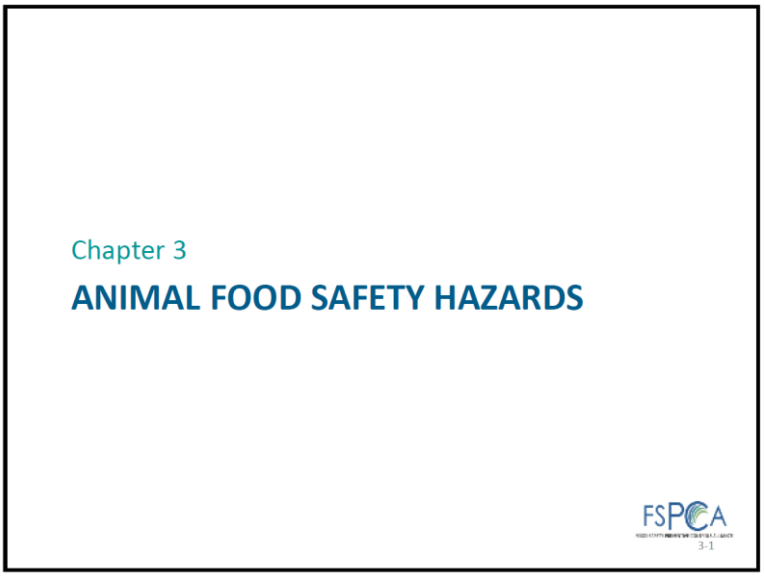
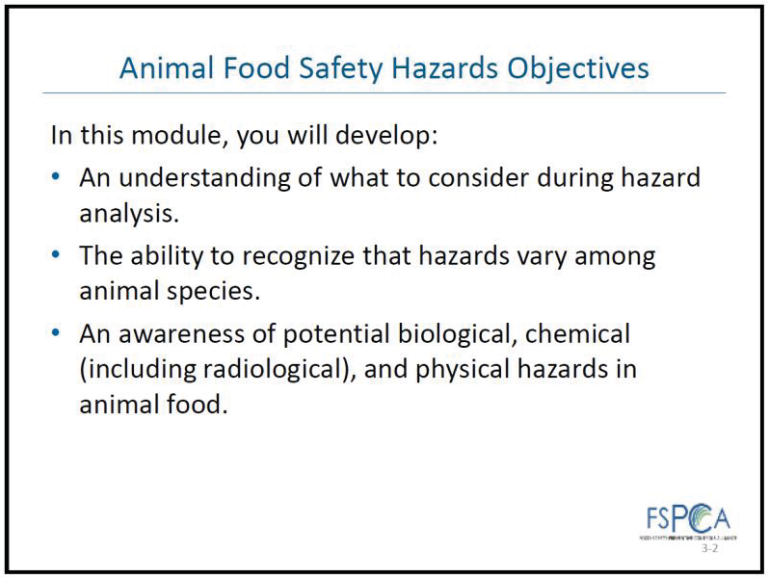
CHAPTER 3. Animal Food Safety Hazards



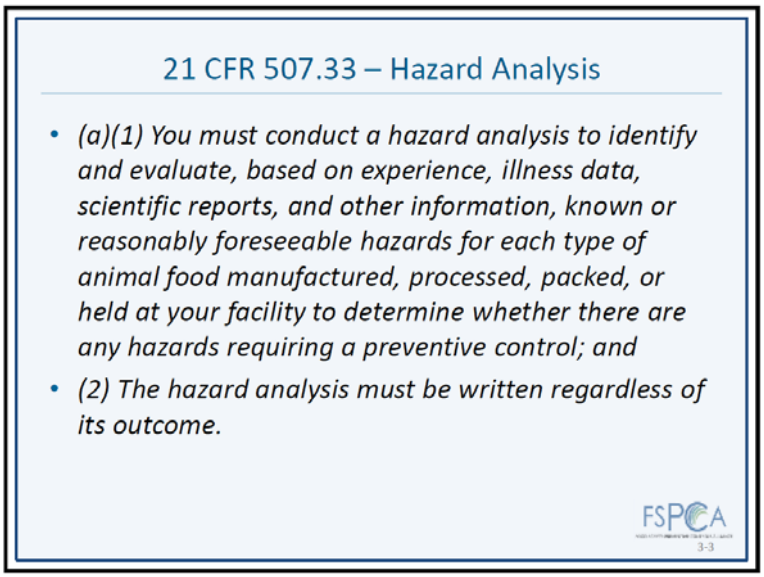
Slide 1

This chapter will focus on types of hazards potentially associated with animal food and will provide background information that will be useful during the hazard identification process.



Slide 2

In this module, participants will develop: 1) an understanding of what should be considered during hazard analysis; 2) the ability to recognize that hazards vary among animal species; 3) and an awareness of potential biological, chemical (including radiological), and physical hazards in animal food.



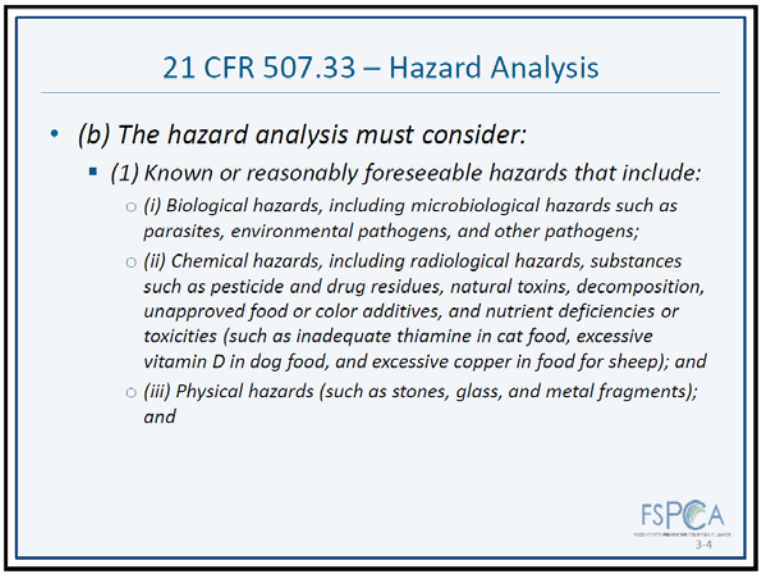
Note that when the *Preventive Controls for Animal Food* rule refers to 'you,' as it does in this section, the 'you' is the owner, operator, or agent in charge of the facility.

The owner, operator, or agent in charge of the facility is responsible for the hazard analysis described in this section. However, the owner, operator, or agent in charge of the facility may designated the responsibility of conducting the hazard analysis to the *Preventive Controls Qualified Individual*, as long as they recognize that the ultimate responsibility rests with the owner, operator, or agent in

Slide 3

The Hazard Analysis section begins on page 56345 of Appendix 1. Specifically, *You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and the hazard analysis must be written.*

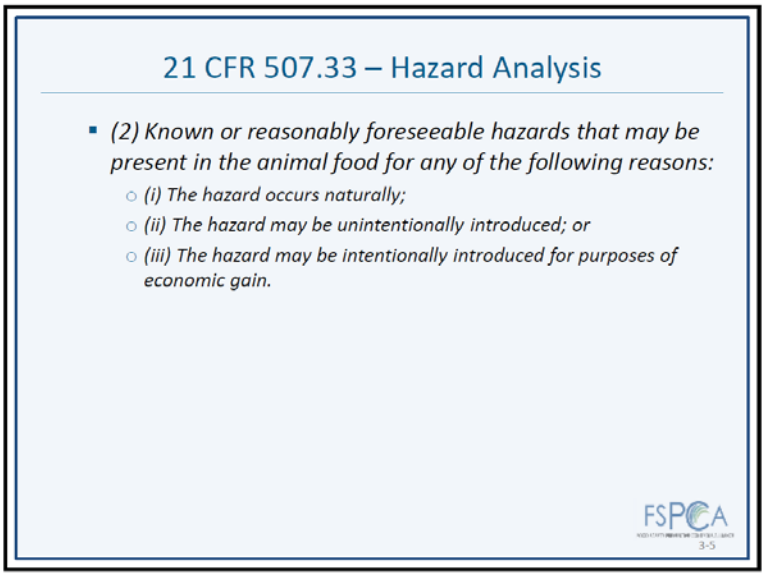
The majority of the hazard analysis requirements, including additional hazard evaluation components, will be covered in Chapter 5: Hazard Analysis and Preventive Controls Determination. For this chapter, the focus is on the fact that a hazard analysis must be conducted to identify known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at a facility. This first step narrows down an entire universe of hazards to those that are known or reasonably foreseeable.



While these 3 categories of hazards are utilized throughout this chapter, there are additional definitions associated with biological hazards that can be found in 21 CFR 507.3. These include *pathogen*, *microorganism*, and *environmental pathogen*.

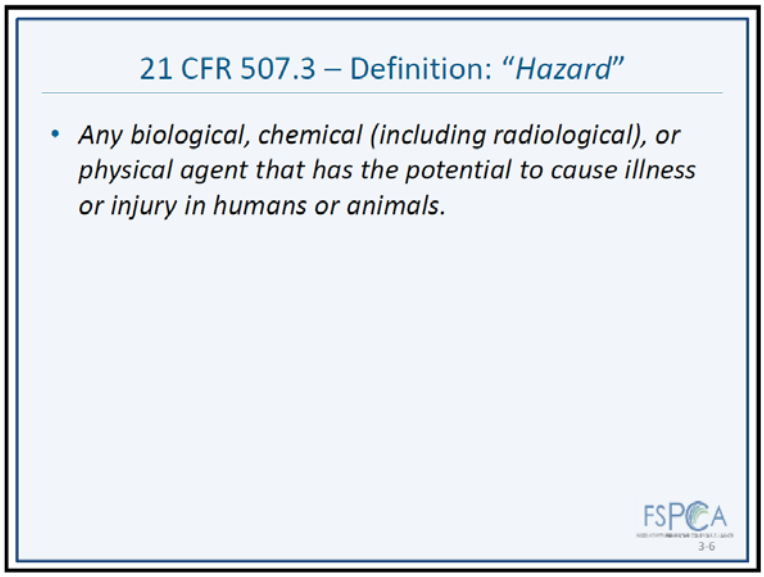
Slide 4

Hazard analysis involves the identification and further evaluation of hazards. Potential hazards in animal food will be classified into three broadly defined categories: biological hazards, chemical hazards, and physical hazards. The regulation provides examples for each of these categories, but this is not an exhaustive list of all known or reasonably foreseeable hazards. The regulation specifically draws out that some hazards are more relevant in one species compared to another. A key takeaway is that when considering hazards, it is important to consider the manufacturing environment and the species for which the animal food is intended when considering hazards.



Slide 5

Finally, the hazard analysis must consider *known or reasonably foreseeable hazards that may be present in the animal food for any of the following reasons: 1) the hazard occurs naturally; 2) the hazard may be unintentionally introduced; or 3) the hazard may be intentionally introduced for purposes of economic gain.*



A key component of this definition is that a hazard may cause *illness or injury* to *humans* ***or*** *animals*. A consideration for severity is part of the hazard analysis process that will be described later, but both the impact on animal and human health must be considered at this stage.

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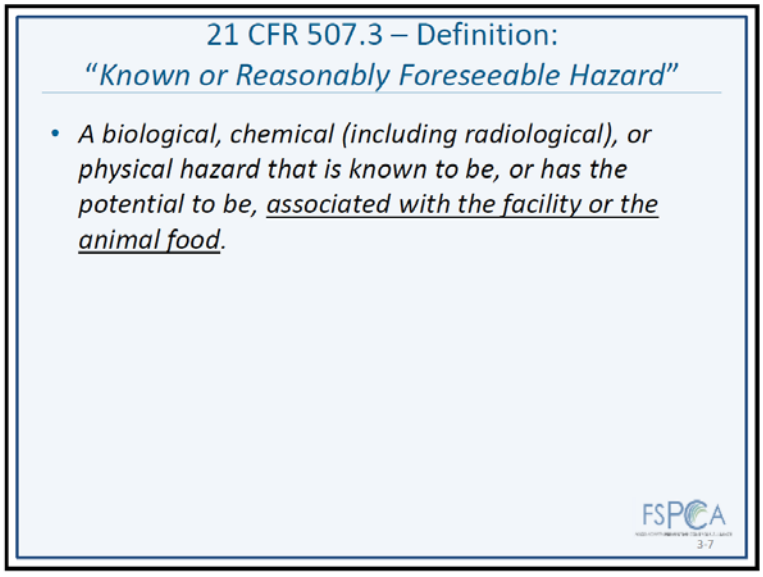
Because this is a chapter about hazards, it is appropriate to introduce the definition of hazard found in 21 CFR 507.3, which can be found on page 56338 of Appendix 1. A hazard means *any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.*

A key part of this definition is that it specifies an agent can be a hazard if it causes illness or injury in humans ***or*** animals. The hazard analysis must consider those hazards that may potentially impact human health due to their role in handling animal food or the edible products (meat, milk, eggs) from animals consuming the food. However, the hazard analysis must also consider the impact on the animal itself. For this reason, some hazards for animal food may be different than those for human food. While human food is only required to consider hazards for a single species (humans), the hazard analysis for animal food often requires the consideration for multiple animal species and humans who may be impacted.



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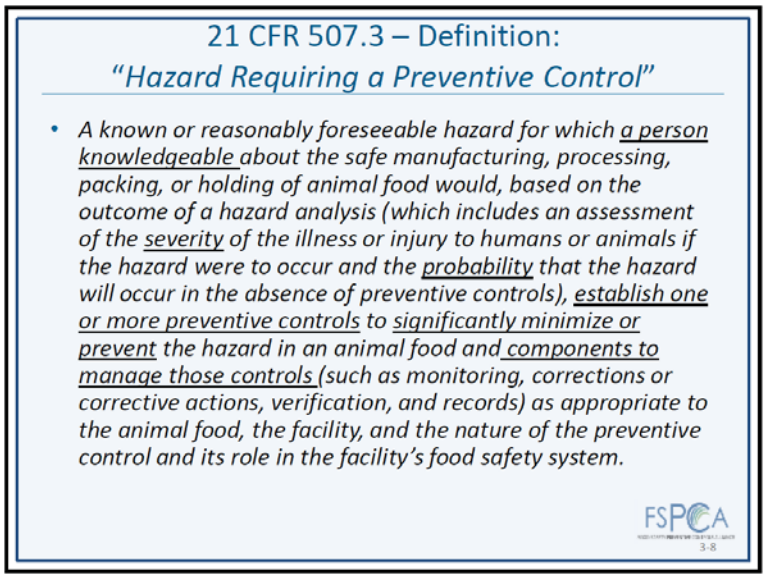
The definition for a *known or reasonably foreseeable hazard* is found on page 56339 of Appendix 1. This is a further classification of a hazard. Distinction between this term and the term *hazard* is key in the hazard identification and evaluation process that is discussed throughout this chapter. A *known or reasonably foreseeable hazard* is "a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food." The critical component of the definition is the known or potential association with the facility or the animal food.



Slide 8

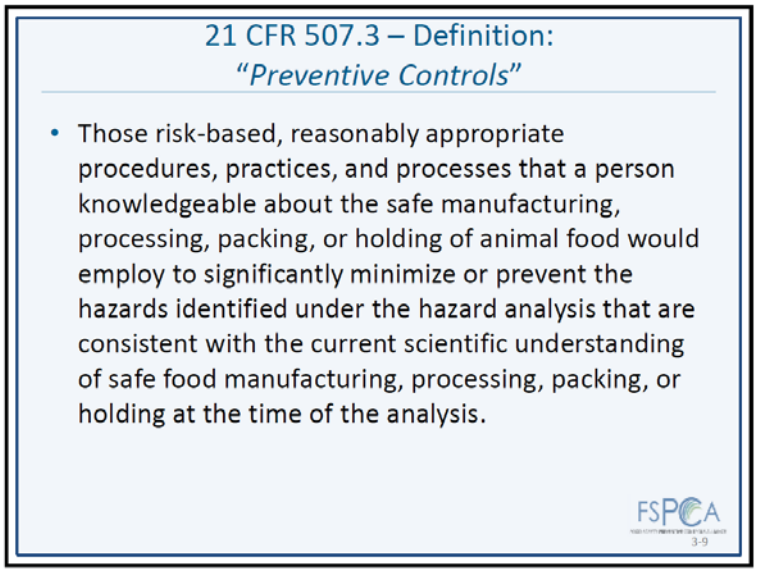
Once a facility has identified a *known or reasonably foreseeable hazard*, the next step of the hazard analysis process is to determine if the hazard is a *hazard requiring a preventive control*. There is a specific definition for this hazard category, which was updated in a technical amendment. The updated definition can be found on page 3717 of the technical amendment (Appendix II).

The first key component of this long definition is that the determination is to be made by "a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food…" This fits the definition of a Preventive Controls Qualified Individual.

Next, the definition calls out that the establishment of preventive controls is dependent upon "an assessment of the severity of the illness or injury to humans or animals if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls." Possible methods to assess severity and probability is described in chapter 5.

The definition goes on to clarify that the hazard can be controlled by either one or multiple controls, which either "significantly minimize or prevent the hazard in animal food."

Finally, the definition states that a *hazard requiring a preventive control* has necessary "components to manage those controls." There is flexibility as the management components are as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system.



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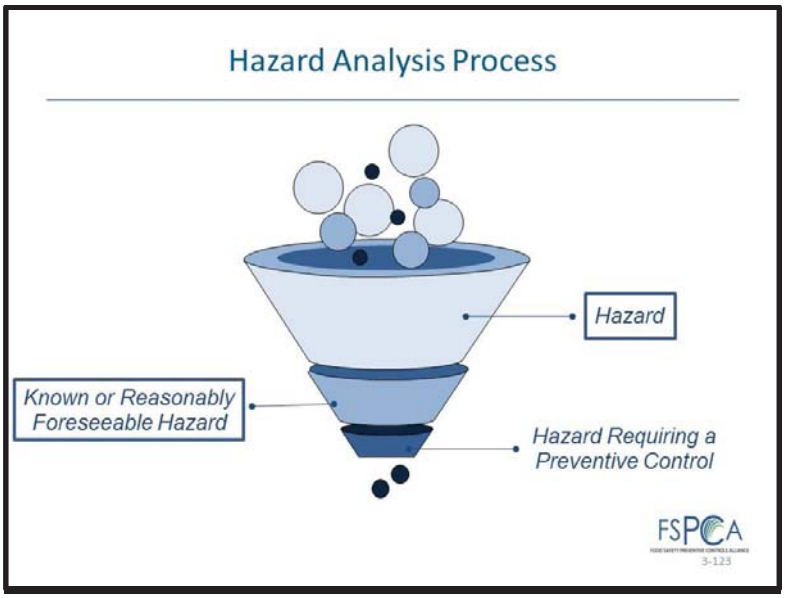
Preventive Controls are those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would employ to significantly minimize or prevent the hazards identified under the hazard analysis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

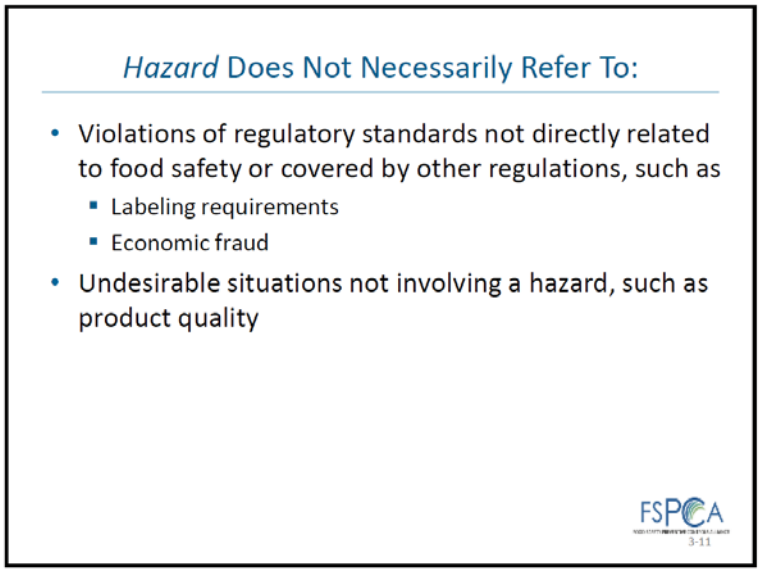
Preventive controls can be categorized by the method employed to control the hazard: process controls (which mitigate hazards through an action during the process itself), sanitation controls (which mitigate hazards through active sanitation procedures to prevent cross-contamination), supply-chain-applied controls (which requires control of the hazard at the supplier level), or other controls (which control hazards through different means other than those previously specified). There will be more discussion of the types of preventive controls and their required management components in the next chapters.



Slide 10

As can be seen, there are many definitions for the various categories of hazards. This slide graphically depicts the hazard analysis process. The process starts with the most general category of hazards – those that have the potential to cause illness or injury to humans or animals. Then, the hazard category gets narrowed to those hazards that are known or reasonably foreseeable based on the types of animal food the facility manufactures, processes, packs or holds. Finally, the combination of severity and probability are considered when further refining hazards to those that require a preventive control. Hazards requiring a preventive control are those that must be significantly minimized or prevented with preventive controls.

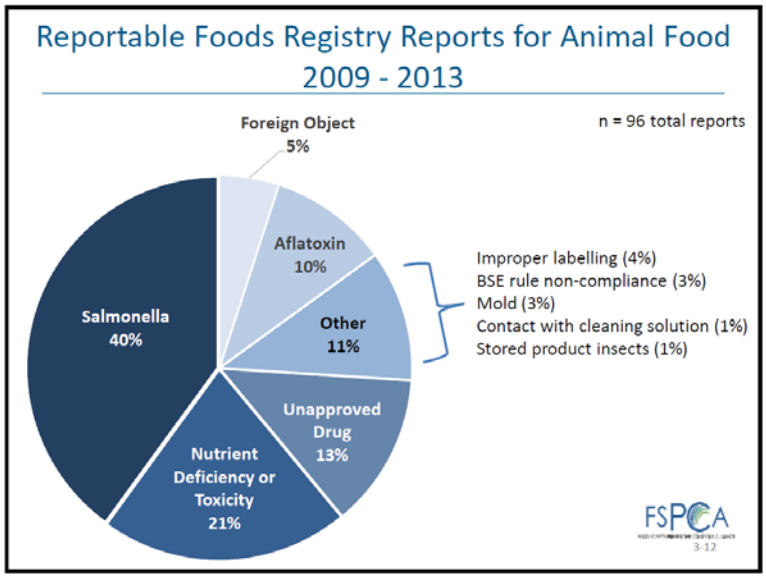
This chapter will focus on hazards, and identifying which hazards are known or reasonably foreseeable in different types of animal food. The determination if they require a preventive control will be described fully in Chapter 5: Hazard Analysis and Preventive Controls Determination.



Slide 11

As participants reflect on the hazard definition, it is important to understand that there are some animal food regulations that will not be discussed thoroughly in this curriculum because they are not likely to lead to food safety concerns. For example, there are specific labeling requirements for both medicated and non-medicated animal foods. These labeling requirements must be met in accordance with various rules, but in some cases, mislabeling or economic fraud is not considered a food safety concern. One such instance is if an ingredient manufacturer intentionally mislabels chicken byproduct meal as duck meal because the two have similar nutrient profiles and duck meal commands a higher price. In this case, the mislabeling is economic fraud and is a regulatory violation of other rules, but does not necessarily constitute a hazard within the *Preventive Controls for Animal Food* rule. Conversely, mislabeling beef meal as pork meal may be considered a hazard if it is sold to a ruminant feeder who then feeds it to beef cattle in violation of the BSE rule.

Furthermore, there are occasional examples where undesirable situations are not necessarily hazards, such as poor product quality. For example, a pelleted goat food manufacturer may not properly cool pellets after thermal processing and prior to packaging. As a result, the product may exhibit poor pellet quality, but would not cause potential illness or injury to humans or animals, and would therefore not meet the definition of a hazard.



The Reportable Food Registry (RFR) is an electronic portal for industry to report when there is a reasonable probability that a food will cause serious adverse health consequences or death. The RFR applies to all FDA-regulated categories of human and animal food, except dietary supplements and infant formula.

Who Should Use the Reportable Food Registry?
Registered Food Facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States under section 415(a) of the FD&C Act (21 U.S.C. 350d) are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals.

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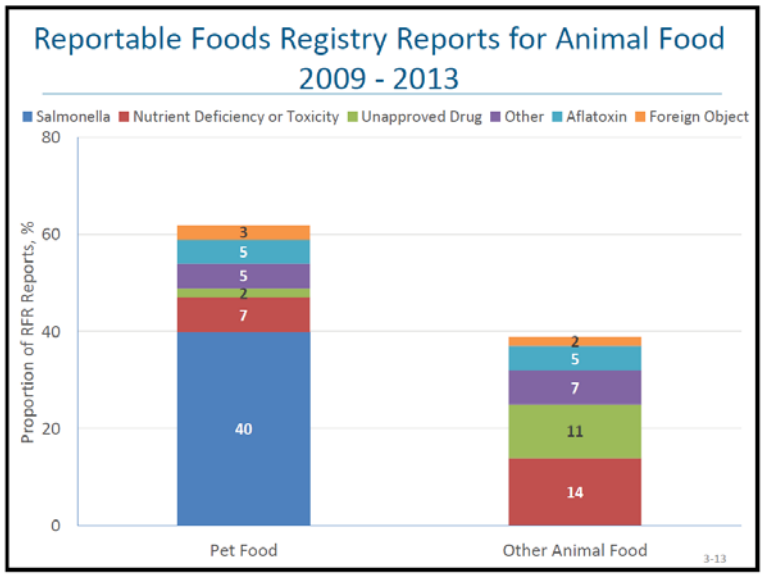
When beginning the hazard analysis process, it is helpful to understand the types of hazards that have previously been associated with the types of animal food that is manufactured, processed, packaged, or hold. A good resource for this data is the Reportable Food Registry, or RFR. This is an electronic portal for Industry where all facilities that manufacture, process, pack, or hold animal food must report hazards. Specifically, they must report to this portal if there is a reasonable probability that the use of, or exposure to, animal food will cause **S**erious **A**dverse **H**ealth **C**onsequences **o**r **D**eath to **H**umans or **A**nimals. These are often abbreviated as SAHCODHA hazards. Since its inception, there have been four annual reports published at the time of this curriculum's development: 2009-2010, 2010-2011, 2011-2012, and 2012-2013, which can be found on the FDA website. A fifth annual report summarizing data from September 2009 to September 2014 was made available on May 24, 2016, but data in this curriculum is from the reports from 2009 to 2013.

There were a total of 96 RFR reports for animal food from 2009-2013. Forty percent of all RFR reports for animal food during this time were due to *Salmonella* contamination. Other major reporting categories included nutrient deficiencies or toxicities (21%), unapproved drug contamination (13%), aflatoxin (10%), and foreign objects, such as metal or glass (5%). All the remaining RFR reports, such as improper labeling, non-compliance with BSE regulations, mold, cleaning solution contamination, or pest activity, totaled 11%. An understanding of the total scope of RFR reports is helpful to prioritize focus during hazard analysis.



The Reportable Food Registry (RFR) is one example of a type of reference that may be used to identify known or reasonably foreseeable hazards in different types of animal food, but other resources are likely needed. These resources will be described in Chapter 5.

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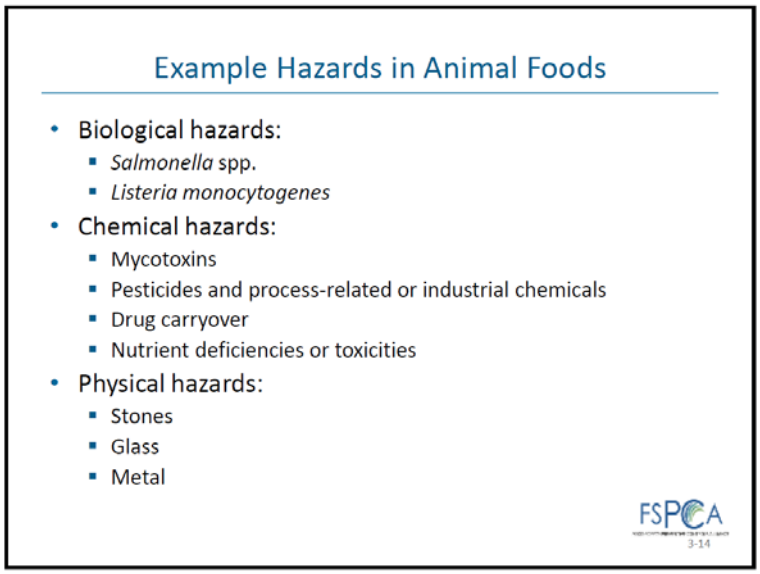
This slide shows the same data, but broken down by the numerical occurrence of RFR reports associated with either pet food or other animal food. As participants can see, all the *Salmonella* RFR reports were associated with pet food, and that hazard was over five times more prevalent than any other hazard. Part of the reason for the greater proportion of *Salmonella* reports in pet food is its potential implications on human health, which is described more fully later in the chapter. Conversely, either nutrient deficiencies or toxicities or unapproved drug contamination accounted for 80% of the other animal food hazards. The RFR reports can be evaluated by breaking down those hazards associated with specific animal species. For example, sheep food was associated with six total RFR reports during these years. Of those, five were due to copper toxicity and one to unapproved drug contamination.

While the RFR annual reports are useful, there are many other resources to consider when identifying hazards. For example, more recent recalls from 2015 reference *Listeria monocytogenes* as a hazard associated with pet food, especially raw, fresh, or frozen dog and cat food. Other resources, such as scientific literature, industry whitepapers, and guidance for industry are available and are important to consider. Those resources and others are discussed in more detail during the hazard identification and evaluation section of Chapter 5: Hazard Analysis and Preventive Controls Determination.



This is a general list of example hazards. Some of the hazards on this list are not associated with all types of animal food, while there are other hazards that may be *known or reasonably foreseeable hazards* for a type of animal food or a facility that are not listed. This is not meant to be a comprehensive list. Each facility must conduct a hazard analysis specific to that facility.

Many of hazards discussed in this chapter are referenced directly in the *Preventive Controls for Animal Food* rule or the Preamble due to their association with animal food in the past.

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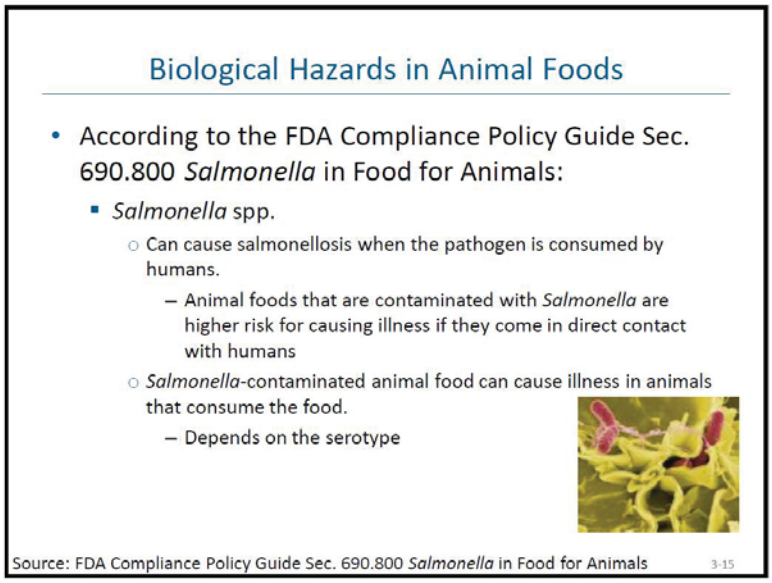
The *Preventive Controls for Animal Food* rule discusses the three categories of hazards and examples of each. This list of example hazards in animal foods is based on the examples in the rule, RFR reports, scientific literature, and other resources. Specifically, biological hazards can include undesirable microorganisms, such as *Salmonella* spp. and *Listeria monocytogenes*. Chemical hazards can include mycotoxins, pesticides, process-related or industrial chemicals, drug carryover, and nutrient deficiencies and toxicities. Finally, physical hazards can include stones, glass, and metal. In the next section, each of these hazard categories are discussed more fully, starting with the biological hazards.

As previously described, biological hazards can include undesirable microorganisms, such as *Salmonella* spp. and *Listeria monocytogenes*. Based on data from the RFR reports, biological hazards are most commonly associated with pet food. The discussion of biological hazards will start with the hazard responsible for most of those RFR reports, *Salmonella*.



Slide 15

Salmonella is a bacteria that may cause salmonellosis when the pathogen is consumed. It thrives in warm, humid environments, but can survive and form spores in low-moisture situations. Because of this, dehydrated or freeze-dried ingredients or finished foods may be contaminated when they are rehydrated.

In humans, symptoms of salmonellosis include nausea, vomiting, abdominal cramps, minimal diarrhea, fever, and headache. Certain vulnerable populations, such as children, the elderly, and individuals with compromised immune systems, are particularly susceptible to acquiring salmonellosis from pet food, and may experience more severe symptoms. Salmonella also has widespread occurrence in animals, especially poultry and swine. Animals may be infected either clinically, where they show symptoms similar to those in humans, or asymptomatically but are still at a potential for shedding and spreading the bacteria.

The role of *Salmonella* in animal food as a potential hazard to both humans and animals is described in the FDA Compliance Policy Guide Sec. 690.800: *Salmonella* in Food for Animals. It describes that certain animal foods, such as pet food, pose a high risk to human health when they are contaminated with *Salmonella* because they are direct human contact foods. This means that there is a high likelihood that humans will come in direct contact with these foods, such as through direct ingestion by people or from hands or utensils that are contaminated when feeding pets.

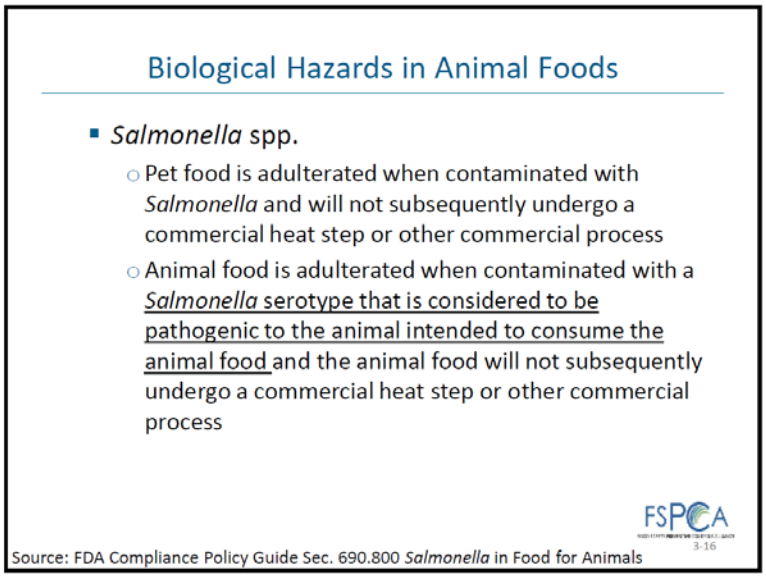
Salmonella-contaminated animal food can cause illness in animals that consume that food. Whether *Salmonella* causes illness in an animal depends on the serotype. A serotype is a further classification of a broad species of bacteria. For example, there are more than 2,500 different serotypes of *Salmonella* that differ from one another by small variations in structure and function. Those serotypes that cause disease in a particular species are referred to as pathogenic for that animal species.

FDA Compliance Policy Guide Sec. 690.800 Salmonella in Food for Animals contains further background and examples of pathogenic *Salmonella* serotypes that have been associated with disease in the particular animal species consuming these animal foods.

There are additional definitions that are associated with biological hazards that can be found in 21 CFR 507.3.

Microorganisms: means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens.

Undesirable microorganisms: includes those microorganisms that are pathogens, that subject animal food to decomposition, that indicate that animal food is contaminated with filth, or that otherwise may cause animal food to be adulterated.



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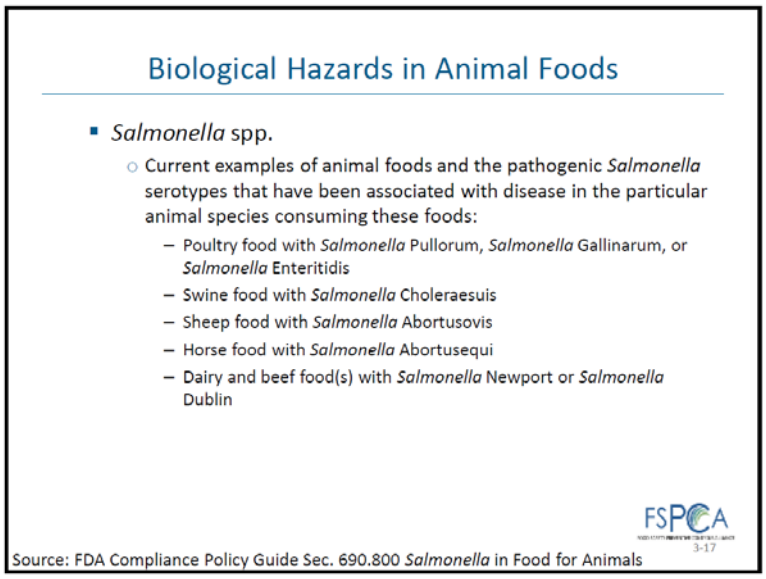
Serotype differentiation is important. FDA considers a pet food or a pet food ingredient to be adulterated when it is contaminated with any serotype of *Salmonella* and will not undergo a commercial heat step that will kill the *Salmonella*. This is partially because pet food is a direct human contact food.

Alternatively, FDA considers other animal food to be adulterated only when it is contaminated with a *Salmonella* serotype considered to be pathogenic to the animal species intended to consume the animal food. Unlike pet foods, the majority of food for other animals is not thermally-processed. When it is, the intent of the process is typically to improve nutrient availability to the animal or other quality aspects of the animal food by pelleting, extruding, or expanding the product. Thus, thermal processing in most foods for other animals is not intended as a *Salmonella* control step.



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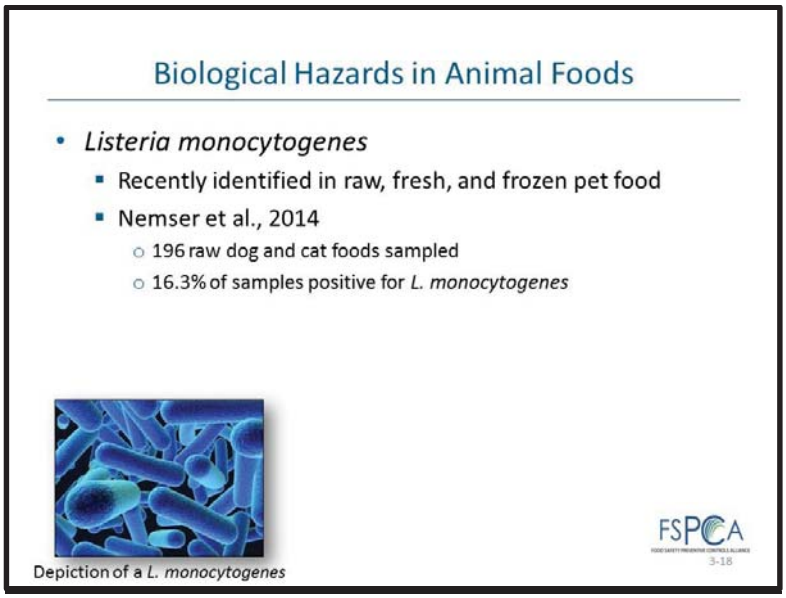
The Compliance Policy Guide lists current examples of animal foods and the pathogenic *Salmonella* serotypes that have been associated with disease in the particular animal species consuming these animal foods. While these are currently the listed serotypes, FDA stipulates that all other *Salmonella* serotypes should be evaluated on a case-by-case basis.



For more information, refer to: Nemser SM, Doran T, Grabenstein M, McConnell T, McGrath T, Pamboukian R, Smith AC, Achen M, Danzeisen G, Kim S, Liu Y, Robeson S, Rosario G, McWilliams Wilson K, Reimschuessel R. Investigation of Listeria, Salmonella, and toxigenic Escherichia coli in various pet foods. Foodborne Pathog Dis. 2014 Sep;11(9):706-9.

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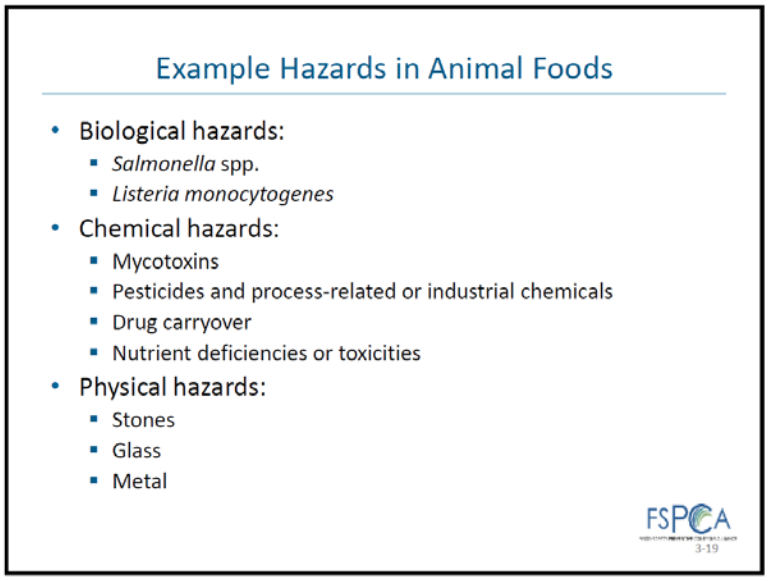
L. monocytogenes is unique in that it can survive in both the presence and absence of oxygen. The bacteria can grow and proliferate in frozen and refrigerated environments. Listeriosis in animals may result in swelling of the brain, neurological-related circling, and late-term abortions.

While the RFR reports in the annual summaries published through 2013 do not implicate *Listeria monocytogenes*, more recent data has associated the pathogen with raw, fresh, and frozen pet foods. For example, there were 4 voluntary recalls of raw, fresh, or frozen pet food associated with *L. monocytogenes* in 2015. Furthermore, a peer-reviewed research paper published in 2014 demonstrated that 16.3% of the 196 raw cat and dog foods sampled were positive for the pathogen. This recent addition of a biological hazard underscores that reanalysis of the hazard identification and evaluation may be necessary as new information becomes available.



In most regions, radiological hazards are not likely to be hazards requiring a preventive control. When they are, the most common way these radionuclides are incorporated into animal food is through use of water that contains a radionuclide. Radiological hazards also may result from accidental contamination, such as contamination arising from accidental release from a nuclear facility or damage to a nuclear facility from a natural disaster.

The Preamble of the Preventive Controls for Animal Food Rule describes decomposition as "microbial breakdown of the normal food product tissues and the subsequent enzyme-induced chemical changes.
These changes are manifested by abnormal odors, taste, texture, color, etc., and can lead to reduced food intake or rejection of the food by the intended animal species, resulting in illness or death."

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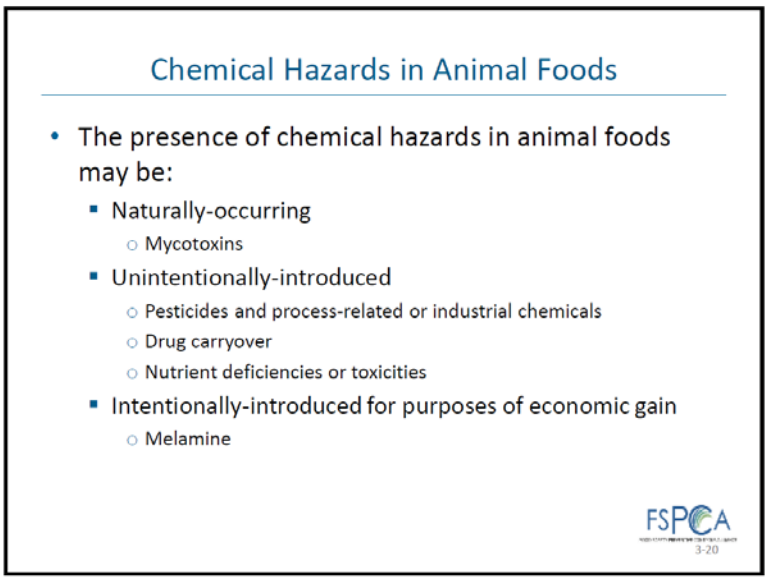
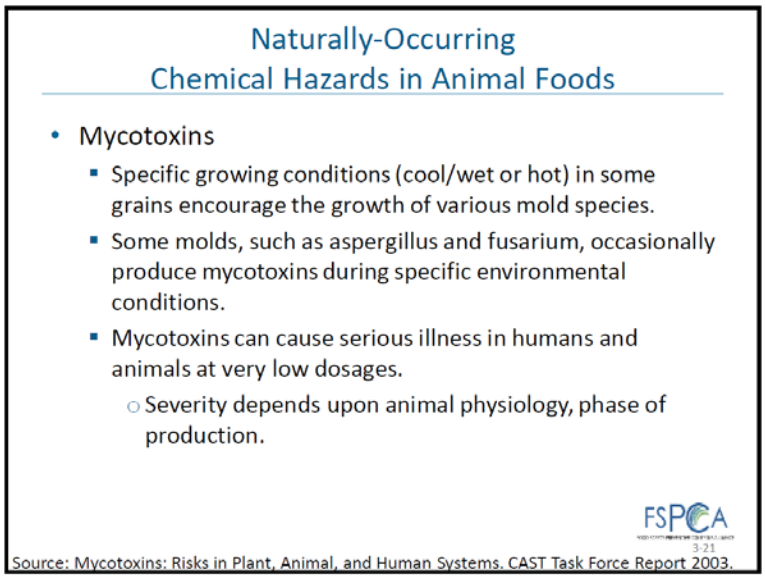
While biological hazards were most associated with pet foods, chemical hazards were responsible for the RFR reports in other animal foods. Chemical hazards can include radiological hazards. This curriculum does not cover radiological hazards in depth because they are not likely to be known or reasonably foreseeable in most regions. More common chemical hazards include substances such as pesticide, drug carryover, natural toxins, decomposition, unapproved food or color additives, and nutrient deficiencies or toxicities. Specific hazards discussed here include mycotoxins, chemical contamination from pesticides and process-related or industrial chemicals, drug carryover, and nutrient deficiencies or toxicities. However, it should be recognized that chemical hazards can vary widely and certainly may extend to examples not discussed in this chapter.



Slide 20

The hazard analysis process must consider known or reasonably foreseeable hazards that may be present. Examples of naturally occurring, unintentionally introduced, and intentionally introduced hazards are shown above. These reasons for introduction must be considered for all hazards, regardless if they are biological, chemical, or physical in nature.

Mycotoxins are an example of a hazard that occurs naturally and will be discussed in more detail in the next four slides.



While molds and their growth are biological systems, any mycotoxins produced by those molds are considered to be chemical hazards.

Not all molds produce mycotoxins. Even molds that may potentially produce mycotoxins do not produce those toxins except under specific temporal conditions. Thus, molds are not considered biological hazards within this curriculum, while mycotoxins are considered chemical hazards.

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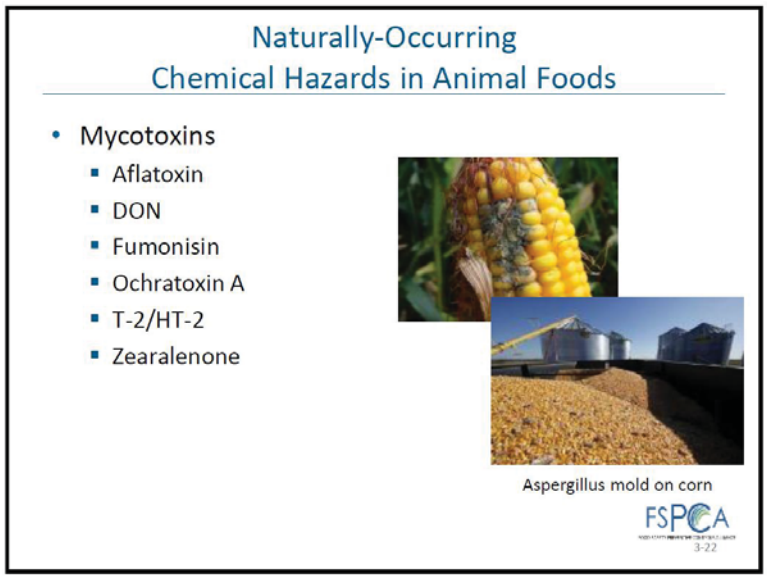
Mycotoxins are naturally-occurring hazards that are a result of specific growing conditions encouraging mold growth in different grains. Some molds, such as aspergillus spp. and fusarium spp., occasionally produce mycotoxins during specific environmental conditions. While these molds may be present without producing mycotoxins, their growth and production of the toxin occurs with specific temporal conditions. 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. Mycotoxins can cause serious illness in humans and animals at very low dosages. The severity of illnesses depends upon the type of mycotoxin present and the animal's physiology. The types of illnesses that may result from these toxins are discussed next.



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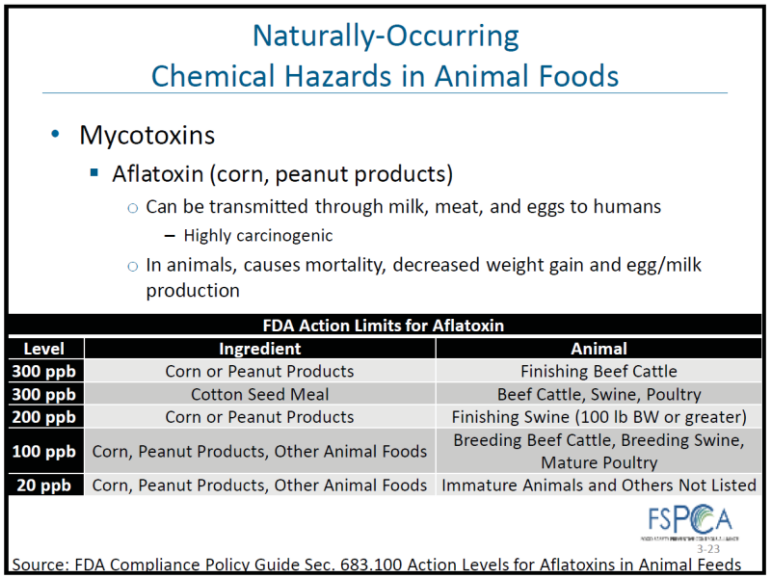
There are several different types of mycotoxins, and severity of illnesses they cause may vary depending upon their concentration and the animal consuming the animal food. Aflatoxins is commonly found in peanuts, corn, wheat, cottonseed, and nuts. Deoxynivalenol, or DON, is sometimes called vomitoxin and is most commonly found in corn, wheat, barley, and oats. Fumonisin is most commonly found in corn, wheat, sorghum, barley, and oats. Ochratoxin A is most commonly found in wheat, barley, oats, corn, and dry beans. Another mycotoxin, T-2, which rapidly metabolizes to HT-2, is found most commonly in barley, wheat and oats. Finally, zearalenone is commonly found in corn, wheat, barley, and rye. Most recalls and RFR reports have been associated with aflatoxin due to its frequency of occurrence and severity of illness, which is why it is focused on the most during this chapter.



Action Levels for Poisonous or Deleterious Substances in Human and Animal Feed contains information on levels of chemicals that are prohibited in certain foods. These levels are based on FDA's assessment of long term and short term effects of consuming the specific chemical.

This slide depicts action levels for aflatoxin, but there are advisory and caution levels for other mycotoxins that can be found in FDA guidance or precautionary levels that may be found in scientific literature. Each facility should consider the mycotoxins that are relevant to the ingredients they utilize and the intended species. The facility should also consider that there may be additive effects of different types of mycotoxins.

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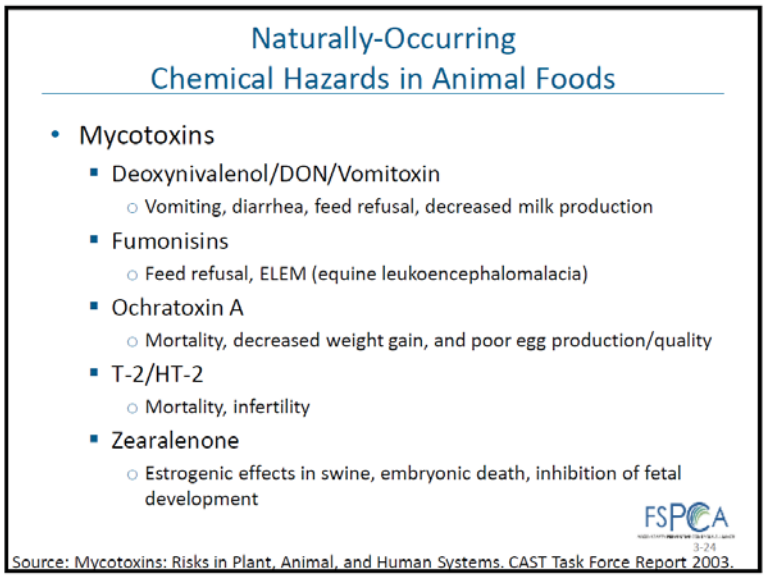
Aflatoxins may cause different levels of illness within animals, but its implications in human health mark its severity. For example, aflatoxins may cause organ failure and mortality in some animal species, such as dogs and cats, while others may experience less severe symptoms, such as depressed milk production in dairy cows. However, aflatoxin can be transmitted from the animal food through milk, meat, and eggs. This is concerning because aflatoxin is one of the most potent naturally-occurring carcinogens known to man. The danger of this toxin to both human and animal health has resulted in the FDA setting levels for the toxin in different types of animal food. These levels are described in the FDA Compliance Policy Guide Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds. If an animal food has an aflatoxin concentration above that outlined for an intended animal species, the FDA may take regulatory action.

The animal's phase of production and physiology may affect how aflatoxin is metabolized, and thus its impact on illness or injury to humans or animals. Therefore, there are different action levels for different species and production phases. The specific levels from the Compliance Policy Guide are listed above. For example, the action level for corn and peanut products intended for finishing beef cattle is 300 parts per billion (ppb), while the action level for immature animals and other animals, such as dairy cattle and pets, is just 20 ppb.



FDA Guidance for Industry establishes limits and levels for deoxynilvalenol and fumonisins in animal food. Other resources to help determine appropriate threshold levels for different species and physiological states of animals include the CAST Task Force Report referenced on the slide and *A Guide for Grain Elevators, Feed Manufacturers, Grain Processors and Exporters* from the National Grain and Feed Association.

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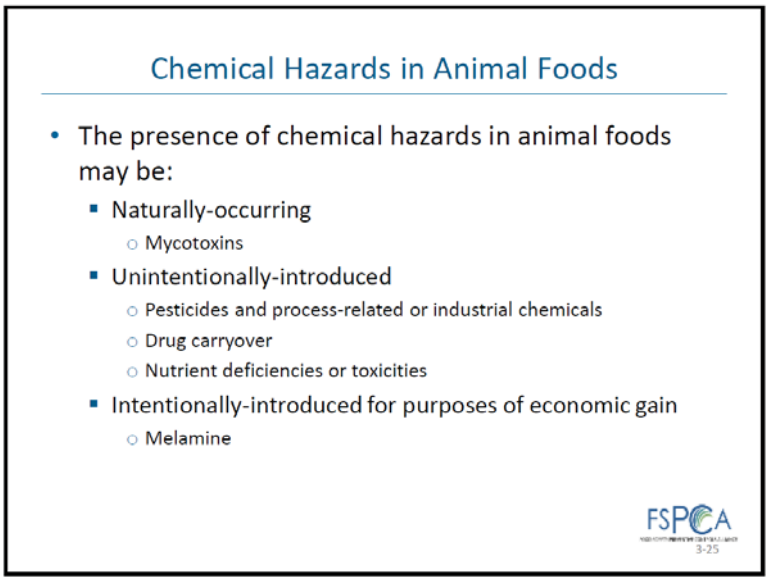
There are also FDA advisory or guidance levels for other mycotoxins, but they are less stringent than those for aflatoxin. Still, those mycotoxins may have dramatic impacts on animal health. Deoxynivalenol concentrations above threshold levels may result in vomiting, diarrhea, animal food refusal, and decreased milk production in animals. Fumonisins can also cause animal food refusal. Horses are particularly susceptible to fumonisins, as they can lead to equine leukoencephalomalacia, or ELEM. Because horses cannot metabolize the toxin well, concentrations greater than 2 parts per million (ppm) in food for horses may cause drowsiness, blindness, circling, staggering, and death within 48 to 72 hours. Ochratoxin A is known to result in mortality and decreased weight gain in many animals, as well as poor egg production and poor egg quality in layer chickens. The T-2/HT-2 described earlier can lead to mortality and infertility in certain species. Finally, zearalenone has been associated with estrogenic effects that lead to embryonic death and the inhibition of fetal growth, as well as infertility. These symptoms are most commonly observed in swine, but can occur in other species.

The type and concentration of a mycotoxin – as well as its interaction within each animal species – impact the likeliness for its consideration as a hazard. The hazard analysis must consider temporal conditions, particularly in the case for mycotoxins, as their presence may change due to geographical location and annual environmental conditions.



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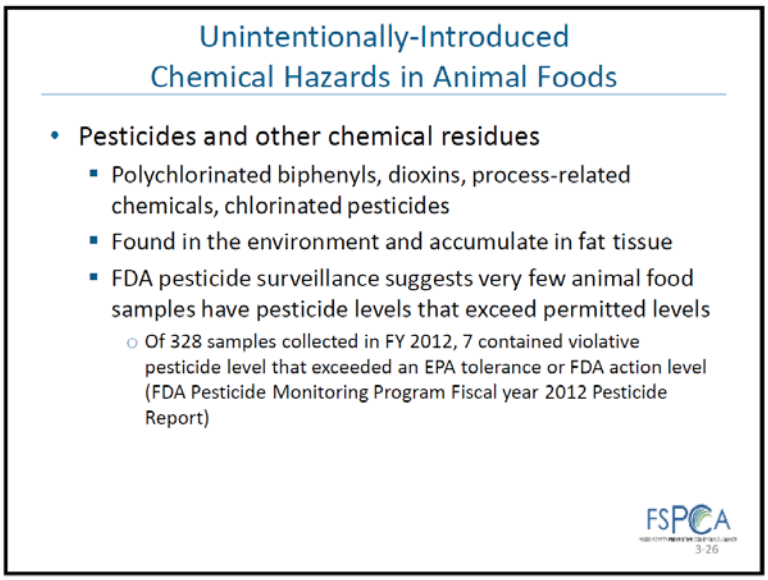
While mycotoxins are an example of chemical hazards that are naturally occurring, some hazards are unintentionally-introduced by humans or the manufacturing process. These include pesticides and process-related or industrial chemicals, drug carryover, and nutrient deficiencies or toxicities.



Compliance Policy Guide Sec. 575.100 Pesticide Residues in Food and Feed contains information for the maximum amount of a pesticide residue that may be present in raw agricultural commodities and animal food.

The 7 violative pesticide levels included *o*-phenylphenol in chicken food and raisin pomice, piperonyl butoxide in soybean meal, acephate in vitamin E, pirimiphos-methyl in soluble wheat protein, and diphenylamine in canola meal.

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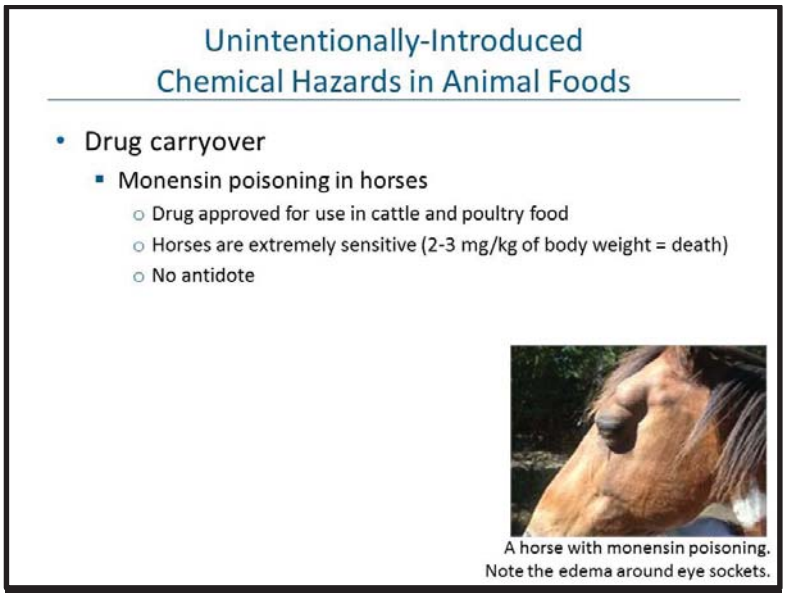
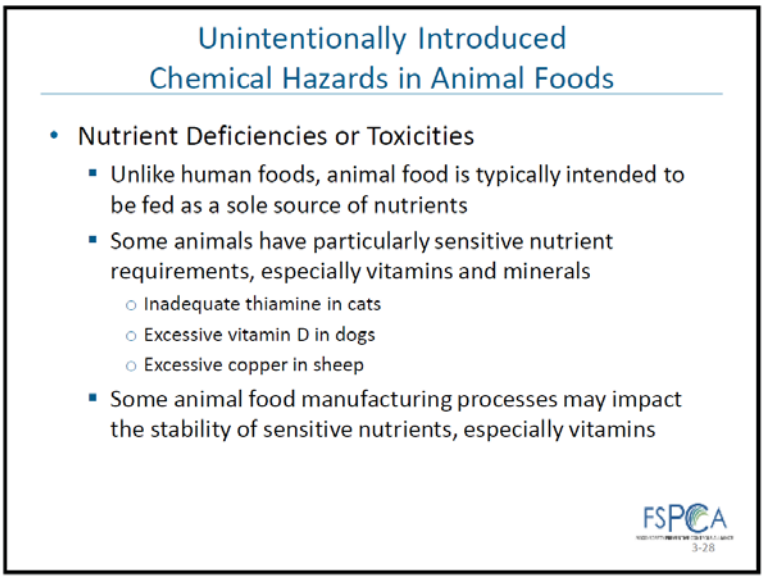
Pesticides may be introduced by direct contamination from facility pesticide programs, from contaminated grains, or from contamination of animal-based products due to tissue accumulation. Dioxins and process-related chemicals, such as chlorinated pesticides, are toxic industrial pollutants that may be found in the environment and accumulate in fat tissue. While these are all concerns, FDA pesticide surveillance suggests that a very small percentage of animal food have pesticide levels that exceed permitted levels. For example, of 328 animal food samples collected in fiscal year 2012, seven contained violative pesticide levels that exceeded an EPA tolerance or FDA action level (FDA Pesticide Monitoring Program Fiscal year 2012 Pesticide Report).



Slide 27

Drug carryover is also a chemical hazard that is usually unintentionally-introduced. All medicated animal foods must be manufactured and distributed in accordance with the Current Good Manufacturing Requirements that are found in 21 CFR Part 225. An example of a drug carryover hazard is monensin poisoning in horses. Monensin sodium is an animal drug approved for use in cattle and poultry. However, there have been instances of monensin contamination in food for horses, where it is very toxic with 2 to 3 mg per kg of body weight likely resulting in death. Early stages of monensin poisoning in horses include elevated heart rate, muscle wasting, and edema, or swelling, around the eyes. Because monensin sodium is so toxic to horses, particular care must be used when a facility manufactures food for horses and animal food containing monensin sodium. This may include procedures to minimize the carryover of monensin from one batch of animal food to the next, such as the use of sequencing or flushing procedures.



The nutrient deficiencies or toxicities used in this chapter are those listed directly in the Preventive Controls for Animal Food rule as examples. These nutrient deficiencies and toxicities have caused animal illness in the past.

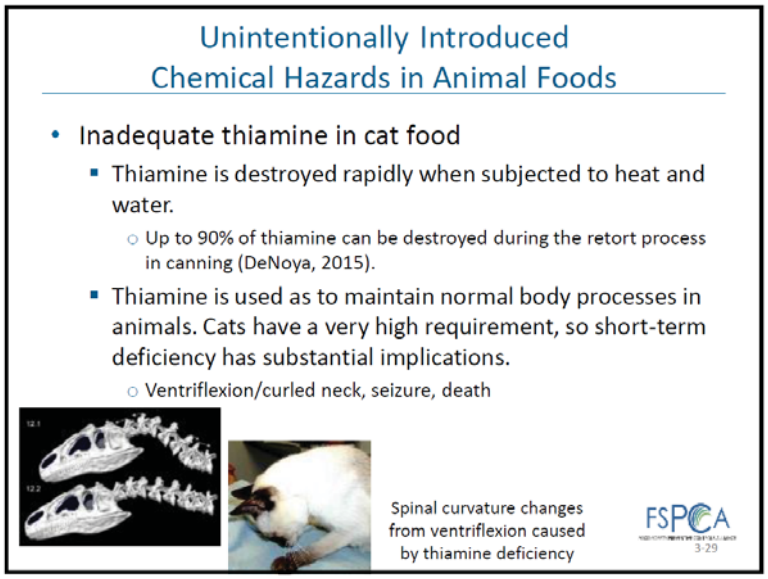
Slide 28

Other unintentionally-introduced chemical hazards may include nutrient deficiencies or toxicities. This is a hazard category that is unique to animal food because nutrient deficiencies or toxicities are a greater risk in animals than humans.

Consider this example: humans may reach their nutrient requirements through a variety of foods consumed throughout the day. For example, a person may choose to eat a serving of fruit, protein (eggs or bacon), and carbohydrate (toast) for breakfast, a salad full of nutritious vegetables and protein (chicken) for lunch, and have a dinner including a serving of protein (beef), carbohydrate (potatoes), dairy (glass of milk), and healthy fat (cheese).

Meanwhile, a single bag of animal food may be the single source of nutrients for an animal over a number of days or weeks. Therefore, it is essential that the diet be wholesome and safe – but also meet the animal's nutrient requirements.

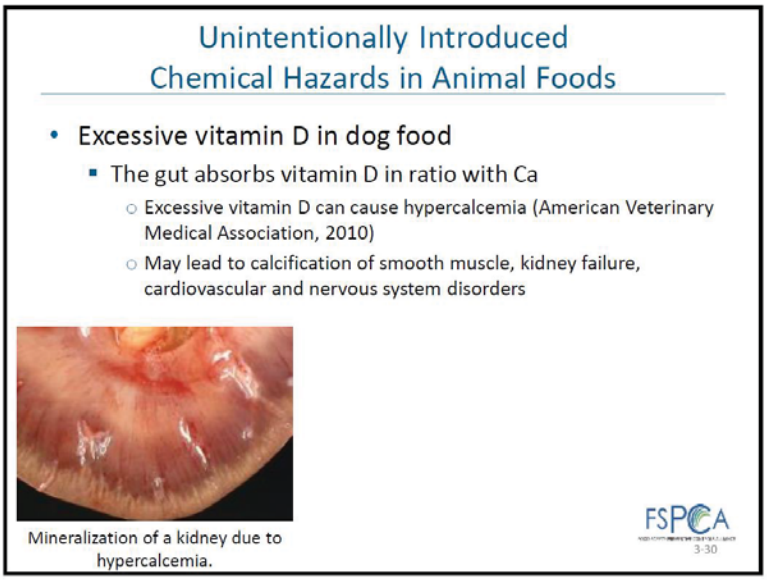
Some animals have particularly sensitive nutrient requirements, especially to vitamins and minerals. For example, common nutrient deficiencies or toxicities that will be discussed are inadequate thiamine in cats, excessive vitamin D in dogs, and excessive copper in food for sheep. In addition to the animal's sensitivity to the nutrient, some animal food manufacturing processes may impact the stability of sensitive nutrients, such as vitamins, and lead to nutrient deficiencies.



Slide 29

Thiamine, sometimes referred to as vitamin B1, is a vitamin that is considered an essential nutrient for many animal species. Essential nutrients are ones that cannot be produced by the body and that must be supplied to an animal at a minimum level to maintain healthy bodily functions. Thiamine is an essential nutrient for cats.

Thiamine has been demonstrated to be rapidly destroyed when subjected to heat and water. These are environmental conditions common to the commercial processes for canned cat food production, and up to 90% of thiamine may be destroyed during the retort process of manufacturing canned cat food. Thiamine deficiency in cats typically manifests itself as ventriflexion, or a curled neck as shown in the picture, followed by seizure and death. Careful maintenance and monitoring of thermal processing parameters are necessary to maintain maximum thiamine activity in cat food.



It is accepted that many nutrients, particularly many vitamins and minerals, are very difficult to analyze consistently. The Association of American Feed Control Officials (AAFCO) Official Publication lists acceptable analytical methods and range of analytical variation for various nutrients and drugs.

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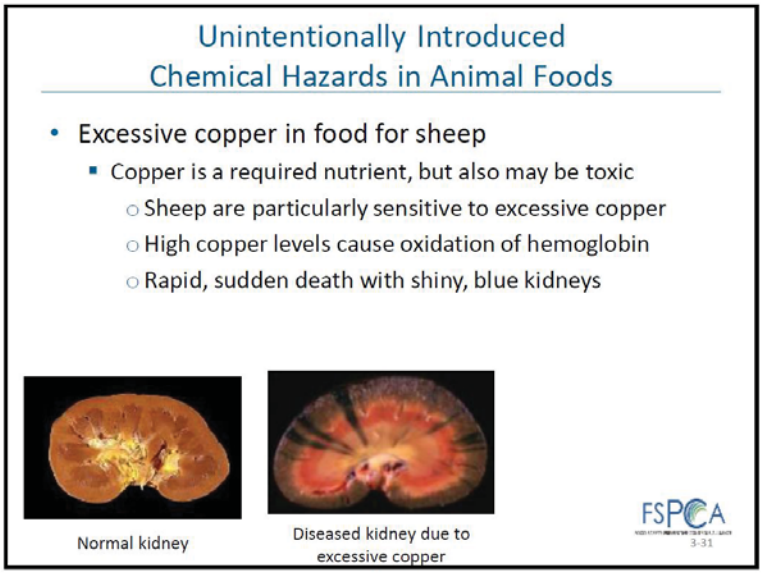
Although some essential nutrients must be fed at a minimum level for proper body function, some essential nutrients can be toxic to animals when fed at high levels. Having too much of a vitamin can be a hazard as well. Excessive vitamin D has been recognized as a potential hazard in dog food. Because the digestive tract absorbs vitamin D in proportion to the quantity of calcium, over-consumption of vitamin D by dogs causes excessive Ca absorption. This ultimately may lead to hypercalcemia, or hardening, of smooth muscle. Further impacts may include kidney failure and disorders of the cardiovascular and nervous system.



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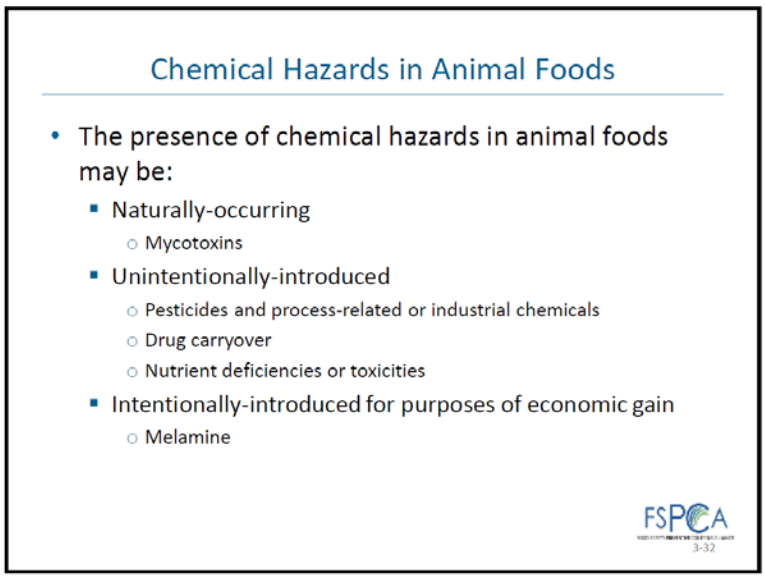
Copper is required, but also potentially toxic, for all animal species. Because molybdenum is responsible for clearing copper from the liver, an overconsumption of copper in ratio to molybdenum may lead to copper toxicity and oxidation of hemoglobin. Copper toxicity can be both chronic and acute. This means that the accumulation of the mineral in the liver can cause toxicity if lower, but still toxic, levels are fed over many days or weeks. However, rapid, sudden death can occur from very high doses in a matter of hours. The picture in the slide shows two kidney, one that is healthy, and one that is shiny and blue in color due to the oxidized hemoglobin that is characteristic of copper toxicity.

While all species may be impacted by copper toxicity, sheep are particularly sensitive to excessive copper because they have inherently lower molybdenum concentrations compared to other species. A typical sheep diet of 20% grain and 80% forage contains approximately 15 ppm copper with no added copper. When molybdenum levels are approximately 3 ppm, the tolerance level of copper for sheep is typically 20 to 25 ppm. Sheep fed diets with lower molybdenum levels would have a lower copper tolerance.



When considering hazards intentionally introduced for purposes of economic gain, a facility is not expected to consider all possible hazards that could fit this category. The preamble of the *Preventive Controls for Animal Food* rule states, "…the requirement to consider hazards intentionally introduced for purposes of economic gain is narrow. Such hazards will be identified in rare circumstances, usually in cases where there has been a pattern of economically motivated adulteration in the past."

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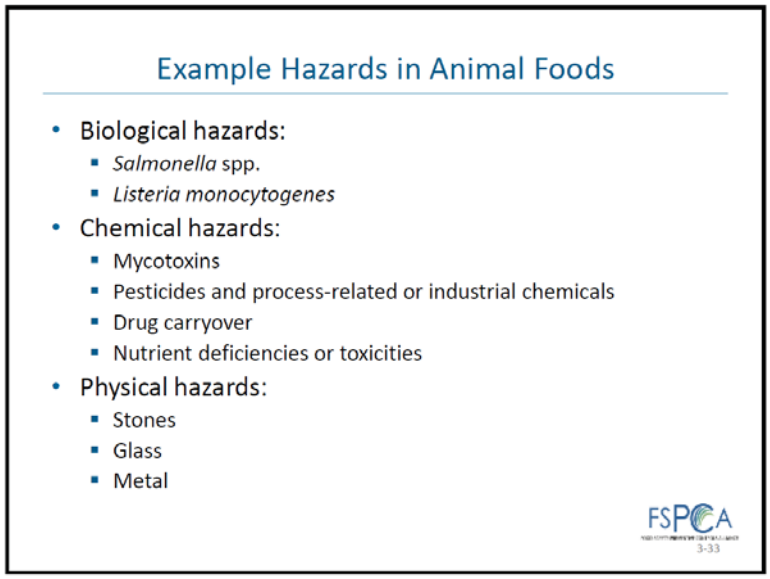
The focus to this point has been on chemical hazards that occur naturally or are unintentionally-introduced, however, there is the rare activity where a hazard is intentionally-introduced for purposes of economic gain. The most well-known example of this was the pet food recall in 2007 due to melamine contamination. This wide recall was due to a single overseas supplier that blended melamine into product labeled as wheat gluten to elevate the crude protein level of the ingredient. The ingredient was later purchased by pet food manufacturers. The combination of melamine with cyanuric acid in the ingredient resulted in more than 8,500 reported animal deaths. The original intent of adding the melamine was to falsify protein content. The unexpected result was that it created a major animal food safety concern. This was a clear incident when a supplier intentionally introduced a hazard for economic gain. Using visual inspection and verified suppliers may have prevented this hazard from entering the animal food supply.



Slide 33

Now that biological and chemical hazards have been discussed, the focus will shift to the final category, physical hazards.

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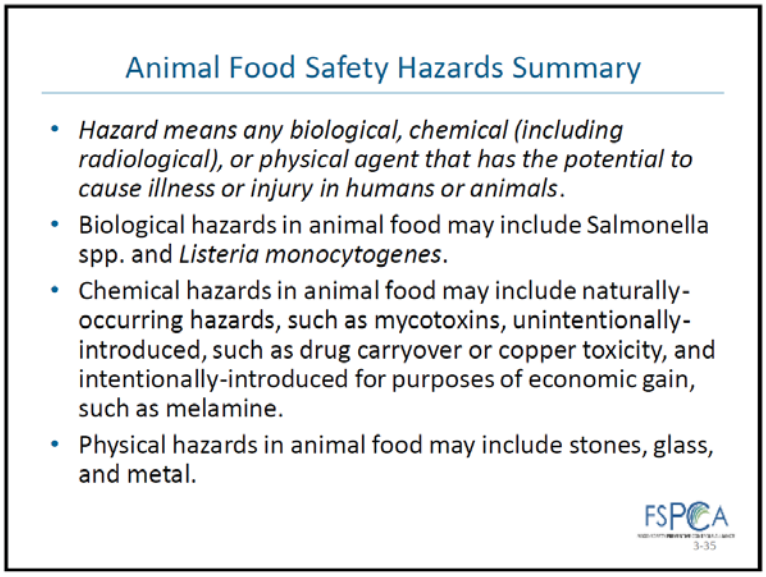
Physical hazards, when present, may result in animal illness or injury. Typically, physical hazards in animal food are not associated with human health concerns, but they are concerns for the animals consuming the food. These physical hazards can include items like stones, which may be introduced with ingredients from fields and cause choking or broken teeth in animals. Broken glass may be introduced from broken light bulbs or other glass in the ingredient or animal food manufacturing facility and result in cuts to the animal. Finally, metal may be introduced at a number of locations because nearly the whole animal food manufacturing process occurs using equipment with metal parts. Metal can result in several injuries to animals when consumed, such as cuts or broken teeth.



Slide 35

That ends our discussion on animal food safety hazards. Remember that a hazard is defined as *any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.* Biological hazards in animal food may include *Salmonella* spp. and *Listeria monocytogenes*. Chemical hazards may include naturally-occurring hazards, such as mycotoxins, unintentionally-introduced hazards, such as drug carryover and copper toxicity, and intentionally-introduced for purposes of economic gain, such as melamine. Finally, physical hazards in animal food may include stones, glass, and metal. Now that the participants have a fuller understanding of hazards associated with different types of animal foods, the next chapter will describe the hazard identification and evaluation process.