



NGFA Guidance on FDA Qualified Individual Training

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Background

In accordance with provisions established by the U.S. Food and Drug Administration's (FDA) final rules for [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food](#) and [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals](#), individuals at facilities subject to either rule who manufacture, process, pack, or hold (store) food are required to be qualified, i.e., have the education, training or experience (or a combination thereof) necessary to ensure safe human and/or animal food as appropriate to the individual's assigned duties.

Following is the regulatory text from the rule for [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals](#) (hereinafter referred to as the "animal food rule") that establishes training requirements to assure that individuals are qualified to perform their assigned duties.

§ 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 are qualified to perform their assigned duties.
- (b) Each individual engaged in manufacturing, processing, packing, or holding animal food (including temporary and seasonal personnel) or in the supervision thereof must:
 - (1) Be a qualified individual as that term is defined in §507.3, *i.e.*, have 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; and
 - (2) Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.
- (c) Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of safe animal food.
- (d) Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part.

Importantly, the term “animal food” encompasses animal feed, pet food, pet treats, grains, ingredients and other food intended for consumption by animals.

Management Responsibility

Management of an establishment subject to the animal food rule is required to ensure that all individuals who manufacture, process, pack, or hold (store) animal food and those individuals who supervise such activities are qualified to perform their assigned duties. Some factors that management might consider when ensuring an individual is qualified to perform assigned duties may include training, experience and competence in carrying out their assigned duties. Under the rule, training and experience may be previously obtained, or may be gained on the job under supervision until the individual can independently perform assigned duties.

To ensure individuals are qualified to perform assigned duties, management should monitor and review individuals’ performance of those duties. If an individual is not able to consistently perform assigned duties in a competent manner, management should consider whether additional actions are necessary. Additional actions may include providing additional training to the individual or reassignment of duties.

In accordance with the provisions of the animal food rule, management is to ensure that individuals who supervise or perform manufacturing, processing, packing or holding activities for animal food: 1) be a qualified individual; and 2) receive training in the principles of animal food hygiene and animal food safety. These requirements are to be met even if the individual only works on a temporary or seasonal basis.

In addition, management is to clearly assign responsibility for ensuring that individuals comply with the requirements established by the animal food rule to supervisory personnel. The clear assignment of this responsibility to supervisory personnel might include: 1) identifying these responsibilities as part of a position description; 2) identifying who holds these responsibilities on an organizational chart; 3) discussing these responsibilities with supervisory personnel; or 4) including assigned responsibilities in a document such as a facility's standard operating procedures.

Qualified Individual Training

Under the FDA rule, a qualified individual is defined as a person who has the education, training or experience (or a combination thereof) necessary to manufacture, process, pack or hold (store) 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. This means that outside contractors and other non-employees involved in manufacturing and handling animal food that are utilized by an animal food facility also are to be “qualified individuals.”

Training in the principles of animal food hygiene and animal food safety is to include information on the importance of employee health and personal hygiene, but the appropriate scope of the training depends on the animal food, facility and assigned duties.

When developing or selecting training, in addition to considering the animal food, facility and assigned duties, management also may want to consider the individuals’ prior experience and education. Training does not need to be specific to each person’s assigned duties, but rather should take into account the range of duties to decide the scope of training(s) and whether a single training would be appropriate for all individuals, or separate audience-specific trainings would be more appropriate.

The training may be provided by facility personnel, an external source, or a combination of both. Training may be provided by any reasonable means, for example, on the job, in a classroom setting or online.

Compliance Dates

Although FDA’s rule does not prescribe the content of qualified individual training or its frequency, the agency expects training to occur before an individual begins independently performing their assigned duties, with periodic refresher training provided thereafter. In addition, the rule requires that training records be established and retained for at least two years after the date of the training.

The compliance date for which the required training is to occur for existing individuals is determined by the first date that the animal food facility is to comply with the animal food rule. Compliance dates for the rule are staggered based upon business size. In addition, the rule provided covered facilities with one additional year to comply with the preventive controls (PC) requirements after being required to be in compliance with the current good manufacturing practice (CGMP) requirements.

The following table summarizes compliance dates for the animal food rule.

Compliance Dates for Rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals			
Date Rule Issued	Large Businesses*	Small Businesses**	Very Small Businesses***
Sept. 17, 2015	Sept. 19, 2016 (CGMP) Sept. 18, 2017 (PC)	Sept. 18, 2017 (CGMP) Sept. 17, 2018 (PC)	Sept. 17, 2018 (CGMP) Sept. 17, 2019 (PC)
<p>* Large Business Definitions: Business (including all affiliates and subsidiaries) that does not meet the definitions for “small business” or “very small business”</p> <p>** Small Business Definitions: Business (including all affiliates and subsidiaries) with less than 500 full-time equivalent employees</p> <p>*** Very Small Business Definitions: Business (including all affiliates and subsidiaries) with less than \$2.5 million in animal food sales, plus market value of animal food not sold</p>			

Note that compliance dates for all business sizes have passed. As such, if a new animal food facility begins operation or an existing facility becomes subject to the rule, FDA expects the training requirement for “qualified individuals” to be completed prior to manufacturing, processing, packing or holding animal food or supervision thereof. That is, FDA provides no compliance “grace” period for qualified individual training for new operations or existing facilities that become subject to the rule.

Record Requirements

Facilities are required to keep records that document the training on the principles of food hygiene and food safety for those who supervise and/or perform manufacturing, processing, packing or holding (storing) activities for food. The facility can generate training records in a format that is convenient, for example: 1) a training checklist for new employees/individuals; 2) sign-in sheets for specific trainings; or 3) computerized training records.

Required records are to include: 1) information adequate to identify the plant or facility; 2) the date and, when appropriate, the time of the training activity documented; and 3) the signature or initials of the person receiving the training. Examples of additional information that may be included in such a record are: 1) name of the trainer; 2) a description of the content of the training; and 3) name and signature of the supervisor responsible for ensuring compliance with the rule.

Required records are to be retained at the plant or facility for at least two years after the date they were prepared. For example, if a facility offers initial and periodic training in the principles of animal food hygiene and animal food safety, it would retain at least the most recent two years of training records for each individual required to have the training.

The required records are to be made available to FDA and FDA-credentialed investigators upon request for review and copying. The records can be stored offsite if they can be retrieved and provided onsite within 24 hours of FDA’s request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location. Facilities are not required to submit or send the required training records to FDA, only to provide access to such records.

Completing the Required Training

Within the preamble of the animal food rule, FDA states that it expects that much of the required training will be provided in-house by knowledgeable employees already working at facilities. In addition, FDA states that the training material developed by the [Food Safety Preventive Controls Alliance](#) (FSPCA) will be useful to facilities when conducting in-house training. The FSPCA has completed standardized training curriculums for the [human food](#) rule and the [animal food](#) rule.

Example Training Topics and Content

To assist animal food facilities in accomplishing the required qualified individual training on the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, the following are some example training topics and content based upon various provisions found within the animal food rule. Facilities should modify the example training topics and content so as to be suitable for their specific operations and qualified individual training needs.

In addition to training on the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, the animal food rule requires that a “qualified individual” also must have the education, training or experience (or a combination thereof) necessary to manufacture, process, pack, or hold (store) safe animal food as appropriate to their assigned duties. Therefore, individuals may need additional experience and/or education to satisfy the requirements associated with having only “qualified individuals” involved in manufacturing, processing, packing or holding (storing) animal food within the facility.

Example Content for Introductory Training Information

The animal food industry is an essential link in the global food chain and plays an integral role in maintaining the wellbeing and health of companion animals. The industry has the responsibility to provide consistently safe and wholesome products that are responsive to the needs of customers, maintain the confidence and trust of consumers, and comply with applicable food safety regulatory requirements.

Meeting this obligation requires a partnership effort and a continuing commitment on behalf of an animal food facility’s management and employees. Assuring animal food safety makes good business sense and is vitally important to the continued success of any company involved with animal food.

The U.S. Food and Drug Administration’s (FDA) final rule for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (hereinafter referred to as the “animal food rule”) issued on Sept. 17, 2015 establishes a variety of current good manufacturing practice (CGMP) requirements associated with the conditions and practices necessary to ensure the safety of animal food products.

The CGMPs serve as baseline standards for producing safe animal food, including preventing insanitary conditions in the production of animal food. Animal food that is not manufactured, processed, packed and held (stored) according to CGMPs may be considered adulterated by FDA. “Adulteration” is a legal term that FDA uses to describe an animal food that is not fit for its intended use. Compliance with the CGMP provisions should reduce the likelihood that the animal food will be adulterated because it was manufactured/processed, packed or held under

insanitary conditions. An animal food does not need to contain a harmful substance to be adulterated. Again, an animal food may be deemed to be adulterated by FDA if it is not manufactured, processed, packed or held in conformance with applicable FDA regulations.

The animal food rule also establishes that covered facilities are to develop a written food safety plan. The cornerstone of the written food safety plan involves an evaluation of known and reasonably foreseeable hazards that are associated with the facility and its animal food to determine whether any hazards require the use of a preventive control to significantly minimize or prevent the hazard from causing animal food to be unsafe. If the need for one or more preventive controls is identified through the hazard evaluation, then management controls are to be implemented to ensure that the preventive control is effectively implemented and working.

One significant requirement established for facilities subject to the animal food rule is that all individuals involved with the manufacturing, processing, packing or holding of animal food be qualified to perform their assigned duties. To be qualified, individuals are to:

(1) Have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack or hold safe animal food as appropriate to their assigned duties; and

(2) Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.

To conform with the rule's requirements and assure the safety of animal food products, "qualified individuals" need to carry out their assigned duties in a manner consistent with the principles of animal food hygiene and animal food safety as appropriate to the animal food and the facility.

Example Content for Personnel Requirements

Animal foods, including raw materials and ingredients, potentially may become contaminated and contain hazards that can affect animal or human health. Personnel who are involved in manufacturing and handling animal food need to follow good practices to protect against contamination.

Some examples of contamination and hazards that can relate to personnel practices include:

- Undesirable microorganisms, including pathogens such as *Salmonella* spp. and *Listeria monocytogenes*.
- Foreign materials, such as metal, plastic or glass.
- Substances not approved for use in animal food, such as pesticides, fertilizers and

lubricants.

- Nutrient deficiencies or toxicities, such as excessive copper in sheep feed or excessive salt in poultry feed.
- Unsafe drug carryover during the manufacture of medicated feeds.

To protect against unsafe contamination of animal food, personnel are to follow appropriate practices to:

- 1. Maintain adequate personal cleanliness.** Appropriate clothing is to be worn at all times when working in the animal food facility. This includes wearing clean and properly fitted shirts, pants and close-toed and secured shoes.
- 2. Wash hands thoroughly in an adequate hand-washing facility as necessary and appropriate to protect against contamination.** Hands are to be washed or sanitized as appropriate:
 - Before beginning work activities.
 - After using the toilet.
 - After eating or smoking.
 - After becoming contaminated with process-related chemicals or other substances not approved for use in animal food.
 - Before touching animal food, animal food contact surfaces, or animal food packaging material when the animal food is a potential source of undesirable microorganisms. Protecting against the potential for undesirable microorganisms is particularly relevant when the animal food is intended to be stored and/or used within the customer's home, such as pet food products.

To adequately wash hands:

- Wet hands and exposed areas of the arms with clean, warm, running water and apply soap.
 - Rub hands/arms for at least 20 seconds.
 - Rinse hands/arms well under clean, running water.
 - Dry hands using a clean towel or by air drying them.
- 3. Remove or secure jewelry and other objects that might fall into animal food, equipment or containers.** Personnel are not to wear jewelry unless it is secured and unable to create a hazard. Other objects, including tools, knives, cell phones, radios, pens and personnel protective equipment, are to be secured so as to not create a hazard by falling into animal food, equipment or containers.

4. **Store clothing or other personal belongings in areas other than where animal food is exposed or where equipment or utensils (e.g., scoops, shovels, buckets, brooms and other tools used in the facility) are cleaned.** Individuals are to store clothing (e.g., coats, boots, gloves, hats, etc.) and other personal belongings (e.g., car keys, lunch boxes, etc.) in areas where they cannot fall into or accidentally end up in animal food, equipment or utensils.
5. **Take other necessary precautions to protect against the contamination of animal food, animal food-contact surfaces or animal food-packaging materials.** The health of individuals involved with manufacturing and handling animal food may be a potential source of contamination. To protect against contamination, individuals with contagious disorders, illnesses, visibly infected skin and open sores are not to be engaged in activities associated with animal food, animal food-contact surfaces or animal food-packaging materials.

At animal food facilities involved in manufacturing and distributing animal food that is intended to be stored and used in the customer's home – such as pet food – where protecting against the potential for undesirable microorganisms is particularly relevant:

- Individuals are to wear hair and beard nets and/or other specifically designated clothing as necessary and appropriate.
 - Movement of individuals, raw materials and ingredients is to be restricted as necessary to protect against contamination of finished animal food products, animal food-contact surfaces and animal food-packaging materials.
6. **Protect against nutrient deficiencies or toxicities or unsafe drug carryover in animal food.** The animal food distributed by the plant may be the sole source of food consumed by an animal over several days or weeks. Therefore, it is essential that the food contain the appropriate amount of nutrients and be manufactured and stored in an effective manner to protect against unsafe contamination.

Example Content for Plant Grounds

The condition of the grounds around the plant has the potential to contribute to contamination of animal food. The grounds are close enough to be “around” the plant when they could affect plant operations.

To assure the plant grounds are properly maintained in a way that will not contribute to contamination of animal food:

1. **Equipment is to be properly stored.** When equipment is stored outside, it is to be kept away from building foundations and above ground, if possible, to allow proper ground maintenance.

- 2. Litter and waste are to be removed regularly and properly disposed.** The plant and its premises are to be free of accumulations of spilled animal food and other waste. Individuals are to complete duties to clean-up areas as assigned. Conditions that can attract insects, rodents, microbial contaminants and birds are to be minimized and/or eliminated.
- 3. Grass and vegetation within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests is to be regularly mowed and maintained.** Individuals are to complete duties to mow and maintain grass and vegetation on the plant grounds as assigned.

Example Content for Plant Sanitation

Keeping buildings, structures, fixtures and other physical facilities of the plant clean and in good repair helps prevent animal food from becoming adulterated.

Individuals working within the plant are to ensure that animal food-contact and non-contact surfaces of utensils (e.g., scoops, shovels, buckets, brooms and other tools) and equipment are properly cleaned, maintained and stored as necessary to protect against the contamination of animal food.

Individuals are to perform cleaning, housekeeping and, when necessary, sanitizing duties as assigned. Regarding maintenance, utensils and equipment should be maintained so that parts or pieces do not break or fall off and contaminate animal food.

Example Content for Pest Control

Pests (e.g., rodents, birds, insects, etc.) can contribute to contamination of animal food and can serve as a vector for undesirable microorganisms that may affect animal and human health. An effective pest-control program is necessary to exclude pests from the manufacturing, processing, packing and holding areas and to protect against the contamination of animal food by pests.

To assist in the effective control of pests, individuals are to:

1. Evaluate incoming ingredients, raw materials and other animal foods for the presence of pests.
2. Report to facility management signs of pest activity that may be noticed in the plant and around the grounds. Signs of pests may include dead bugs and/or rodents, pest droppings, bird nestings and odd smells or sounds.
3. Minimize the potential entry of pests into the plant by ensuring window screens are in place and in good repair, keeping exterior doors and windows closed and secured to the

extent possible, and making management aware of excessive openings, cracks, or damaged seals in exterior doors, windows or walls.

Example Content for Toxic Materials

Toxic materials not approved for use in animal food may be stored at animal food facilities and can pose a risk to contaminate animal food. Examples of such materials are fertilizers, pesticides, cleaning compounds, sanitizing agents and industrial lubricants.

To protect against contamination of animal food by toxic materials:

1. The only toxic materials that may be used or stored in the plant area where animal food is manufactured, processed or exposed are those necessary for:
 - Maintaining clean and sanitary conditions.
 - Use in laboratory testing procedures.
 - Plant and equipment maintenance and operation.

Materials necessary for such purposes are to be identified, used and stored in a manner that protects against the contamination of animal food, animal food-contact surfaces or animal food-packaging materials.

2. Other toxic materials not necessary for cleaning, sanitizing or plant or equipment maintenance or operations are to be stored in an area of the plant where animal food is not manufactured, processed or exposed. These toxic materials are to be separated from animal food in the plant by either sufficient space or a sufficient physical barrier so they are not able to contaminate the animal food.
3. Food-grade lubricants and chemicals are to be used during the maintenance and operation of equipment when it can be expected that the lubricant or chemical will come into contact with animal food or an animal food-contact surface.

Example Content for Plant Operations

The consistent use of effective procedures and practices designed to ensure the safety of animal food within plant operations is critical to the success of the plant's animal food safety system.

The following are some key procedures and practices that individuals are to follow as appropriate to their assigned duties to ensure animal food safety.

1. Animal food, including raw materials, other ingredients or rework, is to be accurately identified at all times.

2. Raw materials and other ingredients are to be examined upon receipt and prior to use to ensure they are suitable for manufacturing and processing into animal food.
3. Shipping containers (e.g., totes, drums and tubs) and bulk vehicles used to store raw materials and other ingredients are to be examined upon receipt to determine whether contamination or deterioration of animal food may have occurred.
4. Shipping containers (e.g., totes, drums and tubs) and bulk vehicles used to distribute animal food are to be examined prior to use to protect against the contamination of animal food from the container or vehicle.
5. Animal food returned from distribution is to be assessed for animal food safety to determine the appropriate disposition. Returned animal food is to be identified as such and segregated until assessed.

Example Qualified Individual Training Record

Plant Name and Location: _____

Date and Time of Training: _____

Name of Trainer: _____

Name and Signature of Supervisor:

<u>Name</u>	<u>Signature</u>

Description of Training Content:

Names and Signatures of Individuals Receiving Training:

<u>Name</u>	<u>Signature</u>