a preventive control have been identified before they enter the facility. Written procedures should describe how each item is received and/or rejected. They should also describe how supplier verification activities are conducted for each supplier, including temporary and replacement suppliers. Replacement and temporary suppliers should have the same acceptance criteria as regular suppliers.				
2.4	Food Safety Plan must include a recall plan if a preventive control is identified.				
	Hint: Written protocol that describes steps to be taken during a recall.				
2.5	Food Safety Plan must include monitoring procedures when appropriate to the preventive control.				
	Hint: Establish written procedures that ensure preventive controls are consistently performed as written in the food safety plan.				
2.6	Food Safety Plan includes corrective action procedures if a preventive control is identified.				
	Hint: Written procedures to be taken if preventive controls are not properly implemented to correct the issue.				
2.7	Food Safety Plan includes written validation and verification procedures if a preventive control is identified.				
	Hint: See the FDA definition of validation below. Validation is required for process preventive controls. Validation documentation explains how the established preventive controls are scientifically and technically acceptable for the control of a hazard requiring a preventive control. Verification includes the application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.				
2.8	Food Safety Plan must include record keeping.				
	Hint: If a preventive control is identified then records for implementation must be kept on the monitoring, corrective actions, verification of validation, reanalysis, and record review procedures of the preventive control. Records that may need to be included (depending on food safety plan) are supply-chain, the reasoning for not establishing a preventive control, calibration,				

	and environmental monitoring. Records must be kept for the training of preventive control qualified individual and qualified individuals.

Comments:
The food safety plan is the backbone for the application and documentation of Hazard Analysis and Risk Based Preventive Controls in the plant. The preventive controls qualified individual must do or oversee preparation of the food safety plan. Remember the plan is dynamic. As your facility goes through everyday operations, the optimization of processes, and additional products, check your plan to see what may need to be updated. This link gives you access to a variety of resources that may be beneficial throughout this checklist: https://www.ifsh.iit.edu/fspca/resources/resources-chapter-preventive-controls-human-food.

Definitions (§117.3):

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR part 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of 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), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 3 – §117.130

	Hazard Analysis	Yes	No	N/A	Documents
3.1	Documented assessment of biological, chemical, radiological, and physical hazards to determine whether any hazards require a preventive control.				
	Hint: Biological hazards include undesirable bacteria, fungi, parasites, and other pathogens. Chemical hazards include pesticide and drug residues, toxins, unapproved food or color additives, food allergens, and radiological hazards. Physical hazards include stones, glass, metal fragments, and other undesirable or unsafe physical objects in a food.				
3.2	Describe hazards known or reasonably likely to occur in the food being processed in the facility in the hazard analysis.				
	Hint: These include natural, unintentionally introduced, or intentionally introduced hazards. This is based on experience, illness data, scientific reports, and other information about food safety.				
3.3	Written evaluation of hazards (likelihood that the hazard will occur in the absence of control(s) and the severity of illness/injury caused by the hazard).				
	Hint: This evaluation must include an evaluation of environmental pathogens whenever a ready-to-eat food, such as cut fruit, is exposed to the environment prior to packaging and the packaged food does not receive a treatment or other control measure to minimize the pathogen.				
3.4	The hazard evaluation must consider the safety of the finished food for the intended consumer.				
	Hint: Areas to focus on include but are not limited to: the formulation of the food, the condition/function/design of the facility and equipment, raw materials and other ingredients, transportation practices, manufacturing/processing procedures, packaging activities and labeling activities, storage and distribution, intended or reasonably foreseeable use (including age and health of intended consumer), sanitation of the facility, employee hygiene, and seasonal hazards.				
3.5	Document hazard evaluations of formulations, manufacturing and processing procedures, packaging activities and labeling activities, and sanitation procedures of the finished food.				
	Hint: Determine if there are any biological, chemical, radiological, and physical hazards in the production of the food that can cause injury or illness to humans and animals.				
3.6	Written hazard evaluation of the condition, function, and design of the facility and equipment.				
	Hint: Ensuring the production facility does not introduce, transfer, or promote (growth or survival of) hazards requiring a preventive control into the production of the food.				
3.7	Written hazard evaluation of raw materials and other ingredients, transportation practices, storage and distribution, and the intended and foreseeable use of the product.				
	Hint: Minimizing the risks and effects of contamination of the product outside of facility. Also, understanding how the product will be used and how it can affect at-risk consumers. Describe how raw, rework, and finished items are kept separate and identified.				

Comments:
The hazard analysis is about identifying all the points, from entering the processing facility to the end consumer, where a hazard requiring a preventive control is likely to occur. A hazard analysis should be conducted for each different process and product your facility has. However, if you have two products that have the same process, unless there are different health concerns, they can be grouped together.

Definitions (§117.3):

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic spore-forming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of 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), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 4 – §117.135

Preventive Controls for Hazards		Yes	No	N/A	Documents
4.1	Identify and implement preventive controls for hazards requiring a preventive control to significantly minimize or prevent illness, injury, or death to a consumer of the food. Preventive controls are required for hazards at critical control points and other points that minimize or prevent these risks.				
	Hint: The hazards requiring a preventive control were identified in Part 3 of this checklist. Preventive controls include any process controls, food allergen controls, sanitation controls, supply-chain-applied controls, the recall plan, certain good manufacturing practices, and any other controls appropriate for food safety.				
4.2	Process controls include procedures, practices, and processes to ensure the control of parameters during operations.				
	Hint: Process controls may include heat, acidification, irradiation, and refrigeration. Minimum and maximum values of parameters must be determined and must be based on scientific and technical evidence.				
4.3	Food allergen controls include procedures, practices, and processes to control food allergens.				
	Hint: These controls must include preventing allergen cross-contact through processing, storage, handling, and use, as appropriate, as well as proper labeling of potential allergens in finished products.				
4.4	Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to significantly minimize or prevent hazards.				
	Hint: Sanitation controls help prevent hazards requiring preventive controls due to employee handling, food allergens, and environmental pathogens. These controls include proper cleaning of food-contact surfaces, utensils, and equipment as well as preventing any cross contamination from personnel, packaging, or other surfaces to food and raw product to finished product.				

Comments:
Be sure to think past microbiological concerns and also think about physical and chemical hazards. Allergen control is a large focus of FSMA. To control hazards, think about process, allergen, and sanitation controls.

Definitions (§117.3):

Acid foods/acidified foods/acidification means foods that have an equilibrium pH of 4.6 or below.

Allergen cross-contact/contamination means the unintentional incorporation of a food allergen into a food.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic spore-forming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of 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), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiving facility means a facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 5 – §117.136

When Preventive Controls Are Not Required		Yes	No	N/A	Documents
5.1	When selling a food that could not be consumed without application of a control.				
	Hint: These are foods, such as milled grains and seeds for oil, which have a required control step to create a final product. Must document why preventive controls are not required for the particular hazard in the food.				
5.2	You rely on your customer to provide assurance it is manufacturing, processing, or preparing food in accordance with food safety requirements.				
	Hint: You must disclose in documents accompanying the food that the food is "not processed to control [the identified hazard]". You must annually obtain written assurance from the customer that the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements. If the customer is subject to requirements for hazard analysis and risk-based preventive controls, you must obtain written assurance that the customer has established and is following procedures that will significantly minimize or prevent the identified hazard. The customer also needs to provide proof through records that the controls are in place.				
5.3	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 after the customer.				
	Hint: You must disclose in documents accompanying the food that the food is "not processed to control [the identified hazard]". You must annually obtain from your customer written assurance that your customer will disclose in documents accompanying the food that the food is "not processed to control [the identified hazard]" and will only sell to another entity that prepares the food in accordance with applicable food safety requirements or, if the entity is subject to the requirements for hazard analysis and risk-based preventive controls, will follow procedures, identified in a written assurance, that will significantly minimize or prevent the hazard, or the entity will obtain written assurance from the entity's customer as described above.				

Comments:
Communication between suppliers and customers is crucial when claiming a preventive control is not required. Extensive written documentation and proof is necessary.

Definitions (§117.3):
Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

Hazard Analysis and Risk-Based Preventive Controls Part 6 – §117.139

Recall Plan		Yes	No	N/A	Documents
6.1	Step by step written protocol detailing how a recall will take place.				
	Hint: This should include who should have access to the plan, who needs to know how to execute it, all the contacts and responsibilities, different levels of recall, how contaminated product is isolated from safe product, and how to address recalls initiated by suppliers.				
6.2	Written procedure with steps to directly notify the direct consignees and the public of the food being recalled.				
	Hint: Process to follow when customers need to be notified of hazards requiring a preventive control in the food and how to return or dispose of the food.				
6.3	Written procedure with steps to conduct effectiveness checks verifying the recall has been carried out.				
	Hint: Process to follow to verify recall has been carried out fully.				
6.4	Written procedure on how to properly dispose of recalled food.				
	Hint: Process to follow when disposal of food is needed through reprocessing, reworking, using the food in a way that does not present a safety concern, or simply destroying the food.				

Comments:
These procedures should be well documented and understood to be effectively executed when needed. Mock recalls can help practice these situations. Review the steps taken during a mock recall and adjust the plan accordingly. When making phone calls to other companies for mock recalls, ensure to emphasize that it is a mock recall or give the practice recall a different name. Using the term recall can cause other companies to go into panic mode even though it is only a practice recall.

Definitions (§117.3):
Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Hazard Analysis and Risk-Based Preventive Controls Part 7 – §117.145

Monitoring		Yes	No	N/A	Documents
7.1	Written procedures must be established and implemented including the frequency with which they are to be performed if a preventive control is identified in the food safety plan.				
	Hint: The protocol should include a description of the products and hazards, what specifications are checked, how it is monitored, when and how often it is checked, and records of monitoring results.				
7.2	Monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.				
	Hint: How frequently are thorough checks being performed?				
7.3	Records documenting the monitoring of preventive controls to verify the written procedures.				
	Hint: Check the monitoring documentation. Who is monitoring? Who is checking monitoring? How is the check of monitoring being completed?				

Comments:
Monitoring is a check to ensure the processing of the food is going as expected. Corrective actions (Part 9) are taken when monitoring procedures uncover an issue with the food.

Definitions (§117.3):

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 8 – §117.150

Corrective Actions and Corrections		Yes	No	N/A	Documents
8.1	After identifying preventive controls, describe and document the procedures in place to correct a food safety issue.				
	Hint: Should address the appropriate actions to take when hazards requiring preventive controls are detected in food.				
8.2	If an unanticipated food safety problem occurs, identify and correct the problem, evaluate all food for safety, and ensure any distributed food does not enter commerce.				
	Hint: Equipment breaks, employees make errors, and accidents happen. Identify when the problem occurred and isolate all food produced after that point. Evaluate the food to determine if it is safe for distribution and consumption. Determine whether the unanticipated problem may reoccur in the future and adjust the food safety plan accordingly, if necessary. Be sure to address how to reduce the likelihood of reoccurrence of the problem.				
8.3	Corrections are actions taken to correct a minor and isolated problem that does not directly impact product safety.				
	Hint: Take note of these incidents. Minor incidents may affect product quality or cost money but are not required to be documented in records if food safety is not affected.				
8.4	Continuously monitor and update food safety plans as needed.				
	Hint: If corrective actions are taken, you must identify the root cause of the problem to prevent reoccurrence.				

Comments:
Corrective actions can minimize waste and prevent recalls. Corrective actions must be taken in situations where a preventive control failed or was not implemented. When food safety is compromised, take corrective actions. Corrections address less serious issues that are not food safety issues but may affect product quality. Corrections do not have to be documented but they should be to prevent reoccurrence.

Definitions (§117.3):

Correction means an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of 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), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Hazard Analysis and Risk-Based Preventive Controls Part 9 – §117.155, 165

Verification		Yes	No	N/A	Documents
9.1	Verify implementation of food safety plan.				
	Hint: Check records of verification, monitoring, and corrective actions to ensure they are implemented as written in the food safety plan. Review testing procedures identified in the food safety plan.				
9.2	Check calibration and accuracy of monitoring and verification instruments				
	Hint: A third-party group may be used to check instruments to ensure correct calibration.				
9.3	Record all verification processes and/or activities.				
	Hint: You must have written procedures for the method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy), product testing, and environmental monitoring.				

Comments:
Verification procedures are necessary to ensure that the preventive controls are consistently implemented and effectively controlling the identified hazards. A preventive controls qualified individual must perform or oversee verification activities. Remember, verification happens routinely. Verification is done to ensure both that the preventive control(s) are implemented according to plan, and that the preventive control(s) that are implemented according to plan are effectively controlling the hazards. It is a process to provide evidence that the food safety plan is working as planned. Examples of verification are equipment calibrations, environmental monitoring, label review for allergens, and other sampling and testing. Verification of records is important because these are the documents that will be audited.

Definitions (§117.3):
Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Hazard Analysis and Risk-Based Preventive Controls Part 10 – §117.160

Validation		Yes	No	N/A	Documents
10.1	A preventive controls qualified individual must validate or oversee validation of preventive controls to ensure the hazards requiring preventive controls will be controlled as expected.				
	Hint: The person from 1.2 of this checklist must personally conduct validation or ensure that it is done. Validation is not required for sanitation, allergen, and supply-chain preventive controls, or the recall plan.				
10.2	Must revalidate when there is a change in control measures that could affect the hazard.				
	Hint: Whenever there is a change in process, revalidate.				
10.3	Must have scientific evidence to show control of hazards.				
	Hint: Find peer reviewed literature to support your process or perform your own validation studies. Utilize search engines, such as Google Scholar, to find papers that must reference your specific product, specifications, and process. If conducting your own study, three strains of the pathogen of concern should be used. One of those strains must be isolated from an outbreak. When preparing the product for the trial, include customer preparation deviations to add a safety buffer to your process.				

Comments:
Validation is the evidence for the efficacy of a particular process. Ask yourself "can the plan, when implemented, actually control the identified hazards?" Validation demonstrates that following the plan will actually control the identified hazards. It should be done before the implementation of the food safety plan. This link has draft guidance for some validation of controls:
https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517399.pdf.

Definitions (§117.3):

Hazard means any biological, chemical, radiological, or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of 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), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Pathogen means a microorganism of public health significance.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

Hazard Analysis and Risk-Based Preventive Controls Part 11 – §117.170

Reanalysis		Yes	No	N/A	Documents
11.1	Must occur minimally every 3 years.				
11.2	Must occur whenever there is a change in processes, hazards requiring a preventive control, information, or whenever FDA determines it is necessary to respond to new hazards and developments in scientific understanding that may change safety concerns about a product.				
	Hint: When something changes that could impact food safety, reanalyze food safety plan.				
11.3	Must be completed by a preventive controls qualified individual.				
	Hint: Individual from 1.2 of this checklist.				

Comments:
Keep records of each reanalysis. The food safety plan is dynamic and must be reanalyzed to ensure it is current with your processes and general food safety information.

Definitions (§117.3):
FDA means the Food and Drug Administration.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of 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), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Hazard Analysis and Risk-Based Preventive Controls Part 12 – §117.190

Records Required		Yes	No	N/A	Documents
12.1	Required for documentation of the food safety plan.				
	Hint: Based on section 2 of this checklist.				
12.2	Required for documentation of hazard analysis.				
	Hint: Based on section 3 of this checklist.				
12.3	Required for documentation of any established preventive controls.				
	Hint: Based on section 4 of this checklist.				
12.4	Required for documentation for not establishing a preventive control.				
	Hint: Based on section 5 of this checklist.				
12.5	Required for documentation of a recall plan.				
	Hint: Based on section 6 of this checklist.				
12.6	Required for documentation of monitoring preventive controls and corrective actions.				
	Hint: Based on sections 7 and 8 of this checklist.				
12.7	Required for documentation of verification procedures.				
	Hint: Include verification for validation, monitoring, corrective actions, calibration, product testing, environmental monitoring, reanalysis, and record review.				
12.8	Required for documentation of supply-chain program and employee training.				
	Hint: Based on General Provisions, Good Manufacturing Practices, and Supply-Chain Program, 21 CFR 117 Subparts A, B and G.				

Comments:
Record and document everything in processing listed in this checklist. If in doubt, document. Required records include the hazard analysis, any identified preventive controls, supply-chain requirements, the recall plan, monitoring procedures, corrective action procedures, verification procedures, and employee training.

Definitions (§117.3):

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly

minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Current Good Manufacturing Practices

Current Good Manufacturing Practice Checklist Part 1 – §117.4

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

	Qualified Individual	Yes	No	N/A	Documents
1.1	All individuals involved in manufacturing, processing, packing, or holding food must be trained as qualified individuals.				
	Hint: Each employee (qualified individual) must receive training in the principles of food hygiene and food safety that is appropriate to the food, facility, and the individual's assigned duties.				
1.2	Documentation of appropriate training of qualified individuals as appropriate for the job.				
	Hint: Training should be specific to the food safety and hygiene requirements of the job. Records of training completed by qualified individuals should include the date, type of training, and the people trained (21 CFR 117.4(d)).				

Comments:
All employees engaged in the manufacturing, processing, packing, or holding of human food must be qualified individuals and have food hygiene and food safety training as appropriate to each individual's role in the facility.

Definitions (§117.3):

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Current Good Manufacturing Practices Checklist Part 2 – §117.10

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

	Personnel	Yes	No	N/A	Documents
2.1	Training of all employees of the risks of unhygienic practices and appropriate hygienic practices to prevent contamination of food.				
	Hint: Written standard operating procedures for handwashing and when to wash hands. Planned training for employees on handwashing that is documented.				
2.2	Employees must report any health conditions to their supervisors including illness, open lesions, and any other sources of possible contamination.				
	Hint: Written policy on reporting health conditions explaining that employees will be sent home if signs are shown.				
2.3	Written dress code policy for all personnel is enforced.				
	Hint: All personal belongings including jewelry should be stored in a designated area away from possibly becoming a source of contamination.				
2.4	Written policy on personal protective attire is enforced.				
	Hint: Employees are trained on the outer garments like gloves, hair nets, and aprons that are needed.				
2.5	Written policy on food and tobacco use is enforced.				
	Hint: No eating, drinking, or use of tobacco, including electronic cigarettes and vaporizers, in the food production areas. Designated areas are available for eating, drinking, and tobacco use.				
2.6	Training for all employees on proper food handling, food protection principles, and standard working conditions.				
	Hint: Written standard operating procedures for proper food handling and food protection. Ensure employees are able to identify when processing is going correctly and when it is not. Training in food safety and food hygiene requires documentation.				
2.7	Designate personnel to identify and document when plant sanitation fails to meet expectations and when food contamination occurs.				
	Hint: Document failures and contamination. Have written procedures to deal with repeat offenders of poor sanitation practices.				

Comments:
Personnel who understand how and why to do something is a very important component in ensuring a thorough job is done. Standard operating procedures and trainings should be written in plain language to assist with the understanding of the material. Designate personnel to ensure the facility and personnel meet all the above requirements. Be sure to keep records of all training.

Definitions (§117.3):
Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Current Good Manufacturing Practices Checklist Part 3 – §117.20

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Plant and Grounds		Yes	No	N/A	Documents
3.1	Within the immediate vicinity of the plant, removal of litter, waste, weeds and grass occurs regularly.				
	Hint: Regular checking of the grounds, including roads and parking lots, surrounding the facility to ensure the plant doesn't attract or harbor pests.				
3.2	Store all unused and broken equipment in the proper area.				
	Hint: When equipment does not work, isolate it from working equipment to prevent confusion and clutter. Regularly dispose of unused and broken equipment.				
3.3	Areas around and within the facility are well-drained.				
	Hint: Drains are checked and cleared to allow proper drainage to prevent pest infestation.				
3.4	The grounds, buildings, fixtures and other biological hazard areas are regularly maintained and repaired.				
	Hint: Broken items are fixed or removed in a timely manner.				
3.5	The plant must be suitable in size, construction, and design to allow for sanitation and maintenance.				
	Hint: Plant gives adequate space for equipment, bulk storage, and ingredients while still being able to clean.				
3.6	Have a written and validated plan to control allergen cross contact.				
	Hint: Separate allergens from non-allergenic productions by using a different processing location, time between runs to clean and sanitize equipment, air and dust flow, etc.				
3.7	Plant design allows for separation of production by location, time, or other means reducing cross contamination.				
	Hint: Keep production areas separate from storage and shipping areas.				
3.8	Proper lighting throughout the facility that is protected to prevent product contamination.				
	Hint: All fixtures should have shatter resistant light bulbs or non-breakable covers.				
3.9	Dust and vapors are controlled through adequate ventilation.				
	Hint: This helps to prevent allergen and microbial contamination.				

Comments:
The grounds surrounding a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. Be certain your plant and its surrounding environment are not sources of contamination for the food you are producing.

Definitions (§117.3):

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Allergen cross-contact/contamination means the unintentional incorporation of a food allergen into a food.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Current Good Manufacturing Practices Checklist Part 4 – §117.35

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Sanitary Operations		Yes	No	N/A	Documents
4.1	Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated.				
	Hint: Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.				
4.2	All cleaning compounds and sanitizing agents are free from microorganisms and must be safe and adequate under the condition of use.				
	Hint: Certification of chemicals or supplier guarantee of safety.				
4.3	Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be held and stored to protect against contamination of food, food-contact surfaces, and food-packaging.				
	Hint: Designated location away from the food production areas for all chemicals with documentation of the chemicals in the designated location. Be sure to keep track of material safety data sheets.				
4.4	Only toxic materials that are relevant to the food being processed may be stored or used in the plant.				
	Hint: Only materials required for cleaning, sanitation, maintenance, and laboratory testing may be in the plant.				
4.5	Effective pest control program should be established. Guard dogs may be allowed in some areas of a plant if they are unlikely to result in food contamination. Use pesticides only in ways that will protect against the contamination of food, food-contact surfaces, or food-packaging materials.				
	Hint: Pest management system that documents the presence and prevention methods to exclude pests. If using pesticides, ensure they are used in a manner to prevent contamination. Limit the areas a guard dog is allowed within the plant to ensure no contamination occurs.				
4.6	All equipment including food contact surfaces, utensils, and non-food contact surfaces are cleaned on a scheduled basis. All equipment should be stored in a manner that prevents contamination.				
	Hint: Documentation of cleaning that occurs on a regular basis is not required but may be beneficial. Be sure to regularly check for cleaning residues and have a written protocol to account for improperly cleaned equipment.				
4.7	Single-serve articles must be stored, handled, and disposed of in a manner that protects against allergen cross-contamination and contamination of food, food-contact surfaces, and food-packaging.				
	Hint: Designated storage areas for these areas and written standard operating procedure for use.				

Comments:
Sanitation is one of the first and most focused on parts of a food safety inspection. Many plant issues, such as recalls and failed inspections, can be attributed to poor sanitation and pest management. This is the first area to focus on with standard procedures and follow-up verification.

Definitions (§117.3):
Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Allergen cross-contact/contamination means the unintentional incorporation of a food allergen into a food.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Microorganisms mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and include species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Pathogen means a microorganism of public health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Current Good Manufacturing Practices Checklist Part 5 – §117.37

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

	Sanitary Facilities and Controls	Yes	No	N/A	Documents
5.1	The water supply must be adequate for operations intended and must be derived from an adequate source. Any water, steam, or ice that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature and, under pressure as needed, must be provided in all areas of processing, cleaning, packaging, and employee sanitation.				
	Hint: All water coming into the plant needs to be as sanitary as necessary for the intended use.				
5.2	Plumbing must be of adequate size and design, be able to carry adequate quantities of water, remove waste, not become a source of contamination of food or water, be adequately drained from the floor, and not allow backflow or cross-connection from wastewater and sewage.				
	Hint: Plumbing must be able to provide adequate quantities of safe water and drain adequate quantities of wastewater and sewage.				
5.3	Sewage treatment systems and septic systems are free of leaks and are functioning properly.				
	Hint: Regularly inspect sewage treatment and septic systems.				
5.4	Toilets and handwashing stations must be readily accessible, clean, and not a source of contamination.				
	Hint: There must be clean toilets and handwashing stations of a suitable temperature throughout the plant.				
5.5	Rubbish and offal should be labelled. It must be stored and disposed of to minimize the development of odor, the potential to be an attractant for pests, and to not allow contamination of food, water, or surfaces throughout the plant.				
	Hint: Waste must be removed regularly and in a way that minimizes cross-contamination.				

Comments:
Each plant must be equipped with adequate sanitary facilities and accommodations.

Definitions (§117.3):

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening,

trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Current Good Manufacturing Practices Checklist Part 6 – §117.40

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

	Equipment and Utensils	Yes	No	N/A	Documents
6.1	All equipment used in the plant must be designed to be readily cleanable and maintained to prevent allergen cross-contact.				
	Hint: Everything must be able to be thoroughly cleaned and also must be cleaned regularly.				
6.2	Equipment must be designed and maintained to avoid the adulteration of food.				
	Hint: Equipment cannot allow lubricants, fuel, metal fragments, contaminated water, etc. into food. Equipment should be constructed from metal detectable parts.				
6.3	Food contact surfaces must be made of nontoxic materials and must withstand the environment and foods they are used with.				
	Hint: Food contact surfaces must be able to withstand heat, corrosion, and other processing conditions.				
6.4	Seams on food contact surfaces must be smoothly bonded or maintained to minimize the accumulation of food, dirt, and organic matter.				
	Hint: This helps prevent microorganism establishment and growth and minimize allergen cross-contact.				
6.5	All equipment in a food processing area must be kept clean and sanitary.				
	Hint: This includes non-food contact surfaces, hoses, brooms, etc.				
6.6	Any cold storage area must have a thermometer that records accurate temperatures, and temperature must be recorded routinely throughout the day.				
	Hint: The thermometer must be able to accurately display temperatures so that it is obvious when temperatures have not been properly maintained.				
6.7	Devices used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise, maintained, and regularly calibrated.				
	Hint: Such devices include thermometers, pH meters, water activity meters, etc.				
6.8	Any gases introduced into a food or used to clean food-contact surfaces must not be contaminated.				
	Hint: Gases should be free of allergen and microbial contamination as well as physical and chemical hazards.				

Comments:
Clean equipment and processing areas frequently. Records may include records of dates and times of cleaning and notes about the condition of equipment being used. Cleanup after unusual situations (leaks, equipment breakdown) should be noted and explained. Notes regarding equipment that needs immediate repair or replacement should be made and the repair/replacement documented.

Definitions (§117.3):
Allergen cross-contact/contamination means the unintentional incorporation of a food allergen into a food.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and include species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Significantly minimize means to reduce to an acceptable level, including to eliminate.

Water activity **(a_w)** is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Current Good Manufacturing Practices Checklist Part 7 – §117.80

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Processes and Controls		Yes	No	N/A	Documents
7.1	All operations involving food must be conducted under adequate sanitation principles and must be supervised by one or more trained individuals assigned this duty.				
	Hint: This includes manufacturing, processing, packing, holding, receiving, inspecting, transporting, and segregating food.				
7.2	The establishment must have appropriate quality control operations for all food to ensure it is safe for human consumption.				
	Hint: Quality control operations are crucial to confirm the product is safe.				
7.3	Overall plant sanitation should be supervised by one or more trained individuals.				
	Hint: All sanitation procedures should be written and documented. The individual is responsible for training employees in sanitation procedures and how to identify contamination issues.				
7.4	Ensuring all steps and precautions are taken to prevent allergen cross-contamination.				
	Hint: Be careful to make certain there is no allergen cross-contamination at any step of the process, from the supplier to the customer.				
7.5	Testing procedures must be in place to identify sanitation failures or possible contamination of product.				
	Hint: Use chemical, microbial, and other tests (such as a metal detector) to find any points of allergen or other food contamination.				
7.6	All food that is contaminated to the point of adulteration must be rejected, treated, or processed to eliminate the contamination.				
	Hint: If product was processed incorrectly and does not eliminate microbial contamination, it may be deemed appropriate to be reintroduced into the raw materials stream. It must be labelled as rework. Otherwise, when in doubt, throw it out.				
7.7	Raw materials must be inspected and handled to ensure suitability for processing into final product. Raw materials should be washed, cleaned, and stored appropriately to avoid contamination.				
	Hint: Raw ingredients must be inspected for safe levels of microorganisms, pests, and toxins (such as aflatoxin) and stored in a way that prevents future allergen or other food contamination.				
7.8	Raw materials must be held in containers designed to prevent allergen cross-contact and contamination.				
	Hint: Storage conditions, such as temperature, relative humidity, or a rework schedule, may be used to reduce risk for allergen cross-contact and contamination (21 CFR 117.80(b) (5).				
7.9	Frozen raw materials and ingredients must be kept frozen.				
	Hint: If thawing is necessary, do so in a way that prevents adulteration of the food.				
7.10	Any materials that are food allergens must be labelled and handled in a way to prevent allergen cross-contact.				
	Hint: Label all boxes with allergens as allergen and be mindful of their travels through the facility.				

7.11	All food manufacturing, processing, packing, and holding must be conducted under conditions and controls that minimize the potential for the growth of microorganisms, allergen cross-contact, food contamination, and food deterioration.				
	Hint: If a food requires temperature control for safety, temperature must be used to control that food.				
7.12	Work-in-progress, rework, and finished food must be protected at all times to prevent allergen cross-contact, contamination, and growth of undesirable microorganisms.				
	Hint: This applies to all steps in your process, from receiving to distribution.				
7.13	When measures are taken to destroy or prevent the growth of undesirable microorganisms, the measures must be adequate for the food to not become adulterated.				
	Hint: These measures include sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or water activity. There should be documented proof that the correct controls were applied.				
7.14	Heat blanching must heat the food to and hold at the required temperature, then cool or process the food immediately.				
	Hint: Growth of microorganisms in blanchers must be minimized by the use of proper operating temperatures and regular cleaning and sanitizing.				
7.15	Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained as to protect against allergen and other contaminants while minimizing the growth of undesirable microorganisms.				
	Hint: Be mindful of the use and storage of these products as they can also be important for food safety.				
7.16	Foods that rely on water activity control to prevent growth of undesirable microorganisms must be processed to and maintained at a safe-moisture level.				
	Hint: When making dry mixes, nuts, and other low moisture foods, ensure the correct water activity and moisture level is reached and maintained.				
7.17	Foods that rely on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.				
	Hint: Acid and acidified foods must be kept below a pH of 4.6 at all times.				
7.18	When ice is used in contact with food, it must be of safe and sanitary quality and must only be used if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.				
	Hint: Water and ice used in contact with food should always be treated like a food in relation to this checklist.				

Comments:
Every process in the plant should be done in a way that prevents biological, physical, and chemical contamination. Document all processes throughout production.

Definitions (§117.3):

Acid foods or acidified foods mean foods that have an equilibrium pH of 4.6 or below.

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Allergen cross-contact/contamination means the unintentional incorporation of a food allergen into a food.

Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of 21 CFR 117.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and include species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Water activity **(a_w)** is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

Current Good Manufacturing Practices Checklist Part 8 – §117.93, §1.908

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Warehousing and Distribution		Yes	No	N/A	Documents
8.1	Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical, and physical contamination of food, as well as against deterioration of the food and the container.				
	Hint: Food should be stored and labeled appropriately. Keep allergens separate; properly seal containers when not in use, store materials and products in refrigerated storage when necessary.				
8.2	Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse.				
	Hint: Methods of assessment include determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, e.g., for off-odors.				
8.3	Stock rotation should be documented.				
	Hint: First in, first out.				
8.4	Finished product containers must be clearly labelled to identify contents and the presence of any allergens.				
	Hint: Someone with no knowledge of the container should be able to easily understand what ingredients and allergens are present.				

Comments:
It is important to keep warehouses and distribution centers clean to prevent contamination of final product.

Definitions (§117.3, §1.904):

Allergen cross-contact/contamination means the unintentional incorporation of a food allergen into a food.

Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packing means placing food into a container other than packaging the food and also includes repacking

and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Current Good Manufacturing Practices Checklist Part 9 – §117.95

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Holding and distribution of human food by-products for use as animal food		Yes	No	N/A	Documents
9.1	Containers and equipment used to hold human food by-products for use as animal food must be designed, constructed, cleaned, and maintained to protect against the contamination of human food by-products for use as animal food.				
	Hint: The equipment for human food by-products for use as animal food should be treated similarly to equipment used for human food.				
9.2	Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash.				
	Hint: Keep human food by-products in safe and separate containers to prevent contamination.				
9.3	Human food by-products for use as animal food must be accurately identified.				
	Hint: Properly label all human food by-products for use as animal food as such.				
9.4	Shipping containers and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the by-products.				
	Hint: Totes, drums, tubs, and vehicles etc. must be visually examined prior to use. Containers and vehicles should be labelled and properly cleaned to prevent contamination.				

Comments:
Human food by-products are parts of human foods or are foods generated during human food production that are not sold as human food commercially.

Definitions (§117.3):
Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Current Good Manufacturing Practices Checklist Part 10 – §117.110

Note: CGMP provisions do not require records or written procedures, although establishments are certainly encouraged to have written procedures as necessary

Defect action levels		Yes	No	N/A	Documents
10.1	The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level possible.				
	Hint: There are unavoidable defects with legal limits. If you exceed defect action levels, the food may be considered adulterated. Additionally, poor manufacturing practices may result in enforcement action without regard to the action level.				
10.2	Have written procedures for the handling of defective foods.				
	Hint: How will defective foods be disposed? What defects are in the food and can defective food be reworked?				
10.3	The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the food adulterated.				
	Hint: Do not mix food with defects above the legal limit with any other food. The final product is not permitted, regardless of the final level of defects.				

Comments:
See the Defect Levels Handbook for examples, which is accessible at *http://www.fda.gov/pchfrule* and at *http://www.fda.gov*.

Definitions (§117.3):

Defect action level means a level of a nonhazardous, naturally occurring, unavoidable defect at which FDA may regard a food product "adulterated" and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

FDA means the Food and Drug Administration.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Lot means the food produced during a period of time and identified by an establishment's specific code.

Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Sanitary Transportation of Human and Animal Foods

Sanitary Transportation Checklist Part 1 – §1.900

Who is subject to the Sanitary Transportation rule?		Yes	No	N/A	Documents
1.1	The Sanitary Transportation rule applies to shippers, receivers, loaders, and carriers engaged in transportation operations.				
	Hint: This rule applies whether or not the food your business sells is sold into interstate commerce.				
1.2	The requirements of the Sanitary Transportation rule apply to those involved in transportation operations in addition to any other requirements involving food.				
	Hint: These include 21 CFR parts 1, 117, 118, 225, 507, and 589.				
1.3	The requirements of the Sanitary Transportation rule do not apply to shippers, receivers, loaders, or carriers when they are in transportation operations of food that is transshipped through the United States to another country.				
	Hint: Food sent through the United States to another country (for example, transportation of food between Mexico and Canada) and is not sold in the United States is exempt from this rule.				
1.4	The requirements of the Sanitary Transportation rule do not apply to shippers, receivers, loaders, or carriers when they are in transportation operations of food that is imported for future export that is neither consumed nor distributed in the United States.				
	Hint: This is in accordance with section 801(d)(3) of the Food, Drug, and Cosmetic Act. If your business imports food into the United States and exports it out of the United States without sales or distribution in the United States, the Sanitary Transportation rule does not apply to you.				
1.5	Any facilities that are regulated exclusively by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act are exempt from this rule.				
	Hint: If the Food and Drug Administration comes to your facility, you must comply with this rule.				

Comments:
The shipper is the person/group who arranges the transport of food. This may be the manufacturer itself or a freight broker. A loader is the person who puts food onto the vehicle for transportation. A carrier is the person/group that transports the food. A receiver is the person/group who receives the shipped food.

Definitions (§1.904):

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

Sanitary Transportation Checklist Part 2 – §1.902

How does the information in the Sanitary Transportation rule apply under the Food, Drug, and Cosmetic Act?		Yes	No	N/A	Documents
2.1	The Sanitary Transportation rule applies in determining whether food is adulterated with the meaning of section 402(i) of the Food, Drug, and Cosmetic Act in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations under conditions that are not in compliance with this rule.				
	Hint: This means food that was transported in conditions that are not acceptable by this rule is considered adulterated.				
2.2	The failure by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations to comply with the requirements of this rule is a prohibited act under section 301(hh) of the Food, Drug, and Cosmetic Act.				
	Hint: It is illegal to go against this rule if you are subject to it.				

Comments:
Adulterated food cannot be sold or distributed. It is important to prevent adulteration within the plant as well as during transport and storage.

Definitions (§1.904):

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Sanitary Transportation Checklist Part 3 – §1.906

	Vehicles and transportation equipment	Yes	No	N/A	Documents
3.1	Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe during transportation operations.				
	Hint: Any vehicles used must be designed to transport food and prevent contamination of the product.				
3.2	Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.				
	Hint: Any vehicles used must be cleaned and maintained to prevent food safety issues from occurring.				
3.3	Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations.				
	Hint: Vehicles and equipment used for transported refrigerated or frozen foods must be designed and maintained to have the correct and safe operating temperature in the vehicle.				
3.4	Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations.				
	Hint: Do not allow vehicles and transportation equipment to harbor pests or allow contamination of the food product during transport.				

Comments:
Vehicles and transportation equipment are required to be designed, maintained, operated, and stored in a way to prevent the adulteration of food.

Definitions (§1.904):
Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, *e.g.*, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h) (6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Sanitary Transportation Checklist Part 4 – §1.908(a)

General requirements for transportation operations		Yes	No	N/A	Documents
4.1	Responsibility for ensuring that transportation operations are carried out in compliance with all sanitary transportation requirements must be assigned to competent supervisory personnel.				
	Hint: Someone who is knowledgeable about food safety concerns with transportation operations must be assigned the responsibility of compliance to this rule.				
4.2	All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations.				
	Hint: This includes taking effective measures to protect food from contamination by raw foods and nonfood items in the same load, protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations, and ensure that food that requires temperature control for safety is transported under adequate temperature control.				
4.3	The type of food must be considered in determining the necessary conditions and controls for the transportation operation.				
	Hint: Make sure transportation operations are appropriate for that food.				
4.4	Shippers, receivers, loaders, and carriers, which are under the ownership or operational control of a single legal entity, may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of this section.				
	Hint: If the entire transportation process is under one company or legal entity, the operations can be integrated with each other as long as individual records are kept for each part of the operation.				
4.5	If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate actions to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.				
	Hint: If there are any issues detected that may cause food to be unsafe, the food cannot be sold or distributed unless actions must be taken to ensure the issues associated with the food did not make it unsafe.				

Comments:
It is important to have qualified individuals who are trained in food safety in the plant as well as food safety as it applies to transportation to monitor the operation to ensure food is safe.

Definitions (§1.904):
Bulk vehicle means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Cross-contact means the unintentional incorporation of a food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act into food, except animal food.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Sanitary Transportation Checklist Part 5 – §1.908(b)

	Requirements applicable to shippers engaged in transportation operations	Yes	No	N/A	Documents
5.1	The shipper must specify to the carrier and, when necessary, the loader, in writing, of all necessary sanitary specifications for the carrier's vehicle and transportation equipment to ensure sanitary conditions.				
	Hint: This includes any specific design specifications and cleaning procedures. A one-time notification is sufficient unless the design and/or cleaning requirements of the vehicle and transportation equipment changes based upon the type of food being transported. When changes occur, the shipper must notify the carrier in writing before the shipment. See exception in Section 4.4 of this checklist.				
5.2	When shipping foods that requires temperature control for safety, the shipper must specify in writing to the carrier and the loader, the appropriate operating temperature for the transportation operation, including the precooling phase.				
	Hint: One time notification is sufficient unless the conditions of the shipment causes a change in the appropriate operating temperature. When changes occur, the shipper must notify the carrier in writing before the shipment.				
5.3	A shipper must develop and implement written procedures adequate to ensure that vehicles and equipment used in its transportation operations will prevent the food from becoming unsafe during the transportation of the food.				
	Hint: The written procedures must prevent the transportation operation from making food unsafe. The measure to implement these procedures may be accomplished by the shipper or carrier under a written agreement.				
5.4	A shipper of food transported in bulk must develop and implement written procedures, adequate to ensure that a previous cargo does make the food unsafe.				
	Hint: Measures are put in place to prevent cross-contamination from previous loads of transported goods. These measures to ensure the safety of the food may be accomplished by the shipper or the carrier under a written agreement.				
5.5	The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures to ensure that the food is transported under adequate temperature control.				
	Hint: Measures to ensure the safety of the food may be accomplished by the shipper or the carrier under written agreement.				

Comments:
It is the responsibility of the shipper to inform the carrier and loader of all temperature, sanitation, and other specifications they know are important to the safety of the transported food. This information must be documented in writing.

Definitions (§1.904):
Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Bulk vehicle means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, *e.g.*, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Sanitary Transportation Checklist Part 6 – §1.908(c) and (d)

Requirements applicable to loaders or receivers engaged in transportation operations		Yes	No	N/A	Documents
6.1	Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment, the loader must determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food.				
	Hint: This can be judged by the specifications provided by the shipper, if the shipper is in compliance with section 5.1 of this checklist. The vehicle or transportation equipment must be in adequate physical condition, free of visible evidence of pest infestation, and free of previous cargo that could cause the food to become unsafe during transportation.				
6.2	Before loading food that requires temperature control for safety, the loader must verify that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of food.				
	Hint: This can be judged by the specifications provided by the shipper, if the shipper is in compliance with section 5.2 of this checklist. It includes indicating that the container has been properly pre-cooled and meets other sanitary conditions for food transportation.				
6.3	Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse.				
	Hint: This includes determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection for qualities such as off-odors.				

Comments:
Loaders are responsible for ensuring transportation equipment is adequately sanitary and has the proper controls in place. Both receivers and loaders are responsible for checking the temperature of the vehicle and equipment prior to performing their respective duties.

Definitions (§1.904):

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Food not completely enclosed by a container means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subpart.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Vehicle means a land conveyance that is motorized, e.g., a motor vehicle, or that moves on rails, e.g., a railcar, which is used in transportation operations.

Sanitary Transportation Checklist Part 7 – §1.908(e)

	Requirements applicable to carriers engaged in transportation operations	Yes	No	N/A	Documents
7.1	When the carrier and shipper have a written agreement that the carrier is responsible for sanitary conditions during the transportation operation, the carrier is responsible for the functions listed in sections 7.2-7.6.				
	Hint: These responsibilities may be shared with the shipper depending on the logistics of the written agreement.				
7.2	A carrier must ensure that vehicles and transportation equipment meet the shipper's specifications.				
	Hint: These specifications must be appropriate to prevent the food from becoming unsafe during the transportation operation.				
7.3	A carrier must provide the operating temperature and, if requested by the receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature specified by the shipper.				
	Hint: This can be judged by the specifications provided by the shipper, if the shipper is in compliance with section 5.2 of this checklist. This can be done by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment.				
7.4	Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety under the conditions of the shipment during transportation, a carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper.				
	Hint: This must be in accordance with 5.2 of this checklist.				
7.5	A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in and most recent cleaning of the vehicle.				
	Hint: This is if the shipper requests the information.				
7.6	A carrier must develop and implement written procedures subject to records requirements.				
	Hint: These procedures must specify practices for cleaning, sanitizing, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and transportation equipment in sanitary condition. The procedures must also describe how the carrier will comply with rules for temperature control (7.3) and the use of bulk vehicles (7.5).				

Comments:
Carriers are ultimately responsible for the successful and safe transportation of food from shipper to receiver. They must have the written procedures from the shipper and be sure that those specifications are followed. Any previous cargo transported with the same transportation equipment must be identified to the shipper and it must be cleaned prior to transporting new cargo.

Definitions (§1.904):
Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, *e.g.*, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Sanitary Transportation Checklist Part 8 – §1.910

	Training	Yes	No	N/A	Documents
8.1	When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must provide adequate training to personnel engaged in transportation operations.				
	Hint: This training must provide an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier.				
8.2	Carriers must establish and maintain records documenting the training described in 5.1.				
	Hint: The training must be provided upon hiring and as needed thereafter. The records of the training must include the date of the training, the type of training, and the person(s) trained.				

Comments:
Any individual involved in the transportation of food must be trained to facilitate the transport of safe food.

Definitions (§1.):

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Sanitary Transportation Checklist Part 9 – §1.912

Records		Yes	No	N/A	Documents
9.1	Shippers must retain records that demonstrate that they provide specifications and operating temperatures to carriers as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.				
	Hint: Shippers must have these records for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.				
9.2	Carriers must retain records of the written procedures in section 7.6 of this checklist.				
	Hint: These records must be retained for 12 months beyond when the agreements and procedures are in use in their transportation operations.				
9.3	Carriers must retain training records required by section 8.2 of this checklist.				
	Hint: These records must be retained for 12 months beyond when the person identified in any such records stops performing the duties for which the training was provided.				
9.4	Anyone that is subject to any part of this checklist is required to retain any other written agreements assigning tasks that are in compliance with the Sanitary Transportation Rule.				
	Hint: These records must be retained for 12 months beyond the termination of the agreements.				
9.5	Shippers, receivers, loaders, and carriers that are under the ownership or control of a single legal entity must retain records of the written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations.				
	Hint: Even though these are under one entity, they are each required to have their own records.				
9.6	Shippers, receivers, loaders, and carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request.				
	Hint: If records are requested by authorized individuals, such as FDA investigators, the records must be available to that individual.				
9.7	All records are required to be kept as original records, true copies, or electronic records.				
	Hint: True copies include photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records.				
9.8	Offsite storage of records, except for procedures for cleaning, sanitizing, and inspecting vehicles and transportation equipment, is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.				
	Hint: The procedures for cleaning, sanitizing, and inspecting vehicles and transportation equipment must remain onsite as long as the procedures are in use in transportation operations. Electronic records are considered to be onsite if they are accessible from an onsite location.				
Comments: All records required by this section are subject to the disclosure requirements in 21 CFR 20. **Definitions (§1.904):**					

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

FDA means the United States Food and Drug Administration.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.*, the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation equipment means equipment used in food transportation operations, *e.g.*, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Sanitary Transportation Checklist Part 10 – §1.914 - §1.934

	Waiver Requirements	Yes	No	N/A	Documents
10.1	FDA will waive any requirement of this subpart with respect to any class of persons, vehicles, food, or nonfood products when FDA determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and the waiver will not be contrary to public interest.				
	Hint: These are the circumstances given by FDA on how they will waive a requirement.				
10.2	Waivers must be requested via a petition.				
	Hint: FDA will respond with their decision in writing. If the petition is denied, FDA will explain the reasons for denial.				
10.3	FDA will make filed waiver petitions readily accessible to the public.				
	Hint: This will be periodically updated with the status of each petition (pending, granted, or denied).				
10.4	Petitions may be denied because the petition does not provide the required information, FDA believes the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health, or the waiver could be contrary to public interest.				
	Hint: The requirements for information in the waiver come from 21 CFR 1.918 and 21 CFR 10.30.				
10.5	Granted waivers will become effective on the date that the notice of the waiver is published in the Federal Register.				
	Hint: Until then, maintain compliance with the law.				

Comments:
Always be in compliance with the law until FDA officially grants the waiver. If a waiver is granted, be sure to still keep food safety in mind during operations.

Definitions (§1.904):
FDA means the United States Food and Drug Administration.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Vehicle means a land conveyance that is motorized, *e.g.*, a motor vehicle, or that moves on rails, *e.g.*, a railcar, which is used in transportation operations.

Registration of Food Facilities

Registration of Food Facilities Checklist Part 1 – §1.225

	Who must register?	Yes	No	N/A	Documents
1.1	You must register your facility if you are the owner, operator, or agent in charge of either a domestic or foreign facility engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States.				
	Hint: Most facilities are covered under this. Exemptions will be covered Part 2.				
1.2	If you are an owner, operator, or agent in charge of a domestic facility, you must register your facility whether or not the food from the facility enters interstate commerce.				
	Hint: Any facility in the United States covered under 1.1 must register the facility even if their products do not cross state lines.				
1.3	If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to register your facility on your behalf.				
	Hint: Anyone can register your facility for you if you allow him or her to do so.				

Comments:
Facilities which manufacture, process, pack, or holding food for human or animal consumption in the United States must register. To register, go to *http://www.fda.gov/furls*.

Definitions (§1.227):
Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:
(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or
(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Registration of Food Facilities Checklist Part 2: - §1.226

Who does not have to register?		Yes	No	N/A	Documents
2.1	A foreign facility does not have to register if food from that facility is further manufactured, processed, or packaged by another facility outside of the United States.				
	Hint: Foreign facilities who send products to another foreign facilities does not have to register unless the further manufacturing, processing, or packaging only includes labeling or another similar activity of a *de minimis* nature.				
2.2	Farms, retail food establishments, restaurants, and nonprofit food establishments in which food is prepared for, or served directly to, the consumer do not have to register.				
	Hint: Farms may have to register if they also process food. These businesses are covered by other laws.				
2.3	Fishing vessels that harvest and transport fish do not need to register.				
	Hint: Such fishing vessels may engage in practices such as heading, eviscerating, or freezing fish intended solely to prepare fish for holding on board a harvest vessel.				
2.4	Any facilities that are regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act do not have to register.				
	Hint: If your facility handles any products under FDA jurisdiction, you may be required to register if the facility does not meet any of the above mentioned exemptions.				

Comments:
These facilities do not have to register as it applies to this checklist. However, these facilities may be subject to other provisions of the Federal Food, Drug, and Cosmetic Act that may apply.

Definitions (§1.227):
Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

Farm means:

(1) ***Primary production farm***. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) ***Secondary activities farm***. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided th at the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. “Restaurant” does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and

(2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term “retail food establishment” includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term “consumers” does not include businesses. A “retail food establishment” includes

grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Registration of Food Facilities Checklist Part 3: - §1.230

When must you register or renew your registration?		Yes	No	N/A	Documents
3.1	You must register before your facility begins to manufacture, process, pack, or hold food for consumption in the United States.				
	Hint: Registration should be done before production begins. You may allow someone else to register the facility for you.				
3.2	You must submit registration renewal with the information in Part 5 (§1.232) of this checklist between October 1 and December 31 of each even-numbered year.				
	Hint: For example, you would need to renew registration between October 1, 2018 and December 31, 2018.				
3.3	If you are the owner, operator, or agent in charge of a facility, you may authorize an individual to renew registration of your facility on your behalf.				
	Hint: Anyone can renew your facility's registration for you if you allow him or her to do so. If this is done, the renewal must include a statement in which the individual certifies that the information submitted is true and accurate, certifies that they are authorized to submit the registration renewal, and identifies the individual who authorized submission of the registration renewal by name, address, and telephone number.				
3.4	Each renewal must include the name of the individual submitting the registration renewal and the email address of the individual who authorized submission of the registration renewal unless FDA has granted a waiver under §1.245 .				
	Hint: The signature of the individual submitting the registration renewal must be included if the renewal is done on paper. The signature is not required for electronic registration renewal.				
3.5	If there are no changes to any information required in Part 5 of this checklist since the prior renewal or registration, you may use the abbreviated registration renewal process.				
	Hint: You must confirm that no changes have been made to the information required in Part 5 of this checklist since the preceding registration or renewal and certify all information is truthful and accurate. Each abbreviated renewal must include the name of the individual submitting the abbreviated renewal (and that individual's signature on the paper version). If the owner, operator, or agent in charge of the facility is not the one submitting the abbreviated registration renewal, the abbreviated renewal must provide the email address of the individual who authorized submission of the abbreviated renewal unless FDA has granted a waiver under §1.245. You must use Form FDA 3537 to submit abbreviated registration renewals to FDA.				

Comments:
Form 3537 can be found at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf *https://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm?Page=7*. This links you to the PDF and online (HTML) versions of the form. This form is used for registration, renewal, and abbreviated renewal.

Definitions (§1.227):
Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more

than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixedtype facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Registration of Facilities Checklist Part 4: - §1.231

How and where do you register or renew your registration?		Yes	No	N/A	Documents
4.1	To register or renew a registration electronically, you must go to *http://www.fda.gov/furls*.				
	Hint: This website is available 24 hours a day, 7 days a week and from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes.				
4.2	Beginning on January 4, 2020, you must submit your registration or registration renewal to FDA electronically.				
	Hint: This is required unless FDA has granted you a waiver under §1.245.				
4.3	After electronic submission, FDA will verify the accuracy of your unique facility identifier (UFI) recognized as acceptable by FDA and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration.				
	Hint: FDA will not confirm your registration or provide you with a registration number until FDA verifies the accuracy of your facility's UFI and address. When this is done, FDA will provide you with an electronic confirmation of your registration renewal. UFI's are not required until October 1, 2020.				
4.4	When the registration is not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration, FDA will verify that the individual identified as having authorized submission of the registration in fact authorized the submission on behalf of the facility.				
	Hint: FDA will not confirm the registration or provide a registration number until that individual confirms that they authorized the submission. This also happens for registration renewal.				
4.5	For a foreign facility, after you submit your electronic registration, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent.				
	Hint: FDA will not confirm your registration or provide you with a registration number until that person confirms they agreed to serve as your U.S. agent. After electronic registration renewal is complete, FDA will provide you with an electronic confirmation of your registration renewal.				
4.6	You will be considered registered once FDA electronically sends you your confirmation and registration number.				
	Hint: You are registered only after registration is confirmed by FDA.				
4.7	For registration by mail or fax, use form FDA 3537. It must be filled out completely and legibly.				
	Hint: To obtain a copy of this form, write to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or request the form by phone at 1-800-216-7331 or 240-247-8804. The finished registration must be mailed to the address above or faxed to 301-436-2804.				
4.8	FDA will enter complete and legible mailed and faxed registration submissions into its registration system, as soon as practicable, in the order FDA receives them.				
	Any contact between you and FDA will be sent via the same means as what was originally received by FDA (if you sent it in by mail, they will respond by mail).				

4.9	There is no registration fee required and all registration information must be in the English language. Any incorrect information must be corrected immediately and resubmitted.				
	Hint: The individual's name, the company's name, the name of a street, and a trade name may be submitted in a foreign language. All information, including all names, must be submitted using the Latin (Roman) alphabet.				

Comments:

In addition to the requirements described in this checklist, you must comply with any other Federal, state, or local registration requirements that apply to your facility as well as 21 CFR 108. Consequences of failing to register, update, renew, or cancel your registration are described in 21 CFR 1.241. Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

The form can be found at
https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf
https://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm?Page=7 .

Definitions (§1.227):

FDA means the United States Food and Drug Administration.

Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

UFI means the Unique Facility Identifier.

Registration of Facilities Checklist Part 5: - §1.232

	What information is required in the registration?	Yes	No	N/A	Documents
5.1	The name, full address, and phone number of the facility; the preferred mailing address, if different from that of the facility; the name, full address, and phone number of the parent company, if the facility is a subsidiary of the parent company; all trade names the facility uses; the name, full address, email address (unless FDA has granted you a waiver under §1.245), and phone number of the owner, operator, or agent in charge of the facility; the applicable food product categories of any food manufactured/processed, packed, or held at the facility as identified on Form FDA 3537; the type of activity conducted at the facility for each food product category identified (discussed further in 5.2); a statement in which the owner, operator, or agent in charge provides an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Federal Food, Drug, and Cosmetic Act; and a statement in which the owner, operator, or agent in charge certifies that the information submitted is true and accurate.				
	Hint: This information is required for domestic and foreign facilities. More information is required for domestic facilities (5.3) and foreign facilities (5.4).				
5.2	The type of activities conducted at the facility for each food product category as mentioned 5.1 are as follows: ambient human food storage warehouse/holding facility; refrigerated human food warehouse/holding facility; frozen human food warehouse/holding facility; interstate conveyance caterer/catering point; contract sterilizer; labeler/relabeler; manufacturer/processor; acidified food processor; low-acid food processor; farm mixed-type facility; packer/repacker; salvage operator (reconditioner); animal food warehouse/holding facility; and other activity.				
	Hint: For any food product categories identified, select at least one activity type.				
5.3	A domestic facility must also have the email address for the contact person of the facility and an emergency contact phone number and email address if different from the email address for the contact person.				
	Hint: This is required if the facility is in the United States or territory of the United States.				
5.4	A foreign facility must provide the name, full address, phone number, and email address of the foreign facility's U.S. agent and an emergency contact phone number and email address.				
	Hint: This is required for facilities that manufacture/process, pack, or hold food for consumption in the United States but are not located in the United States.				
5.5	There are optional items in the registration form.				
	Hint: FDA encourages, but does not require, you to submit items indicated as optional on the Form FDA 3537 that you submit.				

Comments:
Use the following link to preview the form but be sure to file registration online: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf*.

Beginning October 1, 2020, the facility's UFI recognized as acceptable by FDA will be required to be submitted with the registration information (§1.232(a)(2)).

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(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

FDA means the United States Food and Drug Administration.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

Holding means storage of food and also includes activities performed incidental to storage of a food (*e.g.*, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixedtype facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixedtype facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixedtype facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Packing means placing food into a container other than packaging the food and also includes repacking and activities performed incidental to packing or repacking a food (*e.g.*, activities performed for the safe or effective packing or repacking of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Trade name means the name or names under which the facility conducts business, or additional names by which the facility is known. A trade name is associated with a facility, and a brand name is associated with a product.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent may not be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

Registration of Facilities Checklist Part 6 – §1.234

How and when do you update your facility's registration information?		Yes	No	N/A	Documents
6.1	You must update a facility's registration within 60 calendar days of any change to any of the information previously submitted from Part 5 except for a change of the owner.				
	Hint: Similar to registration and renewal, an individual who is not the owner, operator, or agent in charge of the facility may update the facility's registration. However, the update must provide the email address of the individual who authorized submission of the update, unless FDA has granted a waiver under §1.245. Electronic updates must be done at *http://www.fda.gov/furls*. FDA will not confirm the update until FDA has verified that the individual identified as having authorized submission in fact authorized the submission. Your registration will be considered updated once FDA sends you your update confirmation.				
6.2	If the reason for the update is that the facility has a new owner, the former owner must cancel the facility's registration as mentioned in Part 6 of this checklist (§1.235) within 60 calendar days of the change and the new owner must submit a new registration for the facility.				
	Hint: The former owner may authorize an individual to cancel and submit a new registration for the facility.				
6.3	After you submit your electronic update, FDA will provide you with an electronic confirmation of your update. When updating UFI information, FDA will verify the accuracy of your facility's UFI and will also verify that the facility-specific address associated with the UFI is the same address associated with your registration.				
	Hint: As the case with registration and renewal, FDA will not provide an electronic confirmation of your registration update until FDA verifies the accuracy of your facility's UFI and verifies the address.				
6.4	For foreign facilities, when updating information about your U.S. agent, FDA will verify that the person identified as the U.S. agent for your foreign facility has agreed to serve as your U.S. agent.				
	Hint: FDA will not provide an electronic confirmation of your registration update until that person confirms that the person agreed to serve as your U.S. agent.				
6.5	To update by mail, you must update your registration using Form FDA 3537.				
	Hint: This can be obtained by writing to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or by requesting the form by phone at 1-800-216-7331 or240-247-8804.				
6.6	You must fill out the sections of the form reflecting your updated information. If any updated information submitted is incorrect at the time of submission, you must immediately resubmit your update.				
	Hint: If you make a mistake, mail the corrections to the address in the hint of 6.5 or fax to 301-436-2804. FDA will contact you throughout the process using the same method as you submitted the updates.				

6.7	When FDA completes its update of your facility, it will mail or fax a copy of the update as entered and confirm the update.				
	Hint: FDA's process for confirmation is the same as the electronic version. Your registration will be considered updated once FDA enters your facility's update data into the registration system and the system generates an update confirmation.				

Comments:
Any updates will be done using the Form 3537. The form can also be found at https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071977.pdf *https://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm?Page=7* .

Definitions (§1.227):
Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

FDA means the United States Food and Drug Administration.

U.S. agent means a person (as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(e))) residing or maintaining a place of business in the United States whom a foreign facility designates as its agent for purposes of this subpart. A U.S. agent may not be in the form of a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

(1) The U.S. agent acts as a communications link between FDA and the foreign facility for both emergency and routine communications. The U.S. agent will be the person FDA contacts when an emergency occurs, unless the registration specifies another emergency contact.

(2) FDA will treat representations by the U.S. agent as those of the foreign facility, and will consider information or documents provided to the U.S. agent the equivalent of providing the information or documents to the foreign facility. FDA will consider the U.S. agent the equivalent of the registrant for purposes of sharing information and communications. The U.S. agent of a foreign facility may view the information submitted in the foreign facility's registration.

(3) Having a single U.S. agent for the purposes of this subpart does not preclude facilities from having multiple agents (such as foreign suppliers) for other business purposes. A firm's commercial business in the United States need not be conducted through the U.S. agent designated for purposes of this subpart.

Registration of Facilities Checklist Part 7 – §1.235

How and when do you cancel your facility's registration?		Yes	No	N/A	Documents
7.1	You must cancel a registration within 60 calendar days of the reason for cancellation.				
	Hint: Reasons may include your facility stops operations, stops providing food for consumption in the United States, or is sold to a new owner.				
7.2	The cancellation of a facility's registration must include the following information: the facility's registration number; whether the facility is domestic or foreign; the facility name and address; the name, address, and email address of the individual submitting the cancellation; and a statement certifying that the information submitted is true and accurate and that the person submitting the cancellation is authorized by the facility to do so.				
	Hint: For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, the email address of the individual who authorized submission of the registration cancellation must be provided, unless FDA has granted a waiver under§1.245 .				
7.3	To cancel your registration electronically, you must cancel at *http://www.fda.gov/furls.*				
	Hint: Once you complete your electronic cancellation, FDA will provide you with an electronic confirmation of your cancellation. For registration cancellations not submitted by the owner, operator, or agent in charge of the facility, after submission of the registration cancellation, FDA will verify that the individual identified as having authorized submission of the cancellation in fact authorized the submission on behalf of the facility. FDA will not confirm the cancellation until that individual confirms that they authorized the cancellation. Your registration is considered cancelled once FDA sends you your cancellation confirmation.				
7.4	To cancel registration using mail or fax, you must cancel your registration using Form FDA 3537a.				
	Hint: Registration, renewals, updates, and cancellations must be done electronically after January 4, 2020. To get Form FDA 3537a, write to the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740 or request the form by phone at 1-800-216-7331 or 240-247-8804.				
7.5	The form must be filled out completely and legibly and mailed to the address in the hint of 7.4 or faxed to 301-436-2804.				
	Hint: FDA will contact you via mail or fax based on how the original cancellation was sent. Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and sends you your cancellation confirmation.				

Comments:
Cancellation is completed using Form 3537a. You can cancel your registration electronically at *http://www.fda.gov/furls* or previewed in PDF format at this link: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072017.pdf*

Definitions (§1.227):

Facility means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Nonbottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.

(2) *Foreign facility* means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

FDA means the United States Food and Drug Administration.

Food has the meaning given in section 201(f) of the Federal Food, Drug, and Cosmetic Act:

(1) Except for purposes of this subpart, it does not include:

(i) Food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act; or

(ii) Pesticides as defined in 7 U.S.C. 136(u).

(2) Examples of food include: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

Registration of Facilities Checklist Part 8 – §1.245

	Waiver request	Yes	No	N/A	Documents
8.1	Beginning January 4, 2020, you must submit your registration, renewal, updates, and cancellations to FDA electronically, unless FDA has granted a waiver from such requirement.				
	Hint: After January 4, 2020, registrations, renewals, updates, cancellations sent by mail or fax will not be accepted by FDA.				
8.2	You must provide the email address of the owner, operator, or agent in charge of the facility unless FDA has granted a waiver from such requirement.				
8.3	Registrations, registration renewals, abbreviated registration renewals, updates, and cancellations not submitted by the owner, operator, or agent in charge must include the email address for the individual who authorized the submission, unless FDA has granted a waiver.				
8.4	To request a waiver from these requirements, you must submit a written request to FDA that explains why it is not reasonable for you to submit your registration, registration renewal, update, or cancellation to FDA electronically or to provide the email address of the owner, operator, or agent in charge of the facility.				
	Hint: You must submit your request to: U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-681), College Park, MD 20740.				

Comments:
Waiver requests must be submitted in writing to the following address: U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition 5001 Campus Dr. (HFS-681) College Park, MD 20740.

You may also submit your request by email to FURLS@fda.gov. The waiver request should include the facility name(s) and address(es) and the name of the owner, operator, or agent in charge of the facility. In addition, if the waiver request is being submitted by a U.S. agent on behalf of a foreign facility, the request should include the name of the U.S. agent authorized by the owner, operator, or agent in charge of the facility to submit the waiver request. Once FDA receives and reviews the request, they will notify you if the waiver has been granted or denied.

Definitions (§1.227):
FDA means the United States Food and Drug Administration.
You or registrant means the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption in the United States.

References

- BRC Good Manufacturing Practices Checklist for Human Food. 2016.
- Federal Food, Drug, and Cosmetic Act. Section 201 (qq). 2013.
- Food Safety Modernization Act. 2011. 21 CFR Part 117.
- Food Safety Modernization Act. 2011. 21 CFR Part 1.
- FSPCA Training Manual. 2016.
- Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry. 2016.
- SQF Good Manufacturing Practices Checklist for Human Food. 2016.