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Controlling Mycotoxin Risk in Animal Food

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Disclaimer

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Foreword

This document, developed by the National Grain and Feed Association (NGFA), provides information to assist the grain, oilseed, feed and processing industry in understanding compliance obligations related to the U.S. Food and Drug Administration's (FDA) animal food regulatory guidance and requirements associated with mycotoxins.

As defined by FDA, the term "animal food" means articles used for food or drink for animals and articles used for components of any such article. Thus, animal food includes both livestock feed and pet (companion) animal food, and raw materials and ingredients that are intended for use in animal food. This document summarizes FDA mycotoxin regulatory guidance, provides information to consider when addressing the risk of mycotoxins within written animal food safety plans required by FDA, and discusses other mycotoxin-related practices. The topics discussed and information contained in this document are not intended to be formal recommendations or advice.

We hope you find this document useful. The NGFA encourages member companies to contact the Association with any additional questions. NGFA members may send inquiries via email to ngfa@ngfa.org.

Background

Mycotoxins are toxic chemical compounds that are naturally produced by certain types of molds that can grow on agricultural commodities in the field and during storage. The occurrence of these toxins on commodities is influenced by various environmental factors, such as temperature, humidity, and rainfall during growing, harvesting, and storage. Most mycotoxins are chemically stable and are not destroyed by processes typically used in human or animal food production. When consumed by animals or humans at elevated levels, the results can be detrimental, resulting in illness or even death. Human exposure to mycotoxins also can occur indirectly from food derived from animals that have been fed mycotoxin-contaminated animal food. For example, humans may be exposed to aflatoxin by consuming milk, meat, or eggs derived from animals that have consumed aflatoxin-contaminated animal food.

There are different types of mycotoxins, and the severity of illnesses they may cause in animals varies depending upon the mycotoxin, the concentration, and the animal consuming the animal food. Table 1 lists common mycotoxins of concern and the types of raw agricultural commodities in which they are most frequently found based upon information from the Council for Agricultural Science and Technology (CAST) and the U.S. Food and Drug Administration.

Table 1: Common Mycotoxins and Susceptible Raw Agricultural Commodities*	
Type of Mycotoxin	**Susceptible Raw Agricultural Commodities**
Aflatoxin	Higher susceptibility: peanuts, corn, sorghum, cottonseed, brazil nuts, almonds Lower susceptibility: soybeans, pulses, millet, wheat, oats, barley, rice
Deoxynivalenol	Corn, wheat, barley, oats
Fumonisin	Higher susceptibility: corn, rice Lower susceptibility: wheat, sorghum, barley, oats
Ochratoxin A	Wheat, barley, rice, oats, corn, dry beans
T-2	Corn, barley, wheat, oats
Zearalenone	Higher susceptibility: corn, wheat Lower susceptibility: barley, sorghum, rye
*This table lists common mycotoxins and the types of raw agricultural commodities in which they are most frequently found based upon information from CAST and FDA. The table does **not** provide a comprehensive listing of mycotoxins or a comprehensive listing of raw agricultural commodities that are susceptible to mycotoxins.	

Mycotoxins also may be found in processed by-products derived from raw agricultural commodities that are susceptible to mycotoxins. Examples of grain by-products that may contain mycotoxins include distillers grains, brewers grains, other feeds and meals derived from corn, peanut meal, cottonseed meal, and wheat middlings. Depending upon the activity performed, processing grains may increase or reduce the concentration of mycotoxins in the resulting grain by-product.

FDA Regulatory Guidance for Mycotoxins

FDA has issued action and guidance levels for three mycotoxins that may be present in raw grains, ingredients, animal food and human food: aflatoxin, deoxynivalenol (also known as vomitoxin), and fumonisin.

Under the regulatory framework adopted by FDA for mycotoxins, the agency issues policy guidance or enforcement pronouncements in one of two forms:

- **Advisory (Guidance) Levels:** FDA uses "advisory levels" to provide guidance to the industry concerning levels of a substance present in human or animal food that are believed by the agency to provide an adequate margin of safety to protect human and animal health.

  While FDA reserves the right to take regulatory enforcement action – including seizure of the product – on a case-by-case basis (particularly in egregious situations), enforcement is not the fundamental purpose of an advisory level.

FDA has used advisory levels to provide guidance to the industry on deoxynivalenol and fumonisin.

- **Action Levels:** FDA uses "action levels" when it wishes to specify a precise level of contamination at which the agency is prepared to take regulatory action.

  Action levels are guidelines to the industry for which FDA believes it has the scientific data to support regulatory and/or court action if a toxin or contaminant is present at levels exceeding the action level if the agency chooses to do so.

  Importantly, FDA's regulatory policy provides flexibility to its field offices on whether and when to take enforcement action. For instance, there may be situations where FDA decides circumstances warrant enforcement action at levels below an action level or where enforcement action is not warranted even though an action level is exceeded. To take regulatory action in a given situation, FDA must: 1) confirm the intended use of the human and/or animal food; and 2) show that the level of toxin in the human and/or animal food will support a charge of adulteration under the federal Food, Drug, and Cosmetic Act.

  FDA has used action levels to convey its regulatory policy to the industry on aflatoxin.

Significantly, FDA advisory and action levels are established based on the unavoidability of the toxin or contaminant in human or animal food, and do not represent a permissible level of contamination where it is avoidable.

FDA's authority to take regulatory action related to the presence of mycotoxins in human or animal food is limited to those products that are distributed in interstate commerce. However, it is well established through court decisions that raw grains, grain by-products and other ingredients intended for use as human or animal food are assumed to be fungible and subject to interstate commerce provisions unless they are clearly segregated and distributed to known uses within the same origin state where they were produced. In addition, state departments of agriculture typically apply FDA's action and advisory levels as the basis for regulatory actions they may take regarding products found in intrastate commerce.

FDA Action Levels for Aflatoxin

FDA's current action levels for aflatoxin present in human food, animal food ingredients and finished animal food are indicated in Table 2. The action level represents the level of total aflatoxins (B1+B2+G1+G2) in the human food, animal food or animal food ingredient.

Table 2: FDA Action Levels for Aflatoxin in Human Food, Animal Food and Animal Food Ingredients[1]		
Intended Use	**Human Food, Animal Food and Animal Food Ingredient**	**Action Levels (B1+B2+G1+G2) [parts per billion (ppb)]**
Human consumption	Milk	0.5 ppb (aflatoxin M1)
Human consumption	Foods, peanuts and peanut products, brazil and pistachio nuts	20 ppb
Immature animals[2]	Corn, peanut products, and other animal foods and ingredients, but excluding cottonseed meal	20 ppb
Pets (dogs, cats, rabbits, etc.) of all ages	Corn, peanut products, cottonseed meal, and other animal food ingredients and complete pet food	20 ppb
Dairy animals, and other animal species (including wildlife), or other uses not specified in this table; or, when the intended use is not known	Corn, peanut products, cottonseed meal, and other animal food and animal food ingredients	20 ppb
Breeding beef cattle, breeding swine or mature poultry	Corn and peanut products[3]	100 ppb
Finishing swine of 100 pounds or greater in weight	Corn and peanut products[3]	200 ppb
Finishing (i.e., feedlot) beef cattle	Corn and peanut products[3]	300 ppb
Beef cattle, swine, or poultry (regardless of age or breeding status)	Cottonseed meal	300 ppb

[1] Table 2 summarizes information from FDA's **Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, August 2000** and **Compliance Policy Guide Sec. 683.100 Action Levels for Aflatoxins in Animal Food, March 2019**.

[2] For example, chickens and ducks less than 8 weeks of age; turkeys less than 12 weeks of age; goats, sheep, and pigs less than 4 months of age; cattle and equine less than 6 months of age.

[3] Corn products include distillers grains, corn gluten feeds and corn gluten meals, as well as other corn-based animal food ingredients. Peanut products include peanuts, peanut meal, peanut hulls, peanut skins, and ground peanut hay.

FDA Advisory Levels for Deoxynivalenol

Table 3 lists FDA's current deoxynivalenol advisory levels for finished wheat products, grain and grain by-products. The second figure within the parentheses in the right-hand column of the table (if listed) is the advisory level specified for the animal species' total ration.

Table 3: FDA Advisory Levels for Deoxynivalenol in Human Food, Animal Food and Animal Food Ingredients[1]

Intended Use	Grain or Grain By-Products	Advisory Levels in Grains or Grain By-Products and (Total Ration[2]) [parts per million (ppm)]
Human Consumption	Finished wheat products	1 ppm
Swine	Grain and grain by-products not to exceed 20% of the diet	5 ppm
Chickens	Grain and grain by-products not to exceed 50% of the diet	10 ppm
Ruminating beef and feedlot cattle older than 4 months, and ruminating dairy cattle older than 4 months	Grain and grain by-products[3]	10 ppm (10 ppm beef/feedlot) (5 ppm dairy)
Ruminating beef and feedlot cattle older than 4 months, and ruminating dairy cattle older than 4 months	Distillers grains, brewers grains, gluten feeds and gluten meals derived from grains[3]	30 ppm (10 ppm beef/feedlot) (5 ppm dairy)
All other animals	Grain and grain by-products not to exceed 40% of the diet	5 ppm

[1] Table 3 summarizes information from FDA's **Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol (DON) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed, July 2010**.

[2] The total ration includes grains, all grain by-products including distillers and brewers grains, hay, silage, and roughage.

[3] 88% dry matter basis.

FDA Guidance to Industry on Fumonisin

For animal food, FDA-recommended maximum levels for total fumonisins (FB1+FB2+FB3) in corn and corn by-products are shown in Table 4.

Table 4: FDA Guidance Levels for Fumonisin in Animal Food[1]	
Corn and corn by-products intended for:	**Total Fumonisins (FB1+FB2+FB3) [parts per million (ppm)]**
Equids (i.e., horses) and rabbits	5 ppm (no more than 20% of diet[2])
Swine and catfish	20 ppm (no more than 50% of diet[2])
Breeding ruminants, breeding poultry and breeding mink[3]	30 ppm (no more than 50% of diet[2])
Ruminants 3 months of age or older being raised for slaughter and mink being raised for pelt production	60 ppm (no more than 50% of diet[2])
Poultry being raised for slaughter	100 ppm (no more than 50% of diet[2])
All other species or classes of livestock and pet animals	10 ppm (no more than 50% of diet[2])
[1] Table 4 summarizes information from FDA's **Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds, November 2001**. [2] Dry weight basis. [3] Includes lactating dairy cattle and hens laying eggs for human consumption.	

From an historic standpoint, FDA and state officials also have taken regulatory action in response to excessive levels of other mycotoxins in animal food for which regulatory guidance has not been established. For example, a recall was initiated in 2020 due to elevated levels of zearalenone in cat food. In addition, FDA officials have publicly stated that zearalenone levels of 250 ppb or more are a safety issue in swine feed.

FDA Policy on Labeling of Animal Food Ingredients that Contain Mycotoxins

When animal food ingredients (e.g., grain, grain by-products, peanut products, cottonseed meal, distillers grains, etc.) are placed into commerce and contain aflatoxin, deoxynivalenol or fumonisin in concentrations greater than the lowest FDA-specified action or advisory level (i.e., 20 ppb for aflatoxin, 5 ppm for deoxynivalenol and 5 ppm for fumonisin), it is FDA's policy that the level of the mycotoxin be stated on the ingredient's label and/or bill-of-lading and that directions be provided to ensure the ingredient's safe use.

For example, if a shipment of corn is placed into commerce that has a 150 ppb concentration of aflatoxin, FDA would expect the label or bill-of-lading accompanying the shipment state the corn contains 150 ppb aflatoxin and the intended use of the corn should be either finishing swine of 100 pounds or greater in weight or finishing (i.e., feedlot) beef cattle (since the aflatoxin action levels for these species/classes of animals are 200 ppb and 300 ppb, respectively).

As another example, if a shipment of corn is placed into commerce that has a fumonisin level of 50 ppm, FDA would expect the label or bill-of-lading accompanying the shipment to state the corn contains 50 ppm fumonisin and the intended use of the corn should be ruminants that are 3 months or more of age being raised for slaughter or mink being raised for pelt production (fumonisin advisory level of 60 ppm), or poultry being raised for slaughter (fumonisin advisory level of 100 ppm). In addition, FDA would expect the label or bill-of-lading to state the corn should not exceed 50 percent of the animal's diet on a dry matter basis.

Addressing Mycotoxins within FDA Animal Food Safety Plans

FDA's rule for Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (21 CFR 507) requires most animal food facilities to establish and implement a written food safety plan that includes a documented analysis of known or reasonably foreseeable hazards and, as necessary, implementation of risk-based preventive controls. At animal food facilities that utilize materials susceptible to mycotoxins, certain mycotoxins are known or reasonably foreseeable hazards that need to be addressed within the food safety plan. This means the facility is to evaluate the severity and probability of relevant mycotoxins in ingredients and finished products and apply appropriate controls to adequately mitigate risk.

In addition to evaluating the severity and probability of known or reasonably foreseeable mycotoxin hazards, specific provisions with FDA's final rule require that raw materials and other ingredients used in animal food:

- Susceptible to contamination with mycotoxins or other natural toxins be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans (21 CFR 507.25(b)(2)).

- Be maintained under conditions, e.g., appropriate temperature and relative humidity, that will minimize the potential for growth of undesirable microorganisms (e.g., molds that may produce mycotoxins) and prevent the animal food from becoming adulterated during manufacturing, processing, packing, and holding (21 CFR 507.33(c)(1)).

Generally, FDA's rule provides flexibility so that a facility may choose to mitigate the risk of mycotoxins either through the use of a prerequisite program (that minimizes probability of occurrence) or a preventive control (that requires specified management controls).

A prerequisite program may generally be defined as a procedure or set of procedures that is designed to provide operating conditions necessary for the production of safe food. Examples of prerequisite programs include good manufacturing practices and standard operating procedures (SOPs), training and other controls for certain hazards (e.g., sanitation and pest programs). In contrast, a preventive control is a written procedure or steps that a facility takes to significantly minimize or prevent a particular hazard from occurring in an animal food. The written procedures associated with a preventive control are to include components to manage the control, such as monitoring, corrections or corrective actions, verification, and records, that provide documentation the hazard is significantly minimized or prevented.

Evaluation of Mycotoxin Risk

As previously noted, at animal food facilities that utilize grains and ingredients susceptible to mycotoxins, certain mycotoxins such as aflatoxins, deoxynivalenol and fumonisins are known or reasonably foreseeable hazards that need to be addressed within required food safety plans. FDA's regulations specify a written hazard analysis be performed to: 1) identify known and reasonably foreseeable hazards; and 2) evaluate whether any known or reasonably foreseeable hazards require a preventive control. During the hazard evaluation, each known or reasonably foreseeable hazard is to be assessed in regard to: 1) severity of the illness or injury to humans or animals if the hazard were to occur; and 2) the probability of occurrence of the hazard in the absence of a preventive control.

The following suggestions are intended to support the written hazard analysis of mycotoxins within animal food safety plans.

1. Identify and list within the hazard analysis all ingredients used at the facility that are susceptible to mycotoxin contamination.

2. For ingredients identified, list each <u>specific</u> mycotoxin that is known to be or is reasonably foreseen to be associated with the material. During this evaluation, consideration at a minimum should be given to those mycotoxins for which FDA has issued regulatory guidance – aflatoxins, deoxynivalenol and fumonisins. In addition, it may be appropriate to consider and list other mycotoxins that are associated with the ingredient for which FDA has not issued regulatory guidance.

   FDA's regulations allow facilities to group ingredients during the hazard analysis process if the hazards and controls are essentially the same for all materials within the group. However, it may be advantageous to list materials separately because the probability of occurrence and severity of a specific mycotoxin may be different for various materials and intended uses.

3. List storage of ingredients susceptible to mycotoxins as a process step within the hazard analysis where mycotoxins potentially could be introduced into such ingredients.

   Mycotoxins are produced by molds that typically are classified into two categories: field and storage molds. Field molds grow in grains before harvest and typically require high relative humidity above 70% and grain moisture above 22% for growth. Field molds include the *Fusarium* species, which produce deoxynivalenol, zearalenone, and fumonisin. Storage molds can grow in grains after harvest and during storage of grains and grain-by products. These molds typically do not require high humidity and may grow with relatively low moisture. Storage molds include *Aspergillus* and *Penicillium* species, which produce aflatoxin and ochratoxin. Under certain conditions, storage molds may grow in grains prior to harvest and field molds may grow in products during storage. For example, *Aspergillus* flavus, a mold that produces aflatoxin, often grows in grains prior to harvest. If the storage conditions of susceptible ingredients are conducive to growth of molds within the *Fusarium, Aspergillus,* and *Penicillium* species, mycotoxin formation may occur.

4. Assess the probability of each known or reasonably foreseeable mycotoxin occurring at an excessive level in finished products in the absence of a preventive control by considering:

   a. Temporal (weather-related) conditions under which grains were grown. Mycotoxins are a result of specific growing conditions that encourage mold growth in different grains. For example, *fusarium* molds that produce zearalenone and deoxynivalenol are more likely to occur during cool, wet conditions, while *aspergillus* molds that produce aflatoxin are more likely to occur in hot environments. Evaluating the growing conditions for grain used as an ingredient, if possible, can assist in assessing the likelihood that mycotoxins may be present. Because temporal conditions directly influence the potential for mycotoxin formation, it is advisable to consider these conditions on an annual-growing season basis.

   b. Frequency of association of the mycotoxin with the animal food or facility. Reviewing the history of mycotoxin occurrence within the facility and the animal food industry can help inform the assessment of probability of future occurrence. FDA's Animal Food Recall and Reportable Food Registry reports can provide information on past occurrences of mycotoxins that have resulted in animal food safety incidents.

   c. The inclusion rate of the susceptible ingredient into finished products. A lower inclusion rate of the material generally reduces the likelihood that relevant mycotoxins will adversely affect finished products. However, as previously noted, FDA's regulatory guidance sets action and advisory levels for the presence of certain mycotoxins in ingredients, and in some cases the inclusion rate of the ingredients

into the total ration/diet. It is against FDA policy to utilize ingredients that have higher concentrations of mycotoxins than specified in the FDA action/advisory levels regardless of the inclusion rate of the material into finished product.

d. Processing or manufacturing parameters associated with the facility. As previously mentioned, processing may increase or reduce the concentration of mycotoxins in the resulting product.

e. Effectiveness of facility programs, such as current good manufacturing practices (CGMPs) or other prerequisite programs. FDA's Hazard Analysis and Risk-Based Preventive Controls for Food for Animals - #245 Guidance for Industry states that facilities may consider the implementation of prerequisite programs when evaluating the probability that a hazard will occur in the absence of a preventive control. Proper implementation of an adequate prerequisite program may decrease the probability the hazard will occur. This probability may decrease to such a level that a facility determines the hazard does not require a preventive control. If facilities rely on a prerequisite program when evaluating the probability of occurrence of a hazard, FDA expects adequate information about the prerequisite program to be included in the facility's hazard analysis as part of the evaluation. Adequate information in the hazard analysis could include a copy or sufficient description of SOPs for the prerequisite program to document the procedures being followed at the facility to reduce the probability a hazard will occur in the absence of a preventive control.

f. Expected storage conditions during holding at the facility. Facilities should evaluate conditions associated with the storage of ingredients susceptible to mycotoxins to assess whether the conditions are conducive to mold growth that may produce mycotoxins.

   To help minimize the potential for mycotoxin formation during storage, it is advisable to establish a schedule to routinely empty and clean storage bins of grains and other ingredients. Some factors to consider when determining an appropriate frequency for emptying and cleaning storage bins include bin design and integrity, material throughput, storage time, moisture (inherent or from rewetting from rain or condensation) and/or water activity of material stored, known history of storage "hangs" or "plugs," and presence of mold or mycotoxin in the material before storage.

5. Assess the severity that each known or reasonably foreseeable mycotoxin would pose if present in the finished animal food distributed by the facility. When doing so, consider:

   a. Intended use of the animal food. As previously indicated, the severity of illnesses that mycotoxins may cause in animals varies depending upon the mycotoxin concentration and the species, life stage and size of animal consuming the animal

food. As examples, finishing beef cattle have a significantly higher tolerance for aflatoxins than pets; swine are sensitive to deoxynivalenol; and equines have a low tolerance to fumonisins.

b. Susceptibility of humans to illness or injury from consuming products derived from animals that had consumed mycotoxin-contaminated food. For example, aflatoxin – a potent carcinogen– can be transmitted to humans from animal food through milk, meat, and eggs.

c. Potential magnitude and duration of the illness or injury (e.g., how long an animal may be sick, whether the illness requires veterinary care and hospitalization, and production loss such as a decline in milk or egg production).

In general, the severity associated with mycotoxins for which FDA has issued regulatory guidance is typically characterized as high, since aflatoxin, deoxynivalenol, and fumonisin have been known to cause serious adverse health consequences at levels above FDA regulatory guidance. Facilities should consult animal health experts and scientific literature as needed when characterizing the severity of a mycotoxin hazard for their product's specific intended use.

6. Determine based upon the assessment of severity and probability whether the mycotoxin is a hazard requiring a preventive control. It is more likely to determine that a known or reasonably foreseeable hazard requires a preventive control when the hazard has been characterized as having a high severity and high probability of occurrence in the absence of a preventive control. As previously noted, the severity associated with mycotoxins for which FDA has issued regulatory guidance is typically characterized as high. Therefore, the determination of whether the mycotoxin requires a preventive control likely will be based upon the probability the mycotoxin will occur at an excessive level in finished products in the absence of a preventive control.

   A facility's determination as to whether a known or reasonably foreseeable hazard does or does not require a preventive control is to be justified. This justification is particularly significant when a determination is made that the hazard does not require a preventive control. When a hazard is determined to require a preventive control, the justification is not as critical because management components with the food safety plan will address how the hazard is controlled. If a facility relies on a prerequisite program to reduce the probability of a hazard as justification for why the hazard does not require a preventive control, then adequate information about the prerequisite program must be included in the facility's hazard analysis to support the determination. In addition, it may be helpful to include a brief explanation as to why the prerequisite program is not a preventive control. This information included about the prerequisite program is considered part of the written hazard analysis, and, therefore, subject to FDA review.

If a facility has experienced a mycotoxin-related animal food recall or reportable food registry event, FDA's typical compliance expectation is that the facility will characterize the associated mycotoxin as a hazard requiring a preventive control. In addition, if during an inspection, FDA observes that a facility is not in conformance with mycotoxin-related requirements or is utilizing ingredients in a manner not consistent with its regulatory guidance, FDA may allege control of the mycotoxin is inadequate and that a preventive control(s) should be implemented.

Use of a Prerequisite Program to Control Mycotoxin Risk

If a facility during its hazard analysis determines the risk of mycotoxins is being adequately controlled using a prerequisite program, the program should be effectively implemented and demonstrate mitigation of the mycotoxin hazard. FDA expects adequate information about the prerequisite program to be included in the facility's hazard analysis, which could include a copy or sufficient description of SOPs for the prerequisite program.

Following are suggestions for the design and implementation of a prerequisite program for mycotoxin control:

1. **Acceptance Limits:** Determine and document the specific mycotoxin levels that are acceptable in each ingredient that will be used at the facility based on finished animal food produced. At a minimum, specifications set for mycotoxin levels need to conform with FDA regulatory guidance. To provide greater assurances for finished animal food safety, facilities may wish to establish specifications more stringent than FDA guidance. Ingredients received at the facility that do not meet the acceptance limits should be rejected, discarded, or repurposed accordingly.

2. **Sampling Procedures:** Establish and implement written sampling procedures for ingredients that are susceptible to mycotoxins. The procedures should specify how samples are to be taken, the number of samples, how a composite sample is to be derived, and how samples are identified, including their relationship to specific lots of product.

   Obtaining a representative sample is essential to accurately detect mycotoxins during testing. Mycotoxins are not evenly distributed in materials, so a representative sample is needed for accurate test results. Information resources that may be considered when establishing sampling procedures include the United States Department of Agriculture (USDA) Grain Inspection Handbook, Book 1, Sampling and the Association of American Feed Control Officials Feed Inspector's Manual, Eighth Edition, Chapter 3, Sampling.

   If rapid test methods for mycotoxins are utilized at the facility, sampling and sample preparation procedures for ingredients to be tested should conform with instructions provided by the rapid test kit manufacturer.

3. **Testing Frequency:** Determine and document an appropriate mycotoxin testing frequency for the specific mycotoxin in susceptible ingredients. When doing so, it may be appropriate to test more frequently at the onset of a new crop year to assist in determining the prevalence of mycotoxins. Based upon initial test results, the frequency of testing may be adjusted. In addition, consider testing new suppliers more frequently until a reliable supplier history has been established. At facilities receiving high volumes of grains, it may be appropriate to perform composite testing (combining samples from multiple loads for testing).

   Resampling and retesting of a load in response to a result that does not meet acceptance limits should not be performed since mycotoxins are not normally distributed evenly throughout ingredients.

   It may be appropriate to consider requesting certificates of analysis (COAs) for mycotoxin content from suppliers of materials susceptible to mycotoxins. Obtaining COAs may be particularly relevant for new suppliers and products purchased at the beginning of a new crop year. If COAs are requested, facilities should understand the methods used to determine the analysis result. If COA results do not conform with acceptable levels set by the facility, the lot of product in question should be rejected.

4. **Testing Methods:** Test samples using scientifically valid methods. It is advantageous to use rapid test methods that can be performed at the facility before material is accepted. Rapid test methods typically provide results in a timely manner that allows loads to be rejected if needed. Although not required for use, USDA's Federal Grain Inspection Service administers a program to provide laboratory performance validation for rapid test kits for mycotoxins in grain and other commodities.

   FDA has established official methods for analyzing mycotoxins in laboratories. These methods are found in Chapter 7 of FDA's Compliance Program Guidance Manual on Mycotoxins in Domestic and Imported Foods (CPG 7307.001).

   Results from testing (including COAs) should be documented and retained for an appropriate length of time. Factors influencing an adequate retention time for records include anticipated storage time for the material prior to use in animal food and anticipated time the finished animal food containing the material could be in distribution prior to consumption.

5. **Corrective Actions:** Establish written corrective action procedures to follow in the event mycotoxin test results are unacceptable. Ideally, tests results should be available and evaluated prior to unloading bulk ingredients into storage bins and unacceptable loads rejected. If a load is rejected, consider testing subsequent loads from the same supplier on a more frequent basis until confidence is gained that mycotoxin levels in the product are acceptable. In addition, it may be appropriate to request and receive additional assurances (e.g., COAs, etc.) from such a supplier that future products will conform to

specifications. Records should be established and maintained to document rejection of loads due to excessive mycotoxin content.

If unloading of the material occurs prior to having test results and results indicate the material has an unacceptable mycotoxin level, facilities should have an appropriate plan to direct the material to an acceptable use or disposal. If animal food has been produced from material with an unacceptable result, facilities should have procedures to ensure that the animal food is safe, directed to an appropriate intended use or disposed. For example, a facility could implement a "test and hold" program for final product shipments with documented release criteria to direct product to appropriate use based on results. If product made from material with an unacceptable result is no longer in the facility's control, the facility will need to evaluate if a product recall needs to be conducted.

6. **In-Process Testing and Finished Product Testing:** At some facilities, periodic in-process testing may be appropriate to ensure that mycotoxin levels in materials are acceptable or that materials are directed in-process to an acceptable use. In addition, periodic finished product testing may be used to confirm the facility's inbound (and when applicable, in-process) testing program is effectively mitigating the mycotoxin hazard. However, facilities should not rely solely on in-process or finished product testing in place of testing inbound ingredients. FDA's final rule requires that raw materials and other ingredients used in animal food susceptible to contamination with mycotoxins or other natural toxins be evaluated and used in a manner that does not result in animal food that can cause injury or illness to animals or humans.

   If finished product testing is performed, the facility should consider whether to place the lot of finished animal food tested on hold until results are received that indicate an acceptable mycotoxin level. The release of the lot for shipment outside of company control before results are obtained increases the risk of business and regulatory consequences.

7. **Training:** Train individuals responsible for performing duties associated with the mycotoxin control prerequisite program. FDA's rule requires individuals that manufacture, process, pack or hold food be trained so they are qualified to perform assigned duties. Individuals responsible for performing duties related to the control of mycotoxins are to receive documented training on how to effectively perform assigned tasks. FDA's rule requires such training records be retained for at least two years.

Use of a Preventive Control to Control Mycotoxin Risk

A preventive control is implemented within a facility's food safety plan to control a specific mycotoxin risk when its hazard analysis determines a preventive control is needed to significantly minimize or prevent the specific mycotoxin from occurring at unacceptable levels in finished products.

As previously noted, the severity associated with mycotoxins for which FDA has issued regulatory guidance is typically characterized as high. Therefore, the determination of whether a specific mycotoxin requires a preventive control likely will be based upon the probability that the mycotoxin will occur in finished products at an unacceptable level or at a level above FDA regulatory guidance in the absence of a preventive control. In addition, if a facility has experienced a mycotoxin-related animal food recall or reportable food registry event, FDA's typical compliance expectation is that the facility will characterize the associated mycotoxin as a hazard requiring a preventive control.

FDA's regulations require implementation of a preventive control to include components to manage the control, as appropriate to the nature of the preventive control and its role in the food safety plan, such as monitoring, corrections or corrective actions, verification, and records. The regulations also require a preventive control and its management components to be written, and that specific records be established and retained for activities associated with monitoring, corrections or corrective actions, and verification. In general, records associated with a preventive control are to be retained for at least two years, with certain records being required to be retained longer.

Following are suggestions for the design and implementation of a preventive control within a food safety plan for control of mycotoxins, some of which are similar to those previously described for a prerequisite program:

1. **Acceptance Limits:** Determine and document the specific mycotoxin levels that are acceptable in each susceptible ingredient that will be used at the facility based upon the animal food produced. At a minimum, specifications set for mycotoxin levels need to conform with FDA regulatory guidance. To provide greater assurances for finished animal food safety, facilities may wish to establish specifications more stringent than FDA guidance. Material that does not meet the acceptable levels should be rejected, discarded, or repurposed appropriately.

   When utilizing a preventive control, the specification set for a specific mycotoxin level is referred to as a "parameter value" – the maximum value that must be controlled to significantly minimize or prevent a hazard requiring a process preventive control.

2. **Use of Supply-Chain-Applied Controls:** If the type of preventive control utilized is a "supply-chain-applied control" – a preventive control for a hazard in an ingredient when the hazard in the ingredient is controlled by the supplier before its receipt – FDA regulations require the receiving facility to: 1) use only approved suppliers for the ingredient; and 2) determine, conduct, and document appropriate supplier verification activities that provide assurance the hazard is being significantly minimized or prevented by the supplier.

Based on FDA's regulations, the use of supply-chain-applied controls to control mycotoxins may be challenging, as illustrated by the following information concerning two aspects of the requirements:

a. **Use of only approved suppliers.** Each supplier for the ingredient associated with the mycotoxin requiring a preventive control is to be approved by the receiving facility in accordance with FDA requirements prior to receiving the ingredient from the supplier. When doing so, consideration needs to be given to FDA's definition for "supplier" – 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. Based on this definition, the "supplier" for an ingredient may not be the entity from which a receiving facility receives the ingredient, particularly if the ingredient is handled and stored in a bulk, commingled manner through its supply chain. To utilize a "supply-chain-applied control" the facility must be able to identify the supplier and approve the supplier in accordance with FDA requirements.

b. **Determining, conducting, and documenting appropriate verification activities to gain assurance the supplier is significantly minimizing or preventing the mycotoxin.** FDA's regulations detail that one or more supplier verification activities (i.e., onsite audit, sampling and testing, review of food safety records, and other activities) be conducted for each supplier before using the ingredient susceptible to mycotoxin from that supplier and periodically thereafter. Further, FDA requirements establish when the hazard requiring a preventive control is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (i.e., a SAHCODHA hazard), the appropriate supplier verification activity is an onsite audit of the supplier, and that an audit is to be conducted before using the ingredient from the supplier and at least annually thereafter. Significantly, mycotoxins are characterized as a SAHCODHA hazard, and, therefore, FDA's compliance expectation is that when utilizing a supply-chain-applied control each supplier for an ingredient associated with the mycotoxin would be the subject of an onsite audit prior to approval of the supplier and at least annually thereafter. The audit is to conform with FDA requirements as specified in its regulations.

Facilities should fully understand the requirements associated with FDA's supply-chain program regulations before relying on a supply-chain-applied control to significantly minimize or prevent mycotoxins. Providing complete information about these requirements is outside the scope of this document. FDA has issued Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program - #246 Draft Guidance for Industry to explain requirements for establishing and implementing a

supply-chain program when facilities rely on suppliers to control hazards requiring a preventive control.

3. **Use of Process Preventive Controls**: If the type of preventive control utilized for the mycotoxin hazard is a "process control" – procedures, practices, and processes conducted within a facility's operations to ensure parameter values are being met (i.e., sampling and testing of ingredients) – FDA's regulations require written procedures be developed for such processes and the associated management controls. These procedures are to address:

    a. **Monitoring.** Facilities are to establish written procedures on what to monitor, how to monitor, frequency to monitor, and who will monitor.

        i. **What to monitor.** Parameter values set for specific mycotoxin levels in each ingredient are to be monitored to ensure results do not exceed acceptable levels.

        ii. **How to monitor.** Ingredients that are susceptible to the mycotoxin requiring a preventive control are to be sampled and tested in accordance with written procedures to determine mycotoxin content.

            Sampling procedures are to provide a representative sample of the lot. The procedures should specify how samples are to be taken, the number of samples, how a composite sample is to be derived, and how samples are identified, including their relationship to specific lots of product. Information resources to consider when establishing sampling procedures include the United States Department of Agriculture (USDA) Grain Inspection Handbook, Book 1, Sampling and the Association of American Feed Control Officials Feed Inspector's Manual, Eighth Edition, Chapter 3, Sampling.

            Testing procedures are to identify the test to be performed and how to perform the test, if conducted at the facility. If testing is performed externally, the laboratory conducting the testing should be identified within the procedures. All tests performed are to be scientifically valid.

            It is advantageous to use rapid test methods that can be performed at the facility before material is accepted. Rapid test methods typically provide results in a timely manner that allows loads to be rejected if needed. Although not required for use, USDA's Federal Grain Inspection Service administers a program to provide laboratory performance validation for rapid test kits for mycotoxins in grain and other commodities.

If rapid test methods for mycotoxins are utilized at the facility, sampling and sample preparation procedures for ingredients to be tested should conform with instructions provided by the rapid test kit manufacturer.

FDA has established official methods for analyzing mycotoxins in laboratories. These methods are found in Chapter 7 of FDA's Compliance Program Guidance Manual on Mycotoxins in Domestic and Imported Foods (CP 7307.001).

Requesting certificates of analysis (COAs) for mycotoxin content from suppliers of ingredients susceptible to mycotoxins may be appropriate. Obtaining COAs may be particularly relevant for new suppliers and grains purchased at the beginning of a new crop year. If COAs are requested, facilities should understand the methods used to determine the analysis result. If COA results do not conform with parameter values set by the facility, the lot of material in question should be rejected.

Facilities are to document all testing results associated with use of preventive controls in records that are retained for at least 2 years after they are created. Records are subject to monitoring verification and record review requirements.

iii. **Frequency to monitor.** FDA's regulations provide flexibility when establishing monitoring frequency. However, the frequency is to provide assurance that mycotoxins are effectively being controlled.

When establishing monitoring frequency for a mycotoxin-related preventive control, it may be necessary to test each shipment to ensure the mycotoxin is effectively controlled. If testing each shipment is not done, it may be appropriate to test more often at the onset of a new crop year to assist in determining the prevalence of mycotoxins. Based upon these test results, the frequency of testing may be adjusted. In addition, consider testing new suppliers more frequently until a reliable supplier history has been established. At facilities receiving high volumes of grains, it may be appropriate to perform composite testing (combining samples from multiple loads for testing).

iv. **Who will monitor.** FDA's rule requires individuals that manufacture, process, pack or hold food be trained so they are qualified to perform assigned duties. Individuals responsible for performing duties related to the control of mycotoxins are to receive documented training on how to effectively perform assigned tasks. FDA's rule requires such training records be retained for at least two years.

b. **Corrective actions**. Facilities are to develop written corrective action procedures to be followed if monitoring indicates a deviation from the mycotoxin parameter value or other issues with implementation of the preventive control.

FDA's rule requires corrective action procedures describe steps to ensure: 1) appropriate action is taken to identify and correct the problem that has occurred; 2) appropriate action is taken when necessary to reduce the likelihood that the problem will recur; 3) all affected animal food is evaluated for safety; and 4) all affected animal food is prevented from entering into commerce if the facility cannot ensure the affected animal food is not adulterated.

All corrective actions taken are to be documented in records that are retained for at least 2 years after they were created. Records are subject to corrective action verification and record review requirements.

c. **Verification.** When implementing a preventive control, verification activities are to be conducted as appropriate to the nature of the preventive control. FDA defines "verification" to mean 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.

   Verification activities specified by FDA include: 1) validation of the preventive control; 2) verification that monitoring is being conducted appropriately; 3) verification that appropriate decisions about corrective actions are being made; 4) verification of implementation and effectiveness of the preventive control; and 5) reanalysis of the food safety plan. FDA requires verification activities to be documented in records.

   FDA's verification requirements apply to the use of a process preventive control for mycotoxins as follows:

   i. **Validation of the preventive control:** FDA defines validation to mean 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, and requires preventive controls to be validated as appropriate to the nature of the preventive control and its role in the food safety system.

      Generally, sampling and testing when used as a control measure could be considered a type of preventive control where validation is not applicable. If a facility determines that validation is not an applicable verification activity for sampling and testing, that determination should be documented within its food safety plan.

      If a facility chooses to consider validation as an applicable verification activity for its sampling and testing process preventive control, then it is likely in-plant

studies will need to be conducted to provide technical evidence that the sampling and testing program is effectively controlling mycotoxins in finished products. Generally, FDA's rule provides that validation is to be completed prior to implementation of the food safety plan, but when necessary (e.g., when in-plant studies are required) validation may be completed within a "reasonable" timeframe, as justified by the preventive controls qualified individual (PCQI) who is responsible for preparing (or overseeing the preparation of) the food safety plan.

Validation is to be documented in records that are retained for at least 2 years after the use of the preventive control is discontinued. In addition, validation is to be completed again whenever a change to the preventive control could impact whether the preventive control will effectively control the hazard.

ii. **Verification that monitoring is being conducted in accordance with the food safety plan, and that monitoring records are complete and accurately document activities performed:** This verification activity is to ensure that sampling and testing for mycotoxins is conducted as established by the food safety plan, testing results are documented, and appropriate actions are taken after obtaining results. Monitoring records are to be reviewed by or under the oversight of the PCQI within 7-working days after the records are created or within a reasonable timeframe as justified by the PCQI.

iii. **Verification that corrective action records are complete and appropriate decisions were made about corrective actions:** Facilities are to develop written corrective action procedures to be followed if monitoring indicates a deviation from the mycotoxin parameter value or other issues with implementation of the preventive control. When required, corrective action records are to document actions taken to: 1) identify and correct the problem with implementation of the preventive control; 2) reduce the likelihood that the problem will recur; 3) evaluate the safety of all affected animal food; and 4) direct affected animal food to an appropriate disposition (e.g., diverted to another use, destroyed, etc.). Corrective action records are to be reviewed by or under the oversight of the PCQI within 7-working days after the records are created or within a reasonable timeframe as justified by the PCQI to ensure they are complete and that appropriate decisions have been made.

iv. **Verification of implementation and effectiveness of the preventive control:** Specific verification activities to be performed for implementation and effectiveness relate to:

1. **Calibration of equipment.** Facilities are to establish written procedures that describe the method and frequency for calibrating equipment associated with a preventive control, such as measuring instruments (e.g., scales, etc.).

Calibration means to compare to a standard, with adjustment to correct, as necessary. At a minimum, frequency of calibration should follow the instrument manufacturer's recommendation. Records associated with the calibration of equipment are to be established and retained for at least 2 years. The records are to be reviewed by or under the oversight of the PCQI within a reasonable timeframe after they are created as justified by the PCQI to ensure calibration is occurring in accordance with procedures.

2. **Finished product testing.** FDA's rule states that finished product testing is one type of activity that, as appropriate to the facility, the animal food, and the nature of the preventive control and its role in the facility's food safety system, is to be conducted to verify that a preventive control is consistently implemented and effectively and significantly minimizing or preventing the hazard. Therefore, to verify that mycotoxins are being significantly minimized or prevented, finished product testing may be appropriate. In addition, other types of activities as determined appropriate by the PCQI could be used to verify that a preventive control is effectively implemented and significantly minimizing or preventing the hazard.

   While finished product testing is a potential way to verify the implementation and effectiveness of a preventive control used for a mycotoxin, finished product testing does not prevent or significantly minimize the hazard. Thus, product testing is not a preventive control.

   When finished product testing is performed as a verification activity, written procedures are to be established that:

   a. Are scientifically valid.

   b. Identify the analyte (specific mycotoxin being controlled).

   c. Specify the process for identifying samples, including their relationship to specific lots of products, such as using the lot number as part of the sample identification number.

   d. Include sampling protocols that address the number of samples and sampling frequency.

   e. Identify the type of test to be conducted, including the analytical method that will be used.

   f. Identify the laboratory, which could be an in-house laboratory, that will conduct the test.

g. Include corrective action procedures to be followed if a problem is identified through product testing.

Records associated with finished product testing are to be established and retained for at least 2 years. Records are to be reviewed by or under the oversight of the PCQI within a reasonable timeframe after they are created as justified by the PCQI to ensure test results are appropriate.

If finished product testing is performed as a verification activity, the facility should consider whether to place the lot of finished animal food tested on hold until results are received that indicate an acceptable mycotoxin level. The release of the lot for shipment outside of company control before results are obtained increases the risk of business and regulatory consequences.

v. **Reanalysis of the food safety plan:** Documented reanalysis conducted or overseen by the PCQI is a required verification activity. FDA's rule requires that at least once every 3 years, facilities reanalyze the food safety plan as a whole. A reanalysis of the plan or the applicable portion of the plan also is required whenever:

1. A significant change in the activities conducted at the facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard.

2. The facility becomes aware of new information about potential hazards associated with the animal food.

3. Appropriate after an unanticipated animal food safety problem.

4. The facility finds that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

5. FDA determines a reanalysis is necessary to respond to new hazards and developments in scientific understanding.

Other Practices Related to Mycotoxins

Blending

FDA Compliance Policy Guide Section 555.200 states the deliberate mixing of adulterated food with good food renders the finished product adulterated under the federal Food, Drug, and Cosmetic Act, regardless of the final concentration of contaminant in the finished food.

More specifically, FDA's policy does not permit grain, grain by-products, or human or animal food products containing higher mycotoxin levels to be deliberately blended with other commodities or products with lesser mycotoxin levels as a way to reduce the mycotoxin content of the resulting mixture to levels acceptable for human or animal food unless all of the mixed lots were at mycotoxin levels acceptable for the intended use.

As an example of how FDA's policy is applied, mixing corn containing aflatoxin at levels of up to 300 ppb is permitted so long as the resulting mixture is fed only to finishing (i.e., feedlot) beef cattle (the aflatoxin action level for finishing (i.e., feedlot) beef cattle is 300 ppb). Conversely, the mixture resulting from blending corn with aflatoxin of 250 ppb with corn with lower aflatoxin levels is not to be fed to breeding cattle, breeding swine or mature poultry even if the resulting mixture was 100 ppb or less (the aflatoxin action level for these species/classes is 100 ppb), since some of the corn used to create the mixture was at a level greater than 100 ppb.

On occasion FDA has relaxed its "no-blending" policy for corn in response to widespread incidences of aflatoxin or in response to state-specific requests to address local occurrences. In these situations, FDA has granted "no-blending waivers" to allow blending of corn to occur in accordance with specified conditions and under the direction of the state regulatory authority. In addition, FDA no-blending waivers when granted have permitted blending only for a designated time period or specified harvest.

Use of Additives in Feed

Mycotoxin binders or adsorbents are substances that bind to mycotoxins and prevent them from being absorbed through the digestive system and entering into the blood circulation. Examples of mycotoxin-binding agents are activated charcoal, aluminosilicates (e.g., bentonite, clay, montmorillonite, phyllosilicates, zeolite) and complex indigestible carbohydrates (e.g., cellulose, polysaccharides in the cell walls of bacteria and yeast such as glucomannans and peptidoglycans).

For a substance to be acceptable for use in animal food in the United States, it must be the subject of an FDA-approved Food Additive Petition (FAP), or defined through the Association of American Feed Control Officials' (AAFCO) ingredient definition process, or generally recognized as safe (GRAS) for use in animal food in accordance with its intended use.

To date, no binders or adsorbents have been approved or recognized for use in controlling mycotoxins through regulatory pathways involving FDA review. Sodium aluminosilicate and hydrated sodium calcium aluminosilicate are recognized by FDA as GRAS when used as anticaking agents in animal food at a level not exceeding 2 percent in accordance with good manufacturing or feeding practices. However, FDA has consistently maintained the use of sodium aluminosilicate or hydrated sodium calcium aluminosilicate as binders for mycotoxins is not GRAS and approved FAPs must be obtained before these products may be used or claims made regarding their utility as mycotoxin binders. In addition, attapulgite clay, bentonite,

kaolin, and montmorillonite clays are GRAS for specified uses as designated in the AAFCO *Official Publication,* but have not gained recognition for use in binding mycotoxins.

Currently, the only FDA-approved feed ingredient for use in degradation of a mycotoxin is the enzyme fumonisin esterase, which has been approved for use in degrading fumonisin in poultry and swine feeds under prescribed conditions as detailed in 21 CFR 573.485. Such conditions for use include that the additive is incorporated at a minimum of 15 units of fumonisin esterase activity per kilogram of complete feed, and: 1) complete swine feeds cannot contain more than 10 parts per million of total fumonisins; 2) complete feed for poultry being raised for slaughter cannot contain more than 50 parts per million of total fumonisins; and 3) complete feed for breeding poultry and hens laying eggs for human consumption cannot contain more than 15 parts per million of total fumonisins.

Detoxification

There is no FDA-approved nor sanctioned method for "detoxifying"– through ammoniation or other means – corn that contains aflatoxin. FDA has approved ammoniation as a method for detoxifying cottonseed, as specified within the agency's Compliance Policy Guide Sec. 670.500 Ammoniated Cottonseed Meal - Interpretation of 21 CFR 573.140, March 1995.

Example Hazard Analysis Form for Mycotoxins

The following hazard analysis form for mycotoxins with suggested columns is provided as an example only. FDA's regulations do not prescribe that a specific form or format be used. Facilities may use any method they prefer to document their written hazard analysis, so long as the hazard analysis addresses required elements. If a facility does utilize a specific form or system to evaluate the severity and probability of known or reasonably foreseeable hazards, then FDA will consider the form or system to be part of the hazard analysis, which must be written and is subject to FDA review.

Following is a brief description of the columns in the example form. Additional information about the topics addressed within each column has been previously provided in this document.

- **Column 1 = Ingredients and Process Steps:** Identify the ingredients and process steps to be assessed. FDA's regulations allow facilities to group ingredients during the hazard analysis process if the hazards and controls are essentially the same for all materials within the group. However, it may be advantageous to list materials separately because the probably of occurrence and severity of a specific mycotoxin may be different for various materials and intended uses. Related to processing, steps or operations, such as ingredient storage, where mycotoxins could be introduced or amplified should be listed for assessment.

- **Column 2 = Identify Known or Reasonably Foreseeable Mycotoxins Hazards:** Identify all known or reasonably foreseeable mycotoxin hazards associated with each ingredient. During this step, facilities are to rely on experience, illness data, scientific reports, and other relevant information to identify known or reasonably foreseeable mycotoxin hazards. At a minimum, consideration should be given to those mycotoxins for which FDA has issued regulatory guidance – aflatoxins, deoxynivalenol and fumonisins. In addition, it may be appropriate to consider and list other mycotoxins that are associated with the grain or ingredient for which FDA has not issued regulatory guidance. FDA requires when identifying known or reasonably foreseeable hazards that biological (B), chemical (C) and physical (P) hazards be considered. Mycotoxins are considered a chemical hazard and would be designated as such within this column.

- **Column 3 = Probability that Excessive Mycotoxin Will Occur in Absence of a Preventive Control**: Among other factors, facilities may consider the implementation of prerequisite programs when evaluating the probability that an excessive level of mycotoxin will occur in finished products in the absence of a preventive control. If facilities rely on a prerequisite program when evaluating the probability of occurrence of a mycotoxin, adequate information about the prerequisite program must be included in the facility's hazard analysis as part of the evaluation. Within this column, as an example, probability of occurrence could be characterized as high, medium, or low, or by using some other type of ranking terminology. If ranking terminology is used, it is recommended the terminology be defined in a written format and included within the food safety plan.

- **Column 4 = Severity of Illness or Injury of the Mycotoxin to Humans or Animals:** In general, the severity associated with mycotoxins for which FDA has issued regulatory guidance is typically characterized as high, since aflatoxin, deoxynivalenol, and fumonisin have been known to cause serious adverse health consequences at levels in animal food that exceed FDA regulatory guidance. Facilities should consult animal health experts and scientific literature as needed when characterizing the severity of a mycotoxin hazard for their product's specific intended use. Within this column, as an example, severity could be characterized as high, medium, or low, or by using some other type of ranking terminology. If ranking terminology is used, it is recommended the terminology be defined in a written format and included within the food safety plan.

- **Column 5 = Determination if the Mycotoxin Hazard Requires a Preventive Control:** Determine based upon the assessment of severity and probability whether the mycotoxin is a hazard requiring a preventive control. It is more likely to determine that a known or reasonably foreseeable mycotoxin requires a preventive control when it has been characterized as having a high severity and high probability of occurrence in the absence of a preventive control.

- **Column 6 = Justification for Determination if the Mycotoxin Requires a Preventive Control:** Justification is particularly important when a determination is made that the

mycotoxin does not require a preventive control. When a hazard is determined to require a preventive control, the justification is not as critical because management components with the food safety plan will address and describe how the hazard is controlled. Factors to justify the determination could include: 1) use of prerequisite programs; 2) types of animal food produced; 3) historic prevalence of the mycotoxin within the grain/ingredient sourcing region; 4) evaluation of temporal conditions that affect mycotoxin formation; and 5) others. The justification provided should correspond and align with how probability of occurrence and severity of the mycotoxin were characterized.

Example Hazard Analysis Form for Mycotoxins						
Identification			**Evaluation**			
(1)	**(2)**		**(3)**	**(4)**	**(5)**	**(6)**
List Grains / Ingredients Susceptible to Mycotoxins and Process Steps Where Mycotoxins Could be Introduced or Amplified	**Identify Known or Reasonably Foreseeable Mycotoxins**		**Assess Severity of Illness or Injury of the Mycotoxin to Humans or Animals (Rank High, Medium, or Low)**	**Assess Probability that Excess Mycotoxin Will Occur in Absence of a Preventive Control (Rank High, Medium, or Low)**	**Determine if Mycotoxin Requires a Preventive Control (Yes or No)**	**Justify the Classification for the Mycotoxin in Column 5; Describe Other Mitigation Measures in Place as Applicable**
	C1					
	C2					
	C3					
	C1					
	C2					
	C3					
	C1					
	C2					
	C3					