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§ 507.3 Definitions.

The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public (human and animal) health practice.

Affiliate means any facility that controls, is controlled by, or is under common control with another facility.

Animal food means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients.

Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.

Calendar day means every day shown on the calendar.

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

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 for animals may be contaminated and may result in foodborne illness if that animal food is not treated to significantly minimize or prevent 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 sporeforming 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 this chapter.

Farm means farm as defined in § 1.227 of this chapter.

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.

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

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as animal food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting 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. Examples of harvesting include cutting (or otherwise separating) the edible portion of

the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (*e.g.*, foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

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

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 animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury to humans or animals 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 an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

Holding means storage of animal food and also includes activities performed incidental to storage of an animal food (*e.g.*, activities performed for the safe or effective storage of that animal food, such as fumigating animal 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 animal 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 animal food.

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

Manufacturing/processing means making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating animal 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, extruding, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting, 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 means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term ''undesirable microorganisms'' includes those microorganisms that are pathogens, that subject animal food to decomposition, that indicate that animal food is contaminated with filth, or that otherwise may cause animal 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 animal food into a container other than packaging the animal food and also includes repacking and activities performed incidental to packing or repacking an animal food (*e.g.*, activities performed for the safe or effective packing or repacking of that animal 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 (human or animal) 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 animal 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 animal 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.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or the combination thereof) necessary to perform the auditing function. Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

Qualified end-user, with respect to food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located:

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or retail food establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified facility exemption means an exemption applicable to a qualified facility under § 507.5(d).

Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal 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.

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 E of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

Rework means clean, unadulterated animal 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 animal 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 animals or humans.

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

Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Subsidiary means any company which is owned or controlled directly or indirectly by another company.

Supplier means the establishment that manufactures/processes the animal 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.

Unexposed packaged animal food means packaged animal food that is not exposed to the environment.

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.

Very small business means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee or supplied to a farm without sale).

Water activity (a_w) means a measure of the free moisture in an animal 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.

Written procedures for receiving raw materials and other ingredients means written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

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

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.4 Qualifications of individuals who manufacture, process, pack, or hold animal food.

(a)(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts B and F of this part are qualified to perform their assigned duties; and

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold animal food subject to subparts C, D, E, or F of this part