Guidance for Industry

Ensuring Safety of Animal Feed Maintained and Fed On-Farm

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For further information regarding this guidance document, contact <u>Phares Okelo</u>, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-402-5921, E-mail: <u>Phares.Okelo@fda.hhs.gov</u>.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

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TABLE OF CONTENTS

| I. INTRODUCTION | |
|------------------------------------------------------------------------------------------------|---|
| II. BACKGROUND | |
| III. DEFINITIONS OF FEED CONTAMINANT AND UNACCEPTABLE FEED RISK AND | |
| THEIR INTERRELATIONSHIP | |
| IV. GENERAL PRINCIPLES AND PRACTICES FOR ANIMAL FEED SAFETY ON THE | |
| FARM | |
| V. APPLICATION OF GENERAL PRINCIPLES AND PRACTICES FOR ANIMAL FEED | |
| SAFETY ON THE FARM | |
| A. How can I address unacceptable feed risks at my farm? | 5 |
| B. What feed safety practices should I follow on my farm? | 6 |
| C. What feed safety practices should I follow when I provide pasture, forage, or bedding to | |
| my animals? | 7 |
| D. What feed safety precautions should I take in animal feeding? | 8 |
| E. What feed safety precautions should I take in intensive animal feeding units? | 9 |
| F. What should I consider when I use pesticides, fertilizers and other agricultural chemicals? | 9 |
| G. What are the feed safety considerations in labeling? 1 | 0 |
| H. What are the other feed safety considerations on my farm?1 | 1 |
| I. What feed safety factors are important in personnel training? 1 | 2 |
| J. What actions assist in identifying the origins of feed? 1 | 2 |
| K. If I want to have a feed sample analyzed, what should I keep in mind? 1 | 2 |
| L. What should I do if I have concerns about the safety of my animal feed? 1 | 3 |
| VI. APPENDIX A - FEED CONTAMINANT AND UNACCEPTABLE FEED RISK | |
| EXAMPLES14 | |

Guidance for Industry

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to help animal producers develop procedures and practices to ensure the use of safe feed in animal production. It applies to all feed offered to farm animals,¹ whether the feed is obtained from commercial suppliers, or produced on the farm. It also applies to products consumed by animals during pasture grazing, pre- or post- harvest grazing, free-range feeding, and forage-crop feeding.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. BACKGROUND

This document is intended to help animal producers (persons who feed farm animals) develop and implement on-farm practices to ensure the safety of animal feed maintained and fed to animals on-farm. In this document "farm" means animal production units (for example, integrated poultry grower operations, swine finishing units, and cattle feedlots). This document outlines basic measures which may be taken to maintain the safety of all types of feed held on the farm for use in animal production. This guidance document recommends establishing measures to ensure acquisition of safe feed and maintenance of its safety until the feed is offered to animals in the farm environment. This document does not address feed manufacture, which may also occur on farms.

III. DEFINITIONS OF FEED CONTAMINANT AND UNACCEPTABLE FEED RISK AND THEIR INTERRELATIONSHIP

The main purpose of animal feed used on-farm is to provide the nutrition necessary to support production of meat, milk and eggs. Unfortunately, on occasion, feed can be the source of

¹ For the purposes of this guidance, farm animals include all food-producing animals and horses.

contaminants that may adversely affect the health/production of farm animals and/or the safety of food produced by farm animals. The following definitions are relevant to determining when animal feed is unsafe for animal consumption.

Feed contaminant, for purposes of this guidance, means any biological, chemical (including radiological), or physical agent that if present in feed has the potential to cause illness or injury to animals or humans. (See Appendix A for examples of feed contaminants).

Unacceptable feed risk, for purposes of this guidance, occurs when the level of a feed contaminant in feed is reasonably likely to cause illness or injury in animals or humans. (See Appendix A for examples of unacceptable feed risks).

Significantly minimize, for purposes of this guidance, means to reduce to an acceptable level, including to eliminate.

The presence of a feed contaminant in feed does not necessarily mean that it is unsafe for animal consumption. Only when the contaminant present in the feed reaches the level (e.g., concentration of biological, chemical, physical, or radiological agent) that is reasonably likely to cause illness or injury to animals or to people consuming the meat, milk or eggs derived from the animals, is it considered an unacceptable feed risk. Many states have established maximum tolerance levels for certain types of feed contaminants, specifically mineral tolerances.

A dietary level of an essential nutrient in animal feed that is below the level recommended for the identified animal species could result in an unacceptable feed risk if it is reasonably likely to cause illness or injury to animals. Similarly, when certain essential nutrients are above recommended levels in an animal feed, this also could result in an unacceptable feed risk if it is reasonably likely to cause illness or injury to animals. See the example of selenium toxicity in Appendix A.

Animal feed containing feed contaminants at levels that pose an unacceptable feed risk should not be offered to animals for consumption.

This document contains recommendations for preventing and significantly minimizing feed contaminants that may be associated with your farm so that they will not result in unacceptable feed risks that can jeopardize the health of farm animals and the safety of human food derived from those animals.

IV. GENERAL PRINCIPLES AND PRACTICES FOR ANIMAL FEED SAFETY ON THE FARM

We encourage you to consider the following principles and practices as means of ensuring the safety of the feed you give your animals:

- A. Know what feed contaminants may be present in your animals' feed and the measures known to prevent such contaminants from becoming unacceptable feed risks;
- B. Obtain feed from safe and reliable sources;
- C. Recognize unexpected changes in the feed at your farm (e.g., changes in color, smell, texture, or appearance);
- D. Know where in your animal production system(s) unacceptable feed risks may occur;
- E. Monitor animal feed products for contaminants during receiving, holding, and handling; and,
- F. Be aware that other actions, such as limiting access to the premises to authorized personnel, following feed labeling directions, proper personnel training, and sampling and testing of feed, can help ensure feed safety.

The remainder of this guidance expands on these general principles and practices and how they should be applied to ensure animal feed safety on the farm.

V. APPLICATION OF GENERAL PRINCIPLES AND PRACTICES FOR ANIMAL FEED SAFETY ON THE FARM

A. How can I address unacceptable feed risks at my farm?

- 1. Identify feed contaminants that may be associated with your farm. Both U.S. Department of Agriculture (USDA) Cooperative Extension Service (in conjunction with land-grant universities) and FDA's Center for Veterinary Medicine (CVM) have information they can provide to help you learn more about contaminants likely to occur at your type of feeding operation. Some useful information may be obtained by performing web searches under the following programs:
 - a. The USDA National Institute of Food and Agriculture (NIFA) education and outreach programs on Animal and Animal Products, and Animal Nutrition and Growth (<u>http://nifa.usda.gov/</u>);
 - b. FDA's Animal Feed Safety System articles on food safety (<u>http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemA</u> <u>FSS/ucm350745.htm</u>);
 - c. Land-grant university web sites and private publications may also be of assistance.
- 2. Use the recommendations in the following sections to prevent or significantly minimize feed contaminants so that they do not become causes of unacceptable feed risks.

B. What feed safety practices should I follow on my farm?

- 1. Know the requirements for animal feed in your state. Many states have requirements designed to help ensure feed safety, including requirements relating to maximum tolerance levels² for certain contaminants in animal feed. Do not provide your animals feed that contains feed contaminants above the maximum tolerance levels (where they exist). Your state feed control officials will be able to help provide information on your state's requirements.
- 2. Do not provide your animals feed products that contain feed contaminants such as industrial chemicals, heavy metals, pesticides, pathogens, mycotoxins, or foreign material (e.g., stones, metals, or glass) at levels that would be considered an unacceptable feed risk. In addition to the sources listed in section V.A.1, your state feed control officials and the Association of American Feed Control Officials (AAFCO) Official Publication (http://www.aafco.org) may be sources of information on animal feed contaminants.
- 3. Obtain feed from safe and reliable sources. Examples of safe feed sources may include commercial suppliers known for delivering safe feed products. Ask each of your suppliers whether they are operating under an animal feed quality assurance program and if medicated feed is produced in compliance with applicable current Good Manufacturing Practice (CGMP) regulations (21 CFR part 225).
- 4. Ensure the safety specifications³ of the feed are met by implementing measures such as reviewing the supplier's Certificate of Analysis (COA) indicating safety specifications of the feed are met or reviewing results of analytical laboratory testing of feed samples completed by a qualified testing facility⁴ that uses appropriate analytical methods. In addition, a simple physical examination of the feed may identify abnormalities. Using several of these safety specification measures would help increase assurance that animal feed products you receive are safe.
- 5. Store, transport, and offer the feed to animals in a manner that will prevent or significantly minimize: infestation of the feed with pests (e.g., rodents and insects), pet (e.g., dogs and cats) contact with the feed, and introduction of contaminants into the feed (e.g., medicated feed products in non-medicated feed, pesticides, pathogens, molds, or foreign materials), or conditions (e.g., elevated moisture levels) that can cause unacceptable feed risks.

² Mineral Tolerance of Domestic Animals. National Academy of Science/National Research Council.1980. Washington DC ³ Some useful resources include: 1) 21 CFR Part 509 - Unavoidable Contaminants in Animal Food and Food Packaging Material

⁽http://ecfr.gpoaccess.gov), 2) Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed

http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/chemicalcontaminantsmetalsnaturaltoxins pesticides/ucm077969.htm). ⁴ Examples of such facilities include Agricultural Feed Laboratories that have adopted the AAFCO Quality Assurance/Quality

Control Guidelines for State Feed Laboratories.

6. Take steps to prevent or significantly minimize the occurrence of feed contaminants in feed. The occurrence of mycotoxins in grain and other feed commodities can be prevented or significantly minimized by providing environmental conditions during storage and transport that prevent or significantly minimize the growth of mycotoxin-producing molds. Implementation of an effective pest control program can prevent or significantly minimize contaminants caused by pests. Additionally, regular and adequate cleaning of animal feeding areas and equipment can prevent or significantly minimize the occurrence of feed contaminants caused by the accumulation of filth. Your local agricultural extension service may provide guidance on pest control and good storage practices. For more information, see the website for the USDA Cooperative Research Education and Extension Services education and outreach programs on Pest Management;

http://www.usda.gov/wps/portal/usda/usdahome?contentid=cooperative_research_extensi on_services.xml

- 7. Observe feed consumption patterns of your animals. Unexpected changes in feed consumption patterns can be a good indicator of the occurrence of feed contaminants or unacceptable feed risks in the feed.
- 8. Make sure any equipment used for feed handling such as loaders, mixers, and conveyance devices is dedicated for feed handling. Using the same equipment for both feed and non-feed-related purposes can increase the potential for introduction of feed contaminants into the feed.

C. What feed safety practices should I follow when I provide pasture, forage, or bedding to my animals?

- Make sure all feed obtained from pastures has been produced using good agricultural practices (GAPs) for pasture and forage. For the purposes of this guidance, GAPs are those practices which may improve the safety and quality of crops grown for animal feed and relate to the following areas: soil quality, management of farm manures, water quality, product handling by personnel, and cleanliness of production equipment and work surfaces. Although no one source has information covering each of these areas, we recommend that you consult the following resources for further information: http://www.ams.usda.gov/services/auditing/gap-ghp/audit, http://www.ams.usda.gov/services/auditing/gap-ghp/audit, http://www.ams.usda.gov/services/auditing/gap-ghp/audit, http://www.ams.usda.gov/services/auditing/gap-ghp/audit, http://www.ams.usda.gov/services/auditing/gap-ghp/audit, http://www.ams.usda.gov/services/auditing/gap-ghp/audit, http://www.ams.usda.gov/services/auditing/gap-ghp/audit, http://http://http://http://http://http://http://gap.gap.ghp/audit, http://gap.gap.ghp/audit, http://gap.gap.ghp/audit, http://gap.gap.ghp/audit, http://gap.gap.ghp/audit, http://gap.gap.ghp/audit, <a href="http://ftp.fao.org/docrep/fao/006/y5224e/y52
- 2. Apply all relevant safe feeding practices outlined in this guidance document when your animals use pastures or when they graze on pre- or post-harvest crop residuals (e.g., stover and stubble).

- 3. Use safe pasture/fodder management practices, such as rotational grazing, allowing adequate time between dispersion of animal waste (manure, bedding, etc.) in pastures, and grazing or forage harvesting, to prevent or significantly minimize the occurrence of feed contaminants and exposure of your animals to these contaminants.
- 4. Locate pastures in environments not subject or prone to exposure to feed contaminants from outside sources such as industrial facilities, runoff, ground water, floodwater, or airborne feed contaminants.
- 5. Ensure materials purchased or grown to provide bedding for animals, such as straw and wood shavings, have been produced using GAPs (<u>http://www.ams.usda.gov/services/auditing/gap-ghp/audit, http://umaine.edu/blueberries/factsheets/quality/usda-good-agricultural-practices-good-handling-practices-gapghp/)</u>.
- 6. Ensure bedding materials for animals are free from contaminants that may cause unacceptable feed risks if consumed, absorbed through the skin, or inhaled (e.g., dioxins in wood products and pesticides in straw).
- 7. Store or dispose of farm equipment and chemicals (fertilizers, pesticides, herbicides, etc.) in areas not used to feed, house, and pasture animals.

D. What feed safety precautions should I take in animal feeding?

In accordance with applicable federal regulations, you are required to:

 Ensure certain animal protein products, which could be a source of the Bovine Spongiform Encephalopathy (BSE) agent, are not used in feed for ruminant animals (21 CFR § 589.2000) or certain cattle origin materials in the food or feed of all animals (21 CFR 589.2001), as applicable.

In addition, we recommend that you:

- 2. Store, distribute, and use feed in ways that will maintain feed safety and prevent or significantly minimize the occurrence of feed contaminants. For example, you should not store feed in facilities that are used for other purposes or distribute feed using equipment used in other operations if these practices would lead to the introduction of feed contaminants.
- 3. Use proper procedures to ensure you are giving each animal the correct feed.
- 4. Rotate your feed so the oldest is used first.
- 5. Clearly identify and remove for disposal any feed that would cause unacceptable feed risks for the targeted animals.

- 6. Ensure the drinking water supply for the animals on your farm is maintained in a manner to prevent or significantly minimize the occurrence of feed contaminants in the water.
- 7. Ensure tanks, pipes, and other equipment used to store and convey water are made of materials which do not introduce feed contaminants into the animals' drinking water.
- 8. Establish and implement an appropriate cleaning and maintenance program for water storage equipment to prevent or significantly minimize the occurrence of feed contaminants in water obtained from a safe source. In addition, you should have a plumbing system that is designed to maintain the safety of the drinking water supply for the animals on your farm.

E. What feed safety precautions should I take in intensive animal feeding units?

In addition to items listed in section V.D above, we recommend that you take the following precautions:

- 1. Locate your intensive animal feeding unit in an area not used to store equipment, vehicles, waste (dumps or open burn sites), fertilizers, or pesticides.
- 2. Maintain your indoor feeding unit in a manner that prevents or significantly minimizes access by pests (birds, rodents, insects, etc.). Limit the access of pets (dogs, cats, etc.) to your animal feeding units. While they may not be pests, they can transmit disease to your production animals.
- 3. Establish a practice of regular and thorough cleaning of the animal feeding unit and feeding equipment to remove accumulated undesirable materials such as dust, dead insects, or bird droppings. Make sure chemicals used are appropriate for cleaning and sanitizing feeding equipment and are used according to their labeling. These and other cleaning products should be properly identified/labeled and stored away from feeding equipment, feed storage, and feeding areas.
- 4. Ensure all farm workers observe biosecurity measures (such as ensuring clothes and footwear taken into or through animal production areas are free of organic debris, are disinfected, etc.) and personal hygiene practices to prevent or significantly minimize the introduction of feed contaminants.

F. What should I consider when I use pesticides, fertilizers and other agricultural chemicals?

You are required by law to:

1. Ensure Restricted Use Pesticides are applied by an applicator with the appropriate certification.⁵

⁵ See the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136a(d)(1)(C), and Environmental Protection Agency (EPA) regulations at 40 CFR 152.160.

2. Use, store, and dispose of pesticides in accordance with their labeling and with federal, state, and local environmental laws to prevent or significantly minimize the occurrence of feed contaminants in bodies of water, soil, crops, and feed. Use of (including storage and disposal) a registered pesticide in a manner inconsistent with its labeling is a violation of federal law.⁶ For more information on disposal, we recommend you contact the appropriate regulatory agencies, such as the Environmental Protection Agency (EPA), or your state and local government agencies responsible for regulating the environment.

In addition, we recommend that you:

- 3. Obtain pesticides, fertilizers and other agricultural chemicals from safe and reliable sources.
- 4. Read and follow labeling for use, storage, and disposal of all pesticides, fertilizers, and other agricultural chemicals to significantly minimize the potential for exposing animals to these substances.
- 5. Not store pesticides, fertilizers and other agricultural chemicals with, or adjacent to, feed or animals. Prevent animals from consuming pasture and crops containing pesticides, fertilizers, or other agricultural chemicals which could lead to violative residues in milk, eggs, or edible tissues of food-producing animals. For further information regarding pesticide storage, you should read the product labeling and/or seek assistance from the appropriate regulatory agency (EPA or the USDA).
- 6. Set up and maintain appropriate manure handling and storage systems to prevent or significantly minimize the occurrence of feed contaminants in storage or at the site of feeding.

G. What are the feed safety considerations in labeling?

- 1. Receive, store and handle all feed according to its labeled directions to maintain the feed's integrity and nutrient profile.
- 2. Ensure when receiving or subdividing feed, that you maintain its identity using measures such as storing the feed with its labeling/invoice attached or displayed on the container/bin to ensure important product information is maintained and accessible.
- 3. Use all feed in strict accordance with its labeled mixing and feeding directions.

⁶ 7 U.S.C. § 136j(a)(2)(G).

In addition, you are required by law:

- 4. If you provide medicated feed to your animals, to use it in accordance with its approved uses as listed on its labeling and reflected in FDA regulations at 21 CFR part 558 subpart B.⁷ You are also required to:
 - a. Follow product labeling to determine the animals for which the medicated feed is intended, the indications for use (purpose), and all precautions and instructions on how to handle, store, and use the feed.
 - b. Use medicated feed only under the approved conditions for use, following the limitations for use and withdrawal times. You should refer to the labeling for any required withdrawal times.

H. What are the other feed safety considerations on my farm?

We further recommend that you:

- 1. Maintain any buildings and equipment used for feeding animals in a manner permitting safe operation, maintenance, and cleaning, which will help prevent or significantly minimize the occurrence of feed contaminants. For example, make sure wood products that come in contact with animals or feed for such animals, are not treated with preservation products containing chemical contaminants such as dioxin. In addition, ensure feed troughs and other feed containers are cleaned routinely to prevent or significantly minimize the occurrence of feed contaminants in feed.
- 2. When considering adding new facilities, ensure buildings and equipment used for feeding animals will be constructed in a manner that permits their safe operation, maintenance, and cleaning, which will help prevent or significantly minimize the occurrence of contaminants. For example, animal buildings should be planned so as to allow for raising and feeding animals in batches to facilitate an "all in all out" system that prevents spread of disease from one batch to another. Animal buildings should be planned to allow for age segregation to prevent the spreading of disease from older to younger animals. All in all out and age segregation would not be possible if buildings are not planned for batch production. Spaces in animal buildings should allow for operation of equipment such as pressure washers for cleaning and machinery for bedding removal.
- 3. Dispose of waste (including animal waste) and rainwater (runoff) in a manner which will prevent or significantly minimize the occurrence of feed contaminants in equipment, storage spaces, and areas that may come into contact with feed.

⁷ See Section 512(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360b(a)(2)).

I. What feed safety factors are important in personnel training?

We recommend that you:

- 1. Ensure all personnel involved in the receipt, storage, and handling of animal feed are adequately trained and are aware of their responsibility for ensuring feed safety and safe animal feeding.
- 2. Provide feed safety training which can be easily comprehended by your employees.
- 3. Instill security awareness in all employees. Encourage employees to report suspicious behavior by individuals, such as disgruntled former employees or angry neighbors, and anything not usual to normal operations that may create unacceptable feed risks.

J. What actions assist in identifying the origins of feed?

We recommend that you:

Establish and implement measures so you will know the origins of feed used on your farm. Having such information becomes particularly important in cases where feed is recalled and will help ensure timely and effective removal from your farm and the market of feed products that may have an adverse effect on animal or human health.

K. If I want to have a feed sample analyzed, what should I keep in mind?

- 1. Use testing facilities that employ appropriate analytical methods. Many qualified laboratories exist. Examples of such facilities include Agricultural Feed Laboratories that have adopted the AAFCO Quality Assurance/Quality Control Guidelines for State Feed Laboratories.
- Ensure the sampling procedure is adequate to allow for a useful analytical result. Appropriate sampling procedures can be found in the AAFCO Feed Inspector's Manual available on AAFCO's website in the AAFCO Publication Listings section under the Free Manuals sub-section (http://www.aafco.org/Portals/0/SiteContent/Publications/AAFCO Feed Inspectors Man ual 5th ed.pdf). The feed testing facility you contact may be able to advise you on proper sampling procedures.
- 3. Monitor the analytical results for feed ingredients and mixed feed for problems. If problems do arise involving the product tested, it would be beneficial to have any past analytical results available for comparison.

L. What should I do if I have concerns about the safety of my animal feed?

- 1. Take immediate measures to ensure the product is not fed to animals.
- 2. Contact your feed supplier to report your concerns.
- Review the FDA web site on reporting problems to the FDA at <u>http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm388610.htm</u>. The types of information that would be helpful to FDA include:
 - a. A description of the actual or potential feed safety issue;
 - b. A description of the feed which may have caused the feed safety issue;
 - c. The species for which the product is intended;
 - d. The lot identifier or shipping date for the product;
 - e. The name of the manufacturer of the product; and
 - f. The place of origin of the product.
- 4. Promptly consult your veterinarian once you become aware that animal feed purchased for use on the farm may cause or has caused a negative effect on animal health.
- 5. If you suspect there could be negative effects on human health from ingestion of food products derived from animals that have eaten contaminated feed, you should promptly contact your local and state health departments.

VI. APPENDIX A - FEED CONTAMINANT AND UNACCEPTABLE FEED RISK EXAMPLES

Examples of feed contaminants and unacceptable feed risks. These examples are not intended to be all-inclusive, nor a ranking of the contaminants.

| Feed Contaminant | Species of animals for which animal feed is intended | Level of feed contaminant | Unacceptable feed risk exists? | Rationale |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Aflatoxin (naturally occurring toxin - chemical contaminant) | Dairy cattle, lactating | 20 ppb in corn, peanut products, cottonseed meal, or other animal feed ingredient. | Yes – for humans consuming milk products No – for dairy cattle, lactating | Although the presence of aflatoxin at 20 ppb in the animal feed would constitute a feed contaminant, an unacceptable feed risk would not exist for lactating dairy cattle because it is not "reasonably likely" that lactating dairy cattle provided animal feed products containing aflatoxin at 20 ppb would become ill or sustain injuries. ⁸ However, humans consuming milk products obtained from dairy cattle fed animal feed products containing 20 ppb aflatoxin are reasonably likely to become ill or sustain injuries. |
| Aflatoxin (naturally occurring toxin - chemical contaminant) | Dairy cattle, lactating | 100 ppb in corn, peanut products, cottonseed meal, or other animal feed ingredients. | Yes – for humans consuming milk products Yes – for dairy cattle, lactating | It is reasonably likely that dairy cattle consuming animal feed containing 100 ppb aflatoxin would become ill or sustain injuries and humans consuming milk products obtained from dairy cattle offered such animal feed products would become ill or sustain injuries. ⁹ |
| Salmonella Pullorum, S. Gallinarum, or S. Enteritidis (biological contaminants) in soybean meal. | Dairy and beef cattle | Detectable | No – for dairy and beef cattle | If soybean meal contaminated with detectable <i>S</i> . Pullorum, <i>S</i> . Gallinarum, or <i>S</i> . Enteritidis does not subsequently undergo a manufacturing process that would kill the <i>Salmonella</i> (e.g., rendering, extrusion, irradiation) prior to consumption by dairy or beef cattle, it is not reasonably likely that dairy or beef cattle consuming animal feed products containing the soybean meal would become ill or sustain injuries because these <i>Salmonella</i> serotypes are not pathogenic to dairy or beef cattle. |
| | | | No – for humans consuming meat or milk products | There is no current scientific evidence linking the presence of these three <i>Salmonella</i> serotypes in dairy or beef cattle feed to human illness from consuming milk or meat from these cattle. Therefore, based on current scientific evidence, the route of feed to meat/milk to humans is not likely to be of major importance. |

⁸ Robens, J. F. and J. L. Richard. 1992. Aflatoxins In Animal and Human Health. Reviews of Environmental Contamination and Toxicology. Vol. 127:70-94.

⁹ Ibid.

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| Feed Contaminant | Species of animals for which animal feed is intended | Level of feed contaminant | Unacceptable feed risk exists? | Rationale |
|-------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Salmonella Pullorum, S. Gallinarum, or S. Enteritidis (biological contaminants) in animal protein blend. | Layer chickens | Detectable | Yes – for layer chickens Yes – for humans consuming raw or undercooked eggs contaminated with <i>S</i> . Enteritidis No – for humans consuming chicken meat products | If animal feed products containing an animal protein blend contaminated with detectable <i>S</i> . Pullorum, <i>S</i> . Gallinarum, or <i>S</i> . Enteritidis do not subsequently undergo a manufacturing process that would kill the <i>Salmonella</i> (e.g., rendering, extrusion, irradiation) prior to consumption by layer chickens, the layer chickens are reasonably likely to become ill or sustain injuries because these <i>Salmonella</i> serotypes are pathogenic to layer chickens. In addition, eggs obtained from layer chickens fed animal feed contaminated with <i>S</i> . Enteritidis may also be contaminated with this same <i>Salmonella</i> serotype and thus be reasonably likely to cause illness or injury in humans consuming the eggs (http://www.cdc.gov/salmonella/enteritidis/index. html). There is no current scientific evidence linking the presence of these three <i>Salmonella</i> serotypes in layer chicken feed to human illness from consuming meat from these chickens. Therefore, based on current scientific evidence, the route of feed to meat to humans is not likely to be of major importance. |
| Selenium, an essential nutrient (potential chemical contaminant at excessive levels) | Swine | Greater than or equal to 5.0 ppm in complete swine feed on a dry matter basis | Yes | Swine fed a complete feed containing greater than or equal to 5.0 ppm of selenium on a dry matter basis are reasonably likely to become ill or sustain injuries ¹⁰ . |
| Selenium, an essential nutrient (potential chemical contaminant at excessive levels) | Swine | From ≥ 0.30 to < 5.0 ppm on a dry matter basis in complete swine feed. | No | Swine fed a complete feed containing ≥ 0.30 ppm and < 5.0 ppm of selenium on a dry matter basis are not reasonably likely to become ill or sustain injuries. ^{11,12} |

 ¹⁰ Nutrient Requirements of Swine (11th revised edition, 2012, National Research Council of the National Academies, Chapter 6 on Minerals, pages 86-87).
¹¹ *Ibid.* ¹² Selenium is an essential element so swine do need dietary levels that would be adequate to prevent a nutrient deficiency.