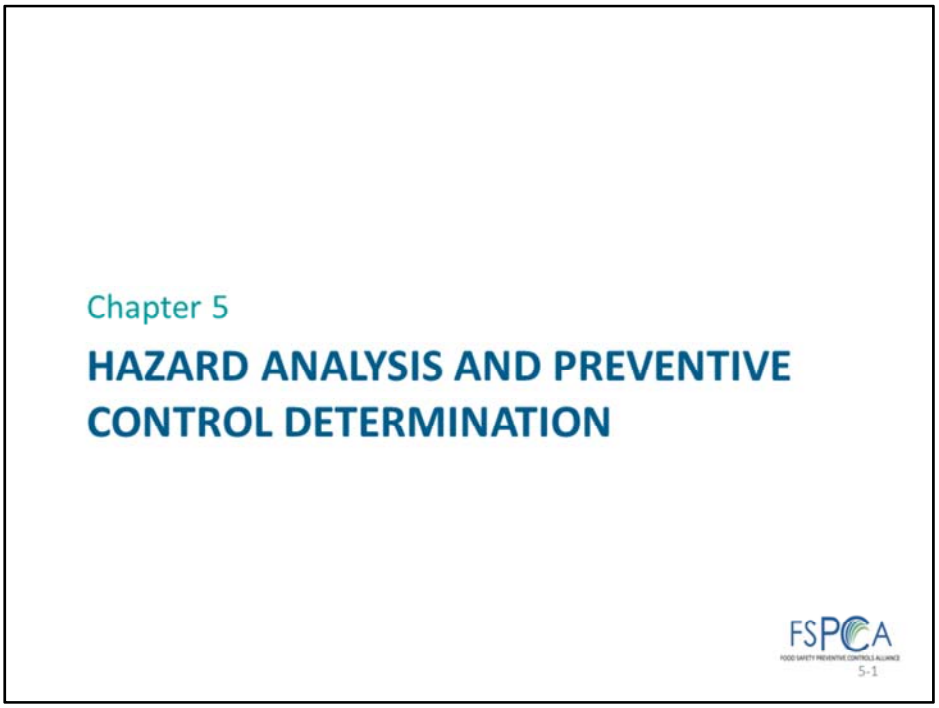
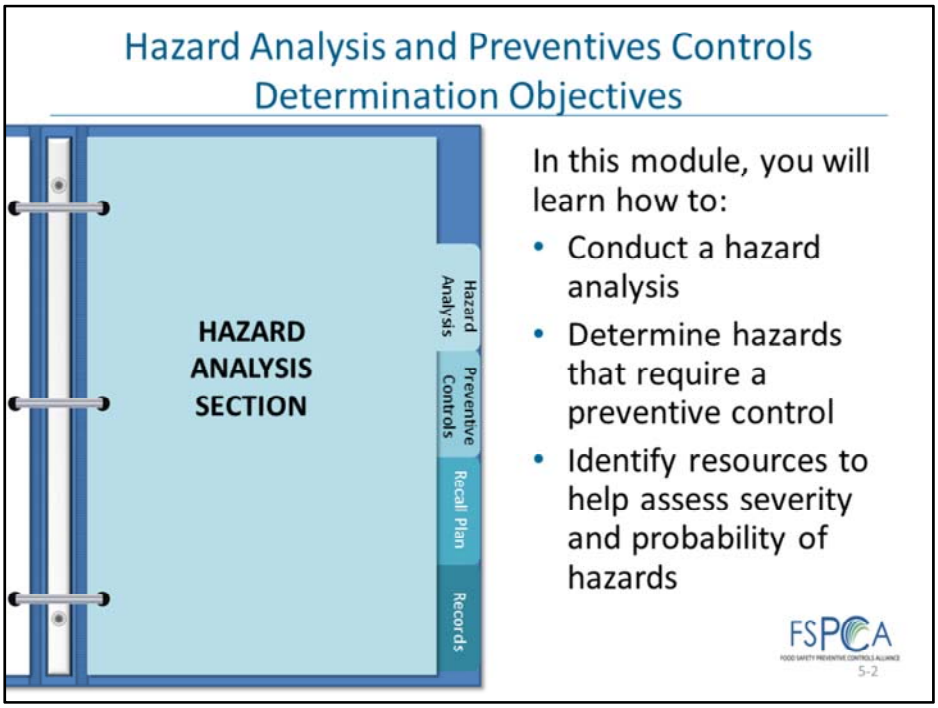
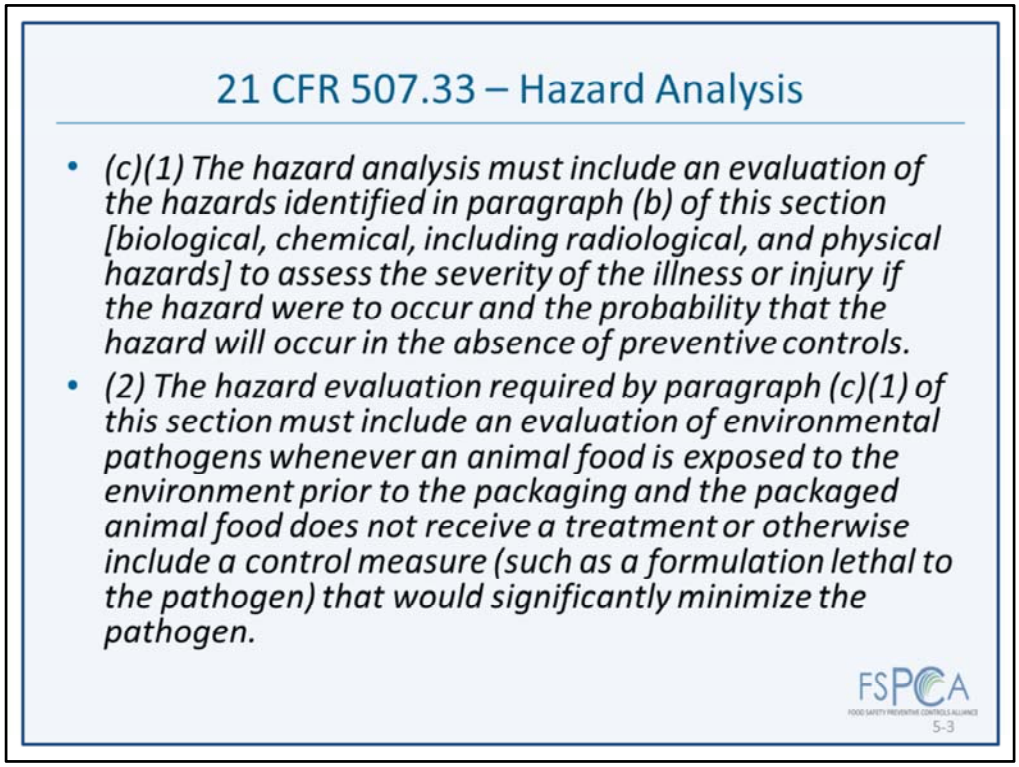


While Chapter 3 discussed examples of hazards that may be considered by facilities, this chapter will help describe how to go through the hazard identification and evaluation process. This information is vital as a thorough hazard analysis is the foundation for the creation and implementation of a successful Food Safety Plan.

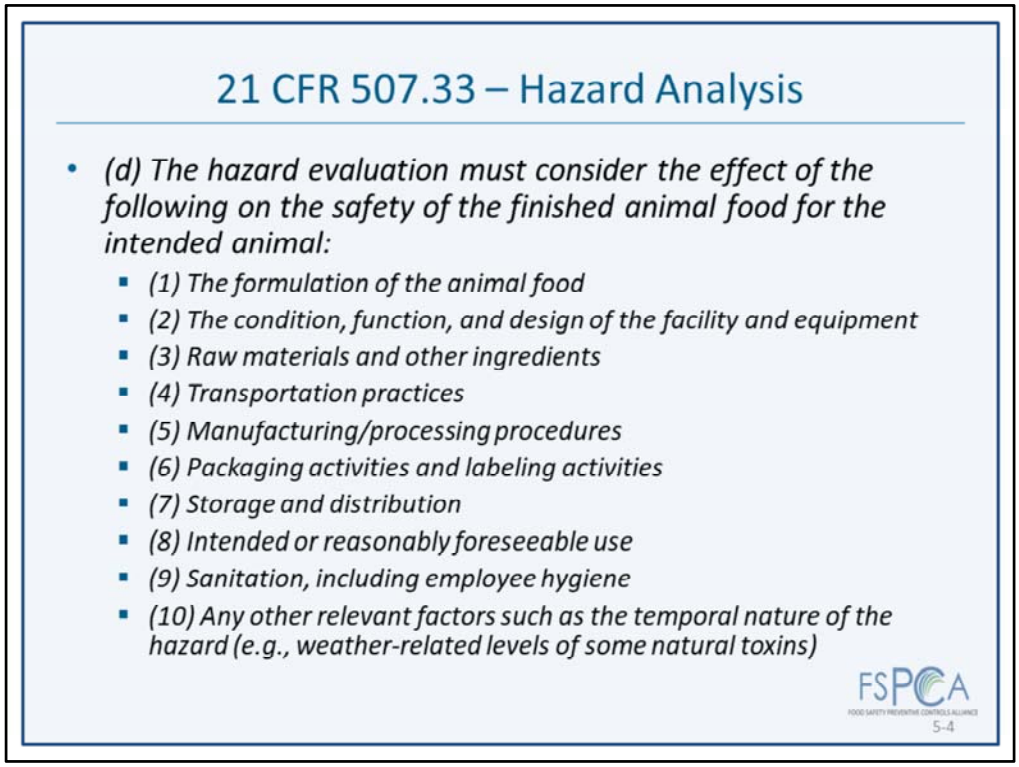


In this chapter, participants will learn how to conduct a hazard analysis, to determine hazards that require a preventive control, and what resources are available to make this determination. These determinations are made by the Preventive Controls Qualified Individual (PCQI) in coordination with the facility's food safety team (as appropriate), and depend upon factors such as the specific animal food ingredients being used, the facility's operation and design, and the intended use of the animal food. The PCQI, in conjunction with the facility's food safety team, will utilize experience, training, and other resources to make these determinations. The requirements for conducting a hazard analysis are found in 21 CFR 507.33, which is found on page 56345 of the *Preventive Controls for Animal Food* rule.

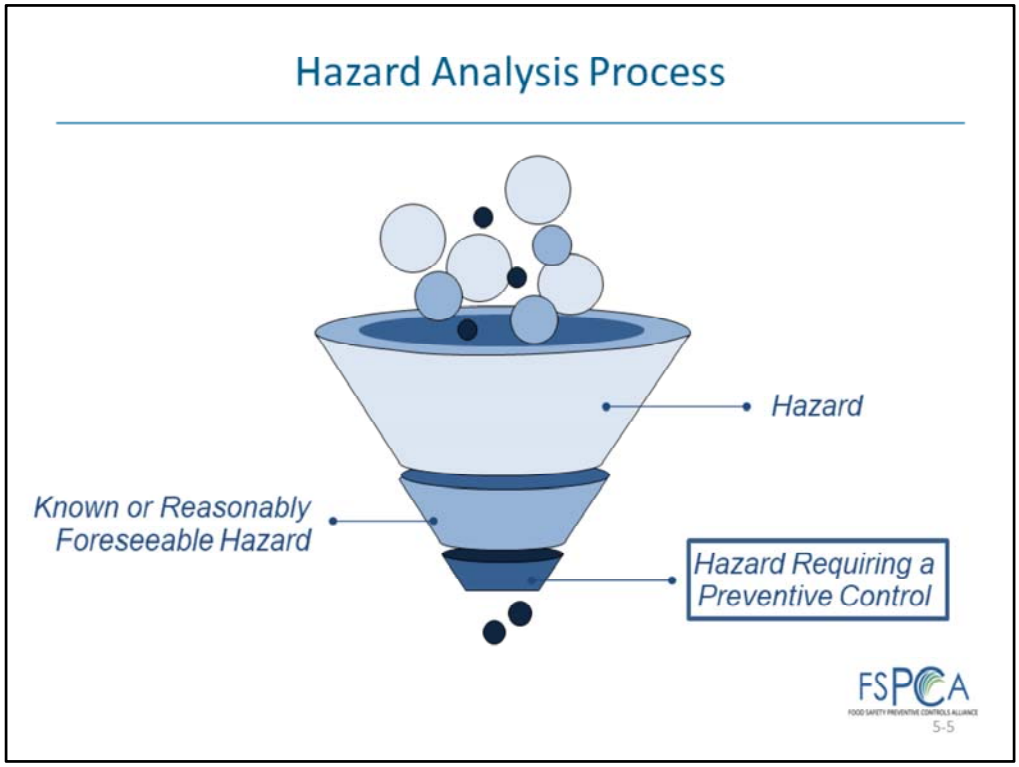


In Chapter 3: Animal Food Safety Hazards, the requirement for hazard identification in 21 CFR 507.33(a) and (b) is discussed. This chapter will focus more on hazard evaluation, and the regulatory requirements for this process are outlined in this slide. Hazard evaluation must include an analysis of both severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

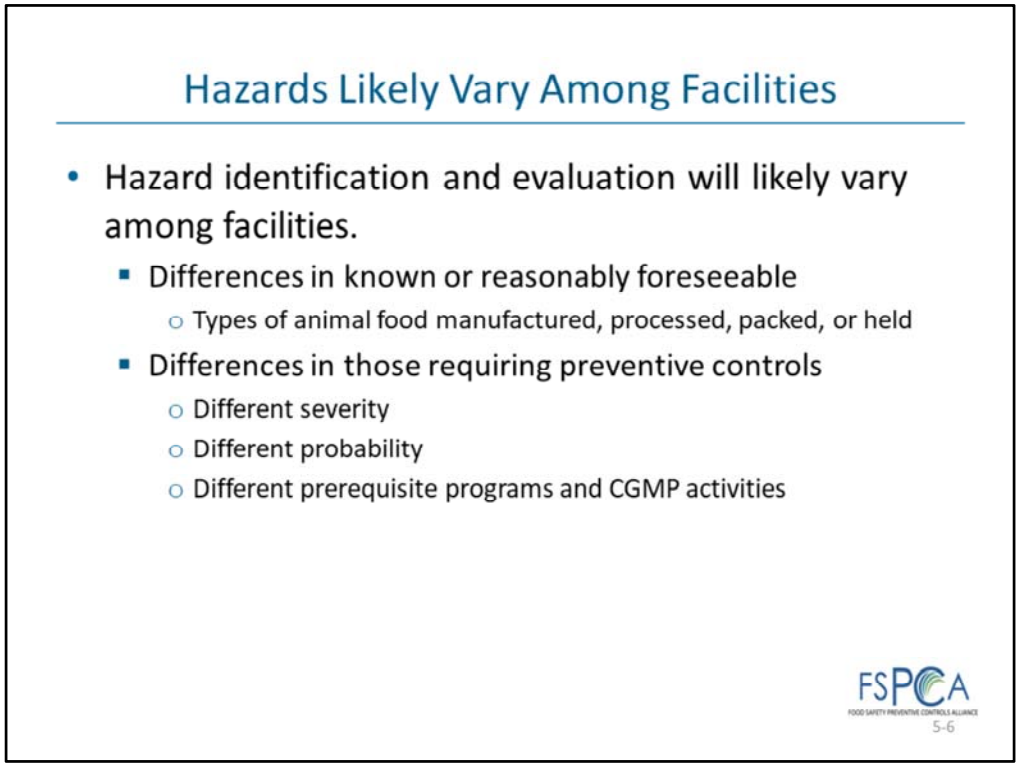
Environmental pathogens must be considered if animal food is exposed to the environment prior to packaging and does not receive a control measure that significantly minimizes the pathogen.



There are a number of factors that must be considered when evaluating the safety of finished animal food. Those are listed in this slide and will be discussed more in depth during this chapter.

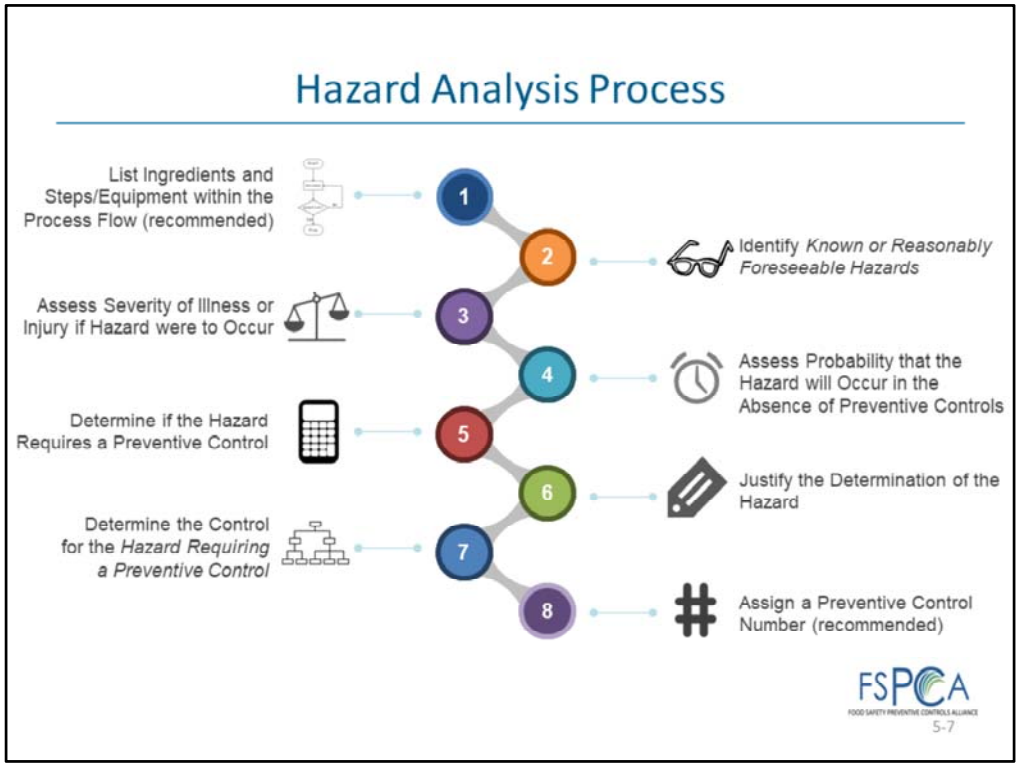


In Chapter 3, the curriculum first introduced the difference between the defined terms *hazard*, *known or reasonably foreseeable hazard*, and *hazard requiring a preventive control*. This chapter will fully describe the necessary steps to conduct the analysis of a *known or reasonably foreseeable hazard* to determine if it falls into the narrowest category of those defined terms, which is a *hazard requiring a prevent control*.



It is important to remember that the hazard evaluation process is likely to change from one facility to another. Because the types of animal food manufactured, processed, packed, or held will vary from one facility to another, the types of hazards that are known or reasonably foreseeable are likely to change. Furthermore, facilities that have similar *known or reasonably foreseeable hazards* may have other variables that impact the hazard evaluation. For example, the types of ingredients used, reasonable or intended use of the animal food, facility and process design, equipment, and environment may impact the severity and/or probability for the hazard.

Just as the identification and evaluation of a hazard can vary from one facility to another, a hazard's control can also be handled differently. Where one facility chooses to employ a combination of Supply-Chain-Applied Controls, Process Controls, and/or Sanitation Controls to address a single hazard, another may choose to utilize only one of those. Other facilities may use prerequisite programs, such as CGMPs, to reduce the probability of hazard occurrence to a sufficient level where the hazard does not require a preventive control. Remember that the ultimate goal is that safe animal food is produced. As long as that goal is being met, the variation in control methods among facilities is acceptable and expected given the flexibility of the *Preventive Controls for Animal Food* rule.

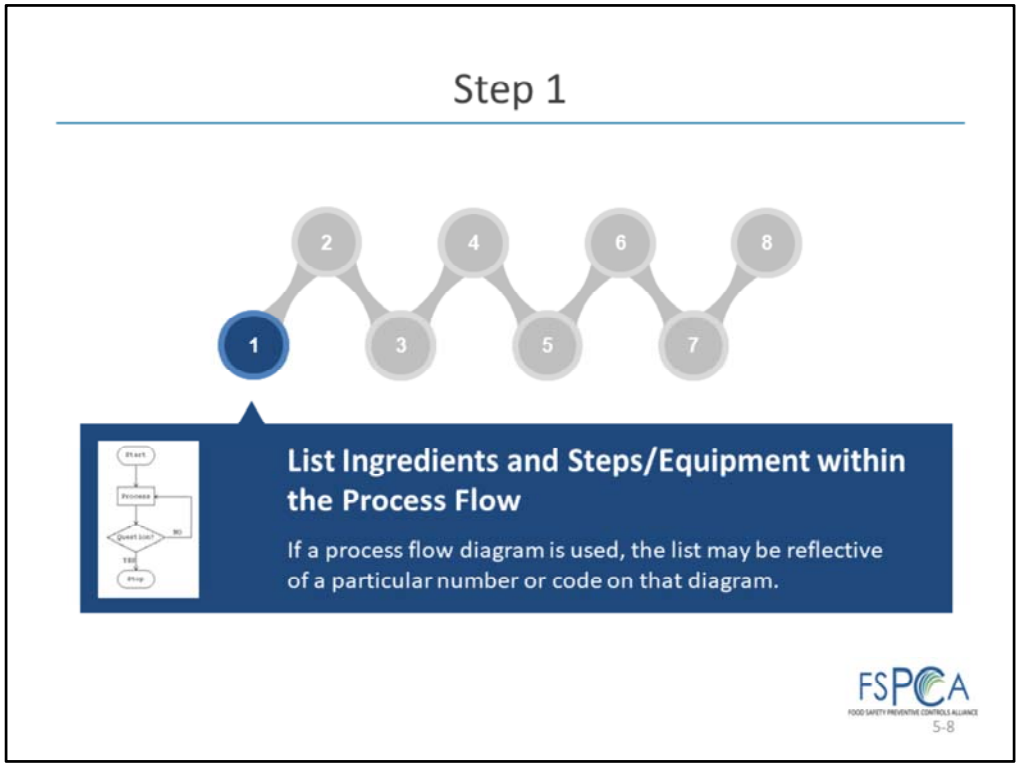


This slide shows a summary graphic of the hazard analysis process.

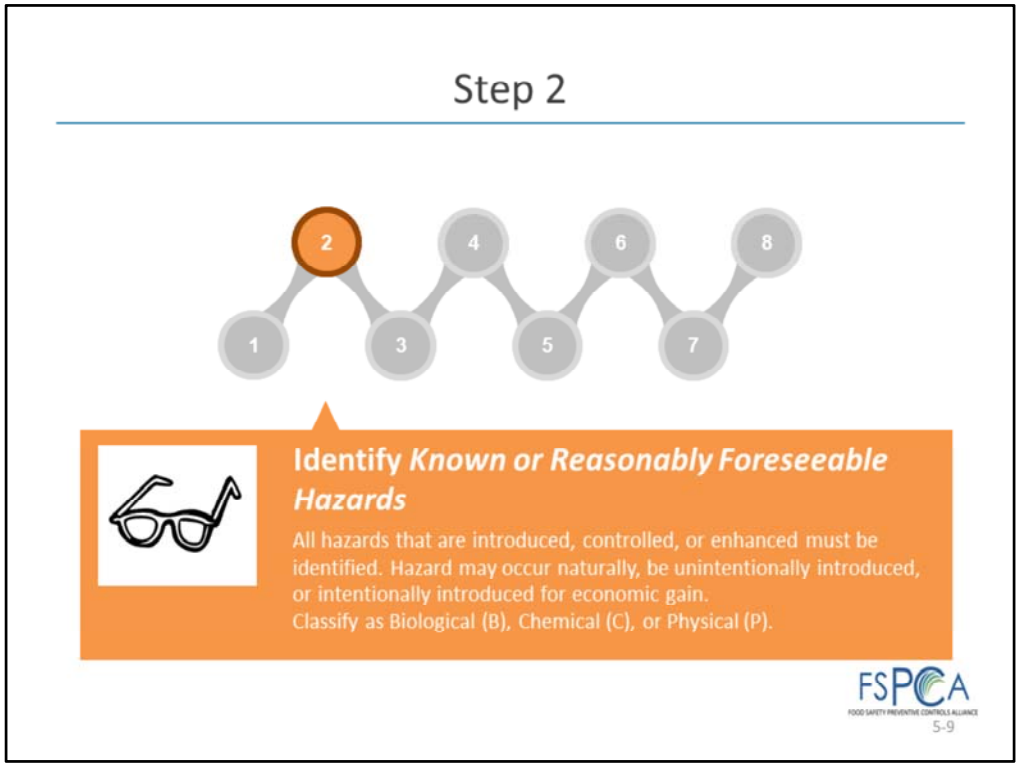
Step 1: Use a flow diagram to identify steps and/or processing equipment (recommended)
Step 2: Identify known or reasonably foreseeable hazards associated with the type of animal food a given facility manufactures, processes, packs, and/or holds
Step 3: Assess known or reasonably foreseeable hazards for severity of illness or injury if the hazard were to occur
Step 4: Assess known or reasonably foreseeable hazards for probability that the hazard will occur in the absence of preventive controls
Step 5: Determine if the hazard requires a preventive control based on Steps 3 and 4
Step 6: Justify the determination made in Step 5
Step 7: Determine the appropriate control for the hazard requiring a preventive control
Step 8: Assign a preventive control number for traceability and identification purposes (recommended)

This slide is a snapshot of the required steps for hazard analysis and preventive controls determination. The rest of this chapter will focus on hazard identification and evaluation steps. The control measures and their management components will

be discussed in detail in later chapters.



A flow diagram is a useful starting point for hazard identification. There are a variety of ways to use the flow diagram, such as by listing equipment directly or by listing the equipment by number or code. Ingredients and equipment can be considered individually or as logical groupings. For example, various grain by-products, such as corn distillers' grains with solubles and corn gluten meal, may be utilized by the facility and have similar hazards. Thus, they may be listed individually or grouped by collective terms when appropriate. Example grouping categories may be: grains, grain by-products, fats, receiving, conveying, storage, batching/mixing, pelleting/cooling, and load- out.

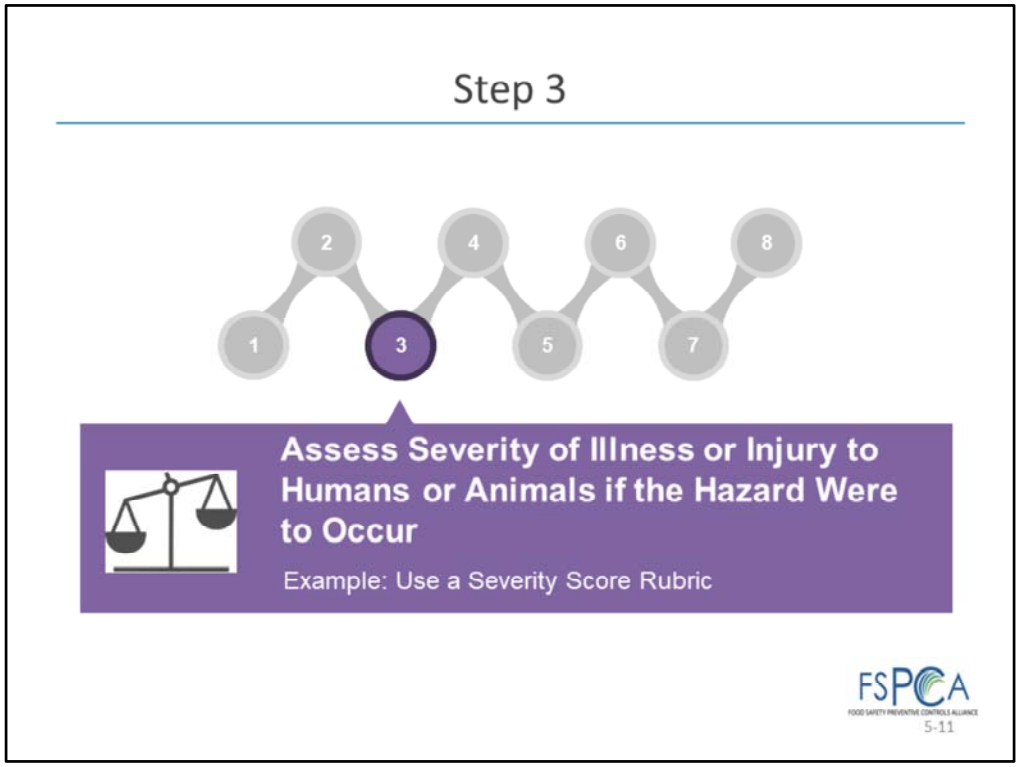


For each ingredient or processing step category, the facility must identify *known or reasonably foreseeable hazards*. This may be accomplished by listing biological, chemical, or physical hazards associated with each ingredient or processing step identified in Step 1. These hazards may occur naturally (such as aflatoxin), be unintentionally introduced (such as metal fragments), or intentionally introduced for economic gain (such as melamine). There is a specific definition for a *known or reasonably foreseeable hazard*, and it centers on the known or potential association of a hazard with the facility or the type of animal food being manufactured, processed, packed, or held.

Some facilities may choose to start with a broad list of hazards through a brainstorming session and narrow it to those that are known or reasonably foreseeable for their facility and animal food. Thus, some facilities may have a hazard that is *known or reasonably foreseeable*, while another may not consider the hazard to meet this threshold. For example, a pet food manufacturing facility may consider *Listeria monocytogenes* to be known or reasonably foreseeable, while a facility manufacturing food for poultry may not even though they use some common ingredients.

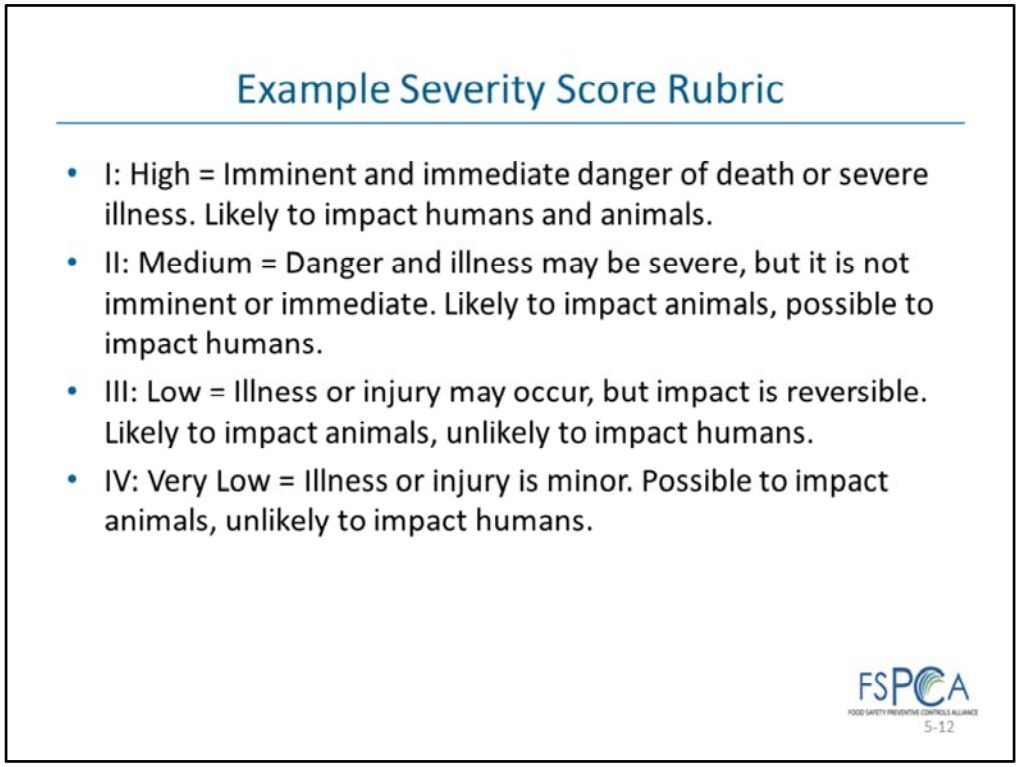
There are a several items that must be considered when evaluating a *known or reasonably foreseeable hazard*. The facility must consider the items above when determining the safety of the animal food.

These considerations are largely a collection of the root cause(s) of hazards that have previously caused illness or injury in humans or animals. For example, improper formulation to reach a specific pH, raw materials and ingredients, and manufacturing/processing procedures may be linked to animal food not meeting the nutritional requirements of an intended species leading to a nutrient deficiency or toxicity hazard. Poor functionality of the equipment or design of a facility may result in physical contamination of the animal food, such as metal in the animal food, or improper mixing causing nutrient deficiencies or toxicities. Improper sanitation or housekeeping, storage, or transportation may lead to cross-contamination of animal food that may lead to a hazard. Finally, specific weather conditions during the growing season of crops may result in a greater likelihood of chemical hazards, such as mycotoxins.



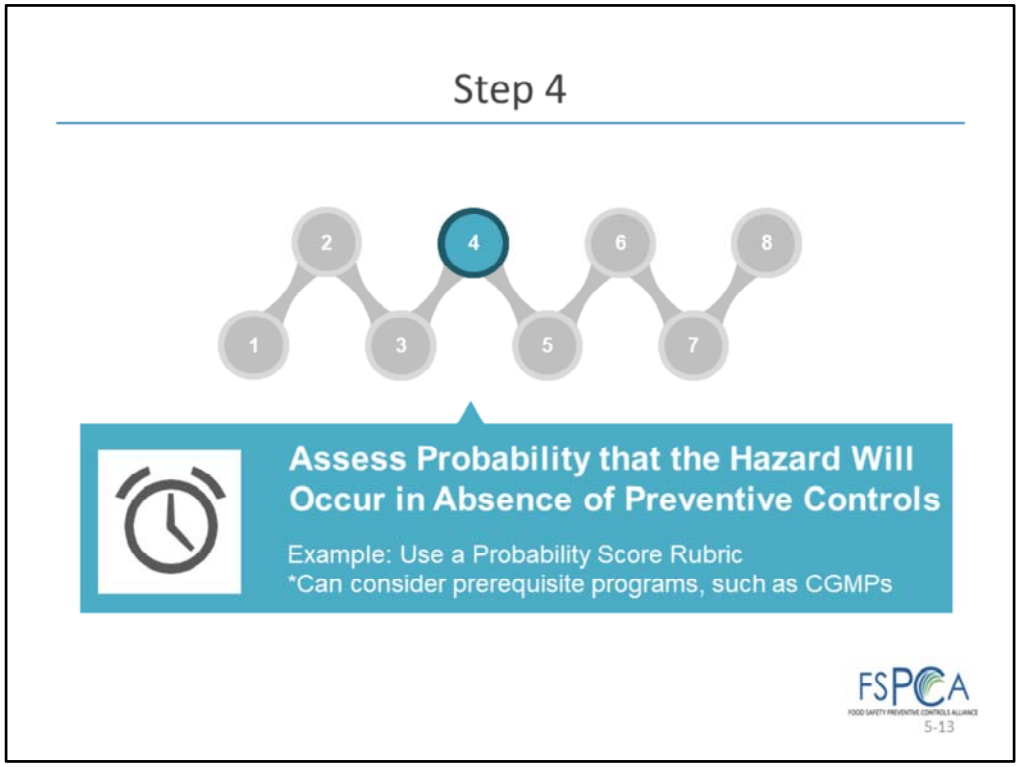
Once hazards have been identified as known or reasonably foreseeable, the hazard evaluation process begins. This is where the facility must assess both the severity and probability of a hazard to humans and animals to determine if the hazard requires a preventive control. How this determination occurs may vary.

One example method to assess the severity of an illness or injury if the hazard were to occur is through the design and use of a severity assessment process where different levels of severity are designated with an alphanumeric key, also referred to as a rubric. This key may consider a number of items, such as the likelihood of mortality or morbidity, whether the hazard affects only animals or also humans, and the number of animals or humans potentially affected if a hazard were to occur.

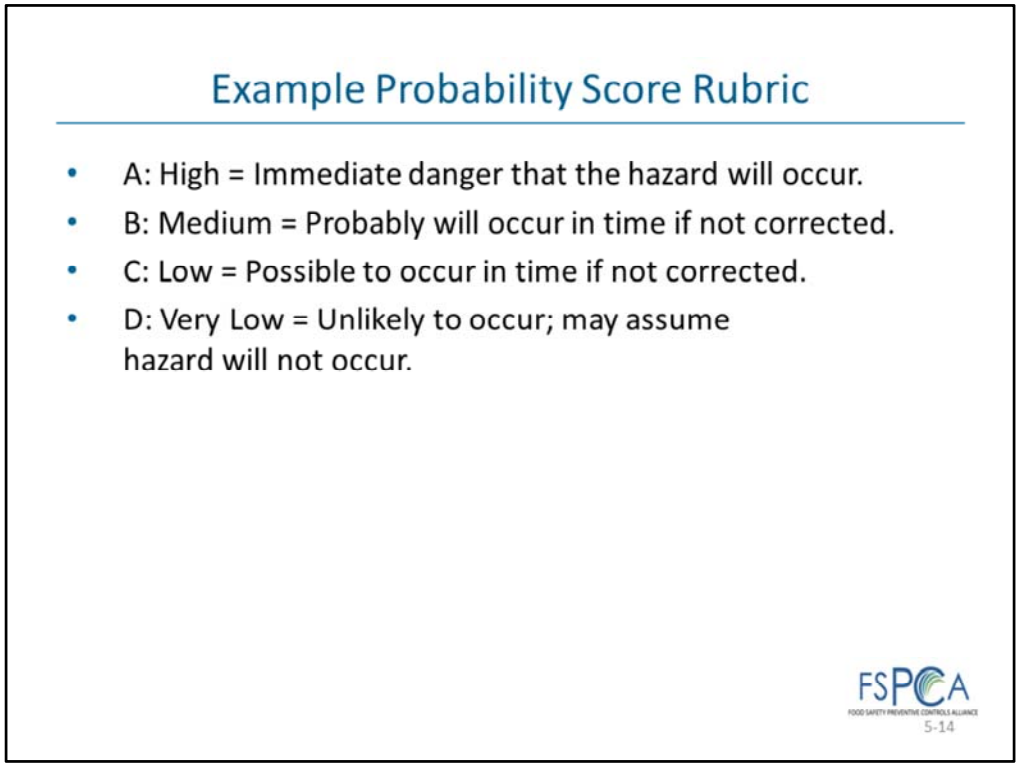


In the example shown here, roman numerals are used to designate severity level.

I = high severity, meaning they would cause imminent and immediate danger of death or severe sickness. This hazard is likely to impact both animals and humans.
II = medium severity; danger and sickness may be severe, but it is not imminent or immediate. The hazard is likely to impact animal health, but only potentially affects human health.
III = low severity; illness or injury may occur, but the impact is reversible. The hazard is likely to impact animal health, but is unlikely to affect human health.
IV = very low severity; sickness or injury is minor. The hazard has potential to impact animal health, but is unlikely to impact human health.

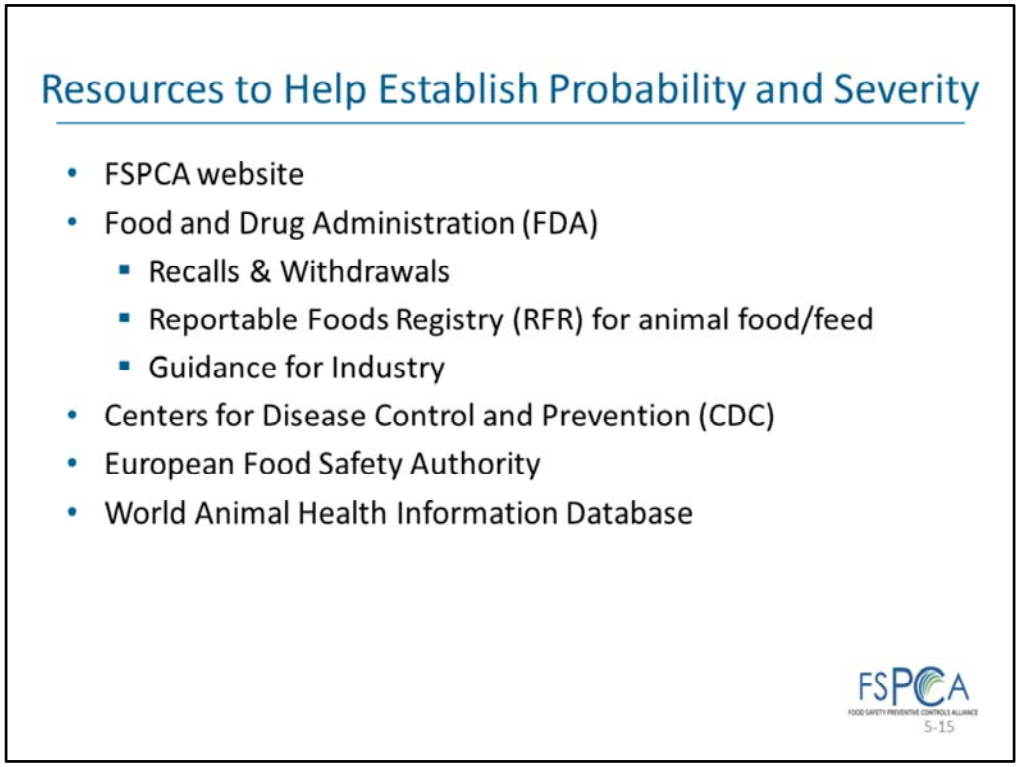


In addition to severity, the probability that the hazard will occur in the absence of preventive controls must also be assessed. Remember that this assessment may take into account prerequisite programs, such as CGMPs, that may help reduce the probability of hazard occurrence. When assessing probability, the facility may choose to employ a scheme using a probability score assignment that is similar to that described for the severity score.



In the example used here, letters are used to represent probability of occurrence.

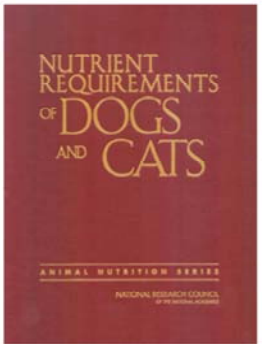
A represents a high probability of occurrence; immediate danger that the hazard will occur if no mitigation measure is applied.
B designates a medium probability of occurrence; the hazard probably will occur in time if no mitigation measures are applied.
C designates a low probability of occurrence; it is possible for the hazard to be present in the animal food if no mitigation measures are applied.
D designates a very low probability of occurrence; it would be unlikely for the hazard to be present in the animal food, or it could be assumed the hazard will not be present in the animal food.



As can be imagined, the assessment of severity and probability is extremely important. When conducting this assessment, the facility will likely need to rely on its own experience and the historical occurrence of hazards within the facility. However, other resources should be used to help make this assessment, especially for the written justification. Many of these resources have been gathered on the website for the Food Safety Preventive Controls Alliance (FSPCA) for reference. There is information available from the FDA, including recalls and withdrawals associated with animal food and Reportable Food Registry (RFR) data for animal food/feed. The FDA will also be publishing several "Guidance for Industry" documents associated with this rule and links to those will be on FDA's FSMA website upon their availability. Outbreak data associated with animal food can be found from the CDC. The European Food Safety Authority has a database of technical reports and guidance that may be helpful for a number of potential hazards. The World Animal Health Information Database is a comprehensive database of animal health and feed- associated disease event reports and health statuses on an international basis.

Resources to Help Establish Probability and Severity

- National Research Council Nutrient Requirements
- Association of American Feed Control Officials (AAFCO) Official Publication
- Feed Additive Compendium
- Peer-reviewed research publications
- Trade association whitepapers



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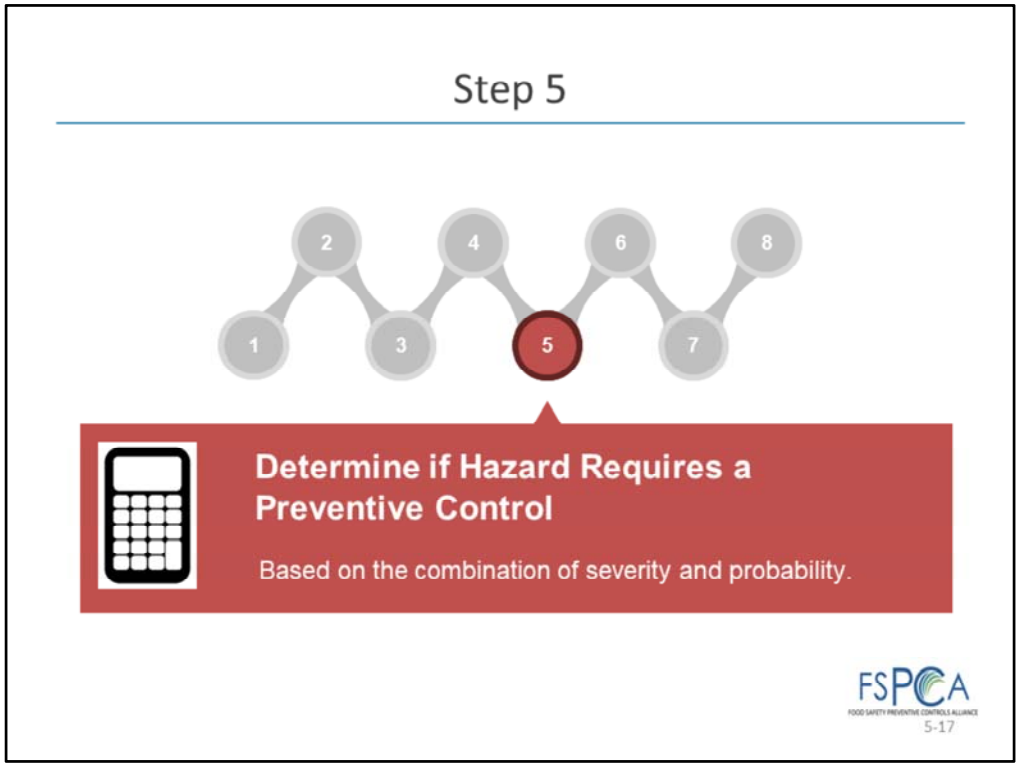
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
5-16

The National Research Council has publications updated on a regular basis regarding the nutrient requirements for various species, such as dogs and cats, beef cattle, dairy cattle, and swine. The Association of American Feed Control Officials, or AAFCO, Official Publication lists ingredient definitions, appropriate analytical methods, and has nutrient profiles for dog and cat food. The Feed Additive Compendium is an updated listing of regulatory and labeling requirements for feed additives, with a particular emphasis on animal drugs. Finally, peer-reviewed research publications and trade association white papers should be reviewed to understand the developing knowledge for different hazards, their severity, and their probability. Again, this is just a short list of some of the resources available that may be used when making an assessment of severity and probability. Many of these and other resources can be found on the FSPCA website.



The next step is to utilize the combination of severity and probability to determine if the hazard requires a preventive control. There are many different ways to make this assessment. We will show different ways to use the previous severity and probability rubrics in a matrix, but a specific score, rubric, or matrix is not required – just that the combination of severity and probability be considered when making the determination of a *hazard that requires preventive controls.*

Process to Identify Hazards and Controls

Hazard Evaluation Example

PROBABILITY \ SEVERITY		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

In this matrix, the severity assessment described on slide 5-12 is listed along the top, while the probability assessment described on slide 5-14 is listed along the left side. The combination of severity and probability make a grid. The combinations in the upper left corner of the matrix, or those with high severity and probability, are more likely to require a preventive control than those that are in the lower right corner of the matrix, or those with a very low severity and probability.

Moving towards the lower right corner, the facility is less likely to determine a need for a preventive control for the hazard. Even though the assessment may identify a hazard with a lower severity and/or probability, the facility may still determine that such a hazard is one for which they want to establish a preventive control based on a business decision.

Process to Identify Hazards and Controls

Hazard Evaluation Example

Critical | Moderate | Negligible

PROBABILITY \ SEVERITY		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

This is the same example as the previous slide but with a different way to use the same 2-way matrix. Some food safety teams may predetermine categories that represent health risks that are critical, moderate, or negligible. Potentially, their predetermined justification was that if hazards fall into the 'critical' category, which are marked in the darkest shade of gray, they would probably require a preventive control. Those hazards that fall into the 'moderate' category, marked by the medium shade of gray, may require a preventive control, or perhaps do not need a preventive control, but may require prerequisite programs, such as CGMPs, to reduce their probability. Finally, those hazards that fall into the 'negligible' category, marked by the lightest shade of gray, probably do not require a preventive control.

Even when utilizing the same 2-way matrix, one facility's determination to require a preventive control may be very different from another's. For example, the facility using this 2-way matrix may potentially be more accepting of risk, as not many of the classification boxes fall into the 'critical' category.

Process to Identify Hazards and Controls

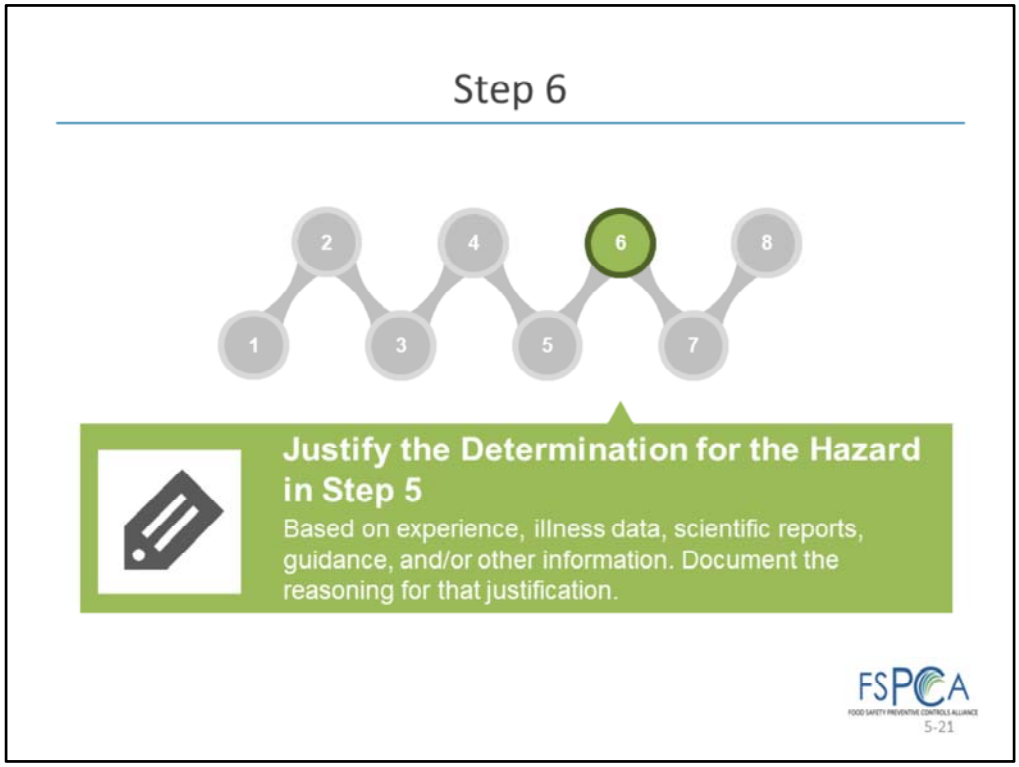
Hazard Evaluation Example

Critical | Moderate | Negligible

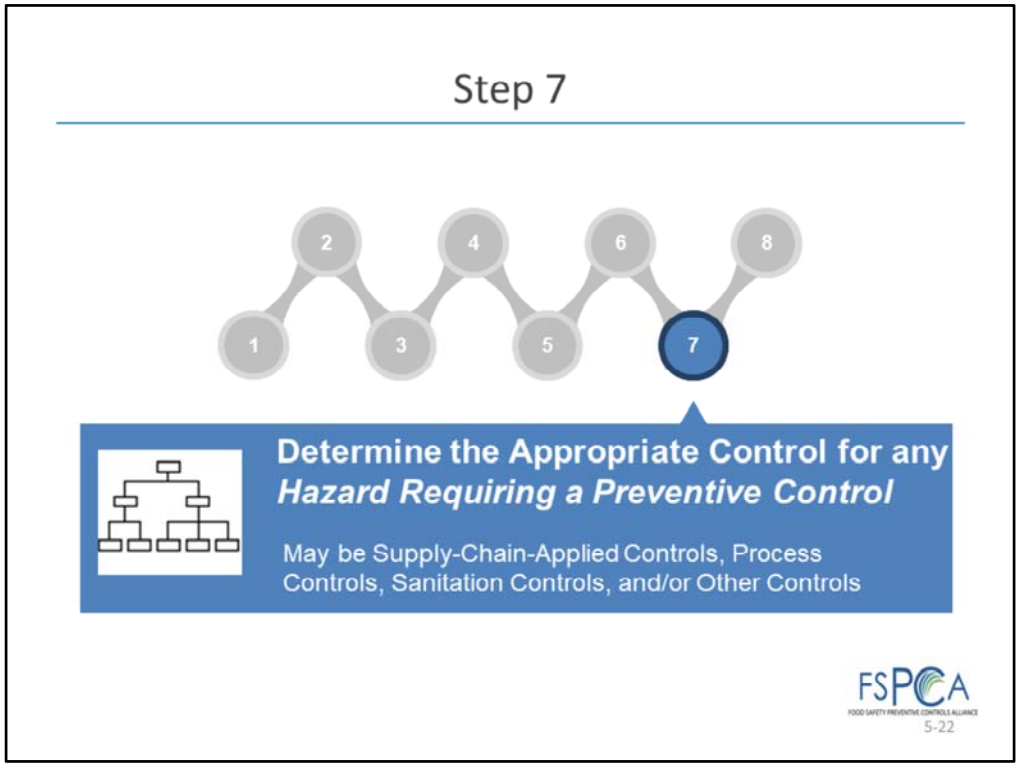
PROBABILITY \ SEVERITY		HIGH (I)	MEDIUM (II)	LOW (III)	VERY LOW (IV)
		Imminent and immediate danger of death or severe illness. Likely to impact humans and animals.	Danger and illness may be severe, but it is not imminent or immediate. Likely to impact animals, possible to impact humans.	Illness or injury may occur, but impact is reversible. Likely to impact animals, unlikely to impact humans.	Illness or injury is minor. Possible to impact animals, unlikely to impact humans.
HIGH (A)	Immediate danger that the hazard will occur.	I-A	II-A	III-A	IV-A
MEDIUM (B)	Probably will occur in time if not corrected.	I-B	II-B	III-B	IV-B
LOW (C)	Possible to occur in time if not corrected.	I-C	II-C	III-C	IV-C
VERY LOW (D)	Unlikely to occur; may assume hazard will not occur.	I-D	II-D	III-D	IV-D

Alternatively, here is an example where the facility is more risk-averse. Again, this is the same 2- way matrix as the two previous slides but this time, a different facility has previously determined which part of the grids represent critical, moderate, or negligible animal food safety risks. This facility has identified more categories that are critical and fewer categories that are negligible compared to the facility that was more risk accepting on slide 5-19.

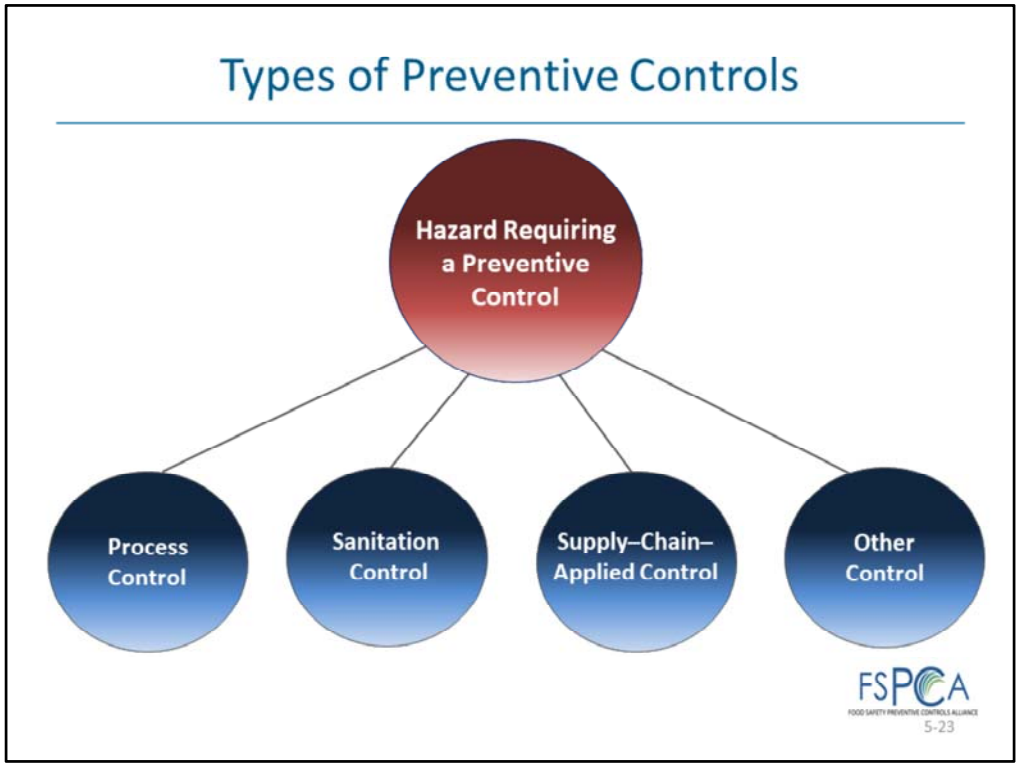
While these are examples to demonstrate a concept, it is important to recognize that the method of hazard evaluation is flexible. Facilities do not need to utilize a rubric scoring or create this type of 2- way matrix. Some may use a numerical scoring method, while others will not score severity and probability at all, and will instead just consider them in the evaluation process. The important point is that there are many methods to reach the final determination, but both severity and probability must be considered when evaluating if a *known or reasonably foreseeable hazard* reaches the threshold of a *hazard requiring a preventive control*.



Once it has been determined if a hazard requires a preventive control in Step 5, the determination should have written justification. This justification is to be based upon facility experience, illness data, scientific reports, guidance, or other information, such as that discussed in the resources slides of this chapter. This justification must be documented. Notably, hazards that are determined to not need a preventive control must also have written justification. The facility should be prepared to explain their justification for this determination.



If the evaluation determines that the hazard requires a preventive control, the type(s) of preventive controls must then be determined. Preventive controls may include Process Controls, Sanitation Controls, Supply-Chain-Applied Controls, and/or Other Controls. Some hazards may be controlled by a single preventive control, while others may have multiple controls. The various types of preventive controls will be discussed in other chapters.



The appropriate control for a hazard is based on the type of hazard, the type of animal food, and the type of facility.

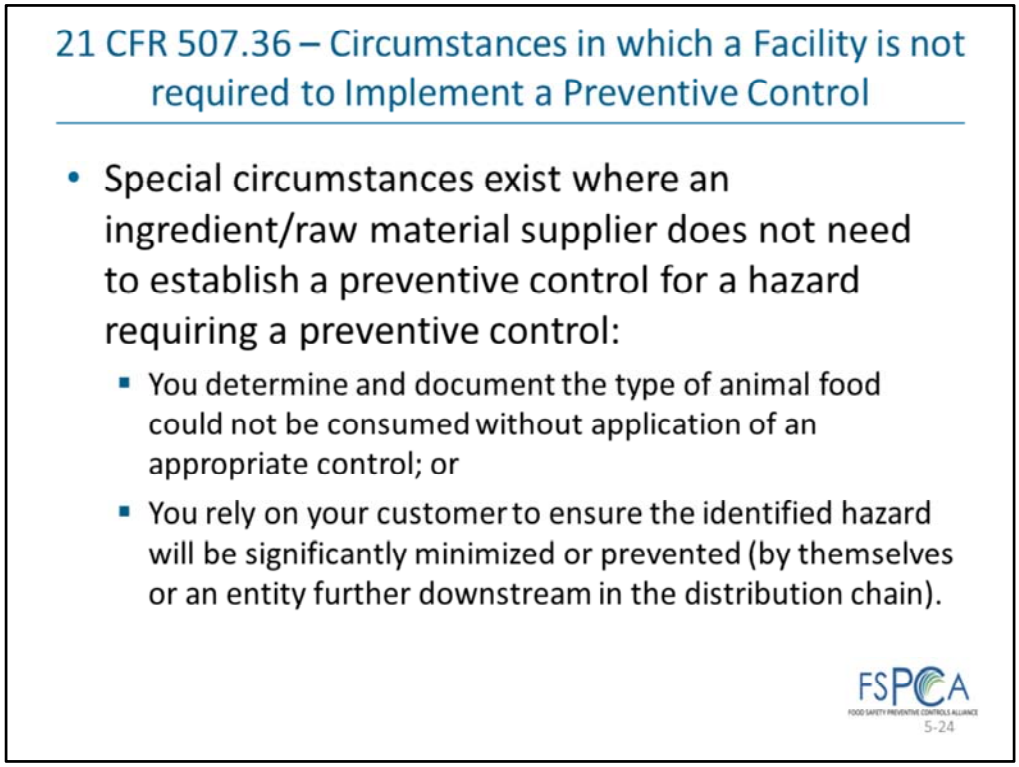
Process controls are used to ensure the control of parameters during manufacturing or processing. Most of the preventive controls in the animal food industry will be process controls, such as extrusion, or flushing or sequencing procedures, which are described in Chapter 7.

Sanitation controls are used to ensure the facility is maintained in a sanitary condition adequate to minimize or prevent hazards, such as environmental pathogens and biological hazards due to employee handling. Most of the sanitation controls in the animal food industry will focus on biological hazards. Examples of sanitation controls would be sanitizing animal food contact surfaces or hygienic zoning, which are described in Chapter 8.

Supplier controls, or supply-chain-applied controls, are used when a hazard in raw material or ingredient is controlled before its receipt. There may be limited applicability of this type of control to parts of the animal food industry. Supply-chain-applied controls will be described in Chapter 9.

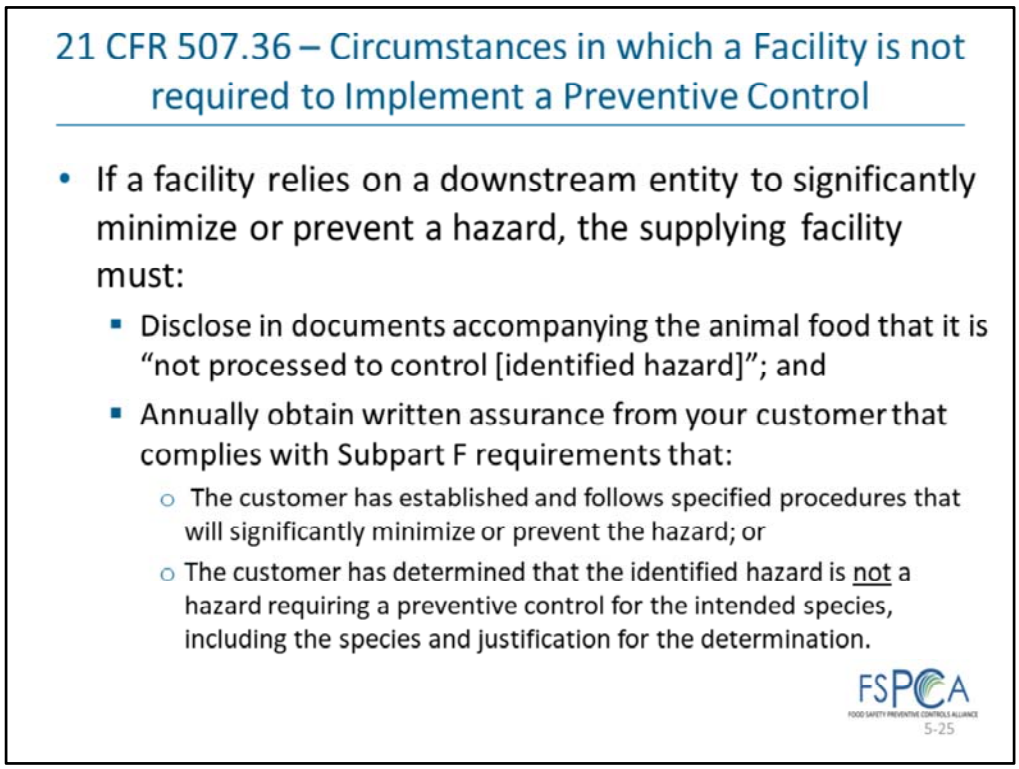
There is another category of preventive controls, called Other Controls, when the

control does not fit the definition of these other controls. There is limited discussion of these occurrences in this curriculum, but examples may be hygiene training or if a *hazard requiring a preventive control* is controlled through a current CGMP or other prerequisite program.



21 CFR 507.36 provides circumstances that allow a manufacturer/processor to not implement a preventive control for a hazard requiring a preventive control. These circumstances include when a facility determines and documents that the type of animal food could not be consumed without application of an appropriate control or if the facility relies on a downstream entity or customer to apply the preventive control.

An example application of an industry segment relying on a customer to apply the preventive control may be a facility manufacturing animal by-product meal. The facility determines that *Salmonella* spp. in the meal is a *hazard requiring a preventive control*, but instead of controlling the hazard in the meal, the facility requires assurance from its customer (an extruded pet food company) that preventive controls will be implemented at the downstream facility to control *Salmonella spp*. In this case, the supplier of the meal may manufacture and ship the animal food to the pet food manufacturer because it has an intended downstream process control.

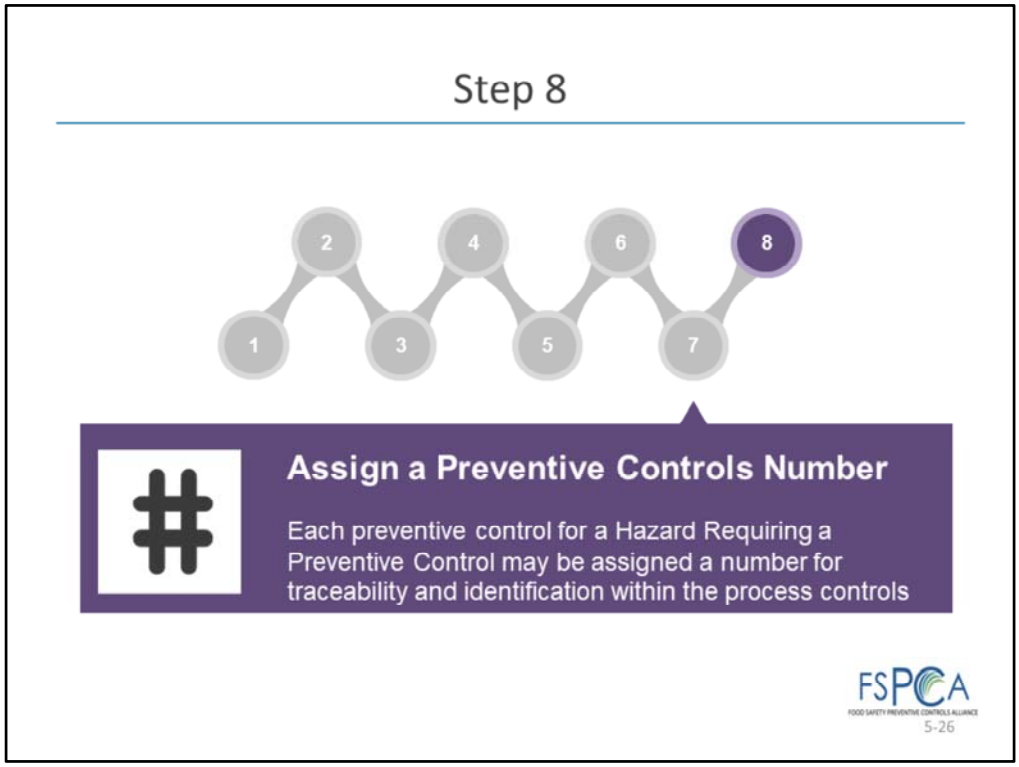


If a facility uses 21 CFR 507.36 to pass control of a hazard to its customer (or another downstream manufacturer), the facility must complete two key requirements, but the timeframe for the completion of these requirements is different.

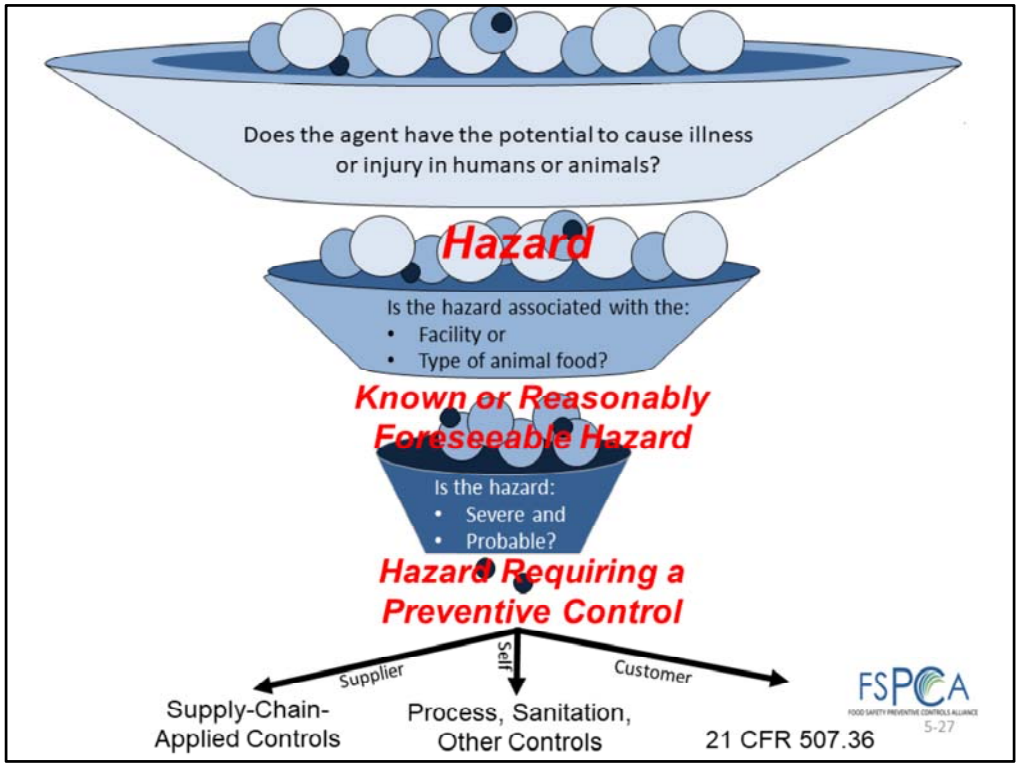
• First, the facility must disclose in documents accompanying the animal food that the animal food is "not processed to control [identified hazard]." This requirement begins whenever the facility must begin complying with Subpart C.

• Second, the facility must annually obtain written assurance that the customer has established and is following procedures (identified in the written assurance) that they will significantly minimize or prevent the identified hazard. Since the publication of the final rule in September 2015, the FDA has published a subsequent extension that extends the compliance requirement for facilities obtaining these written assurances from the original compliance date for subpart C for each business size category. With this extension, the first time facilities that are not small or very small businesses must begin to annually obtain these written assurances is September 18, 2019.

These written assurances must follow the specified recordkeeping requirements in Subpart F.



A best practice recommendation is to assign a preventive control number to all *hazards requiring a preventive control*. Having a number designation for each preventive control in the Food Safety Plan can be helpful to identify and track the preventive control. This concept and other options for documenting the hazard identification and evaluation steps is demonstrated in the next few slides.



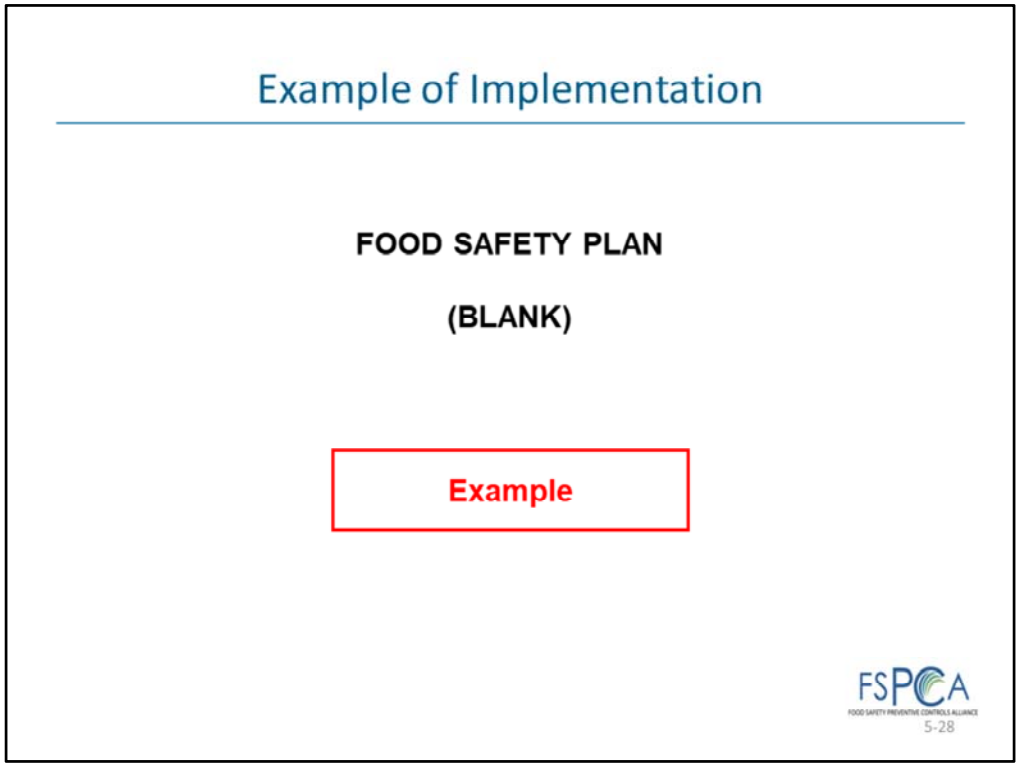
This is a summary of the hazard identification and evaluation process. If an agent has the potential to cause illness or injury in humans or animals, then it is by definition, a *Hazard.* The broad category of a *hazard* is then narrowed to only those agents that are associated with the facility or type of animal food, which are then considered to be a *Known or Reasonably Foreseeable Hazard*.

Next, a *Known or Reasonably Foreseeable Hazard* is evaluated for its severity and probability by considering the 10 items previously described on Slide 5-10, such as transportation practices, intended or reasonably foreseeable use, or condition, function, and design of the facility and equipment.

If the combination of severity and probability is high, even when considering prerequisite programs, such as CGMPs, the agent is then a *Hazard Requiring a Preventive Control*.

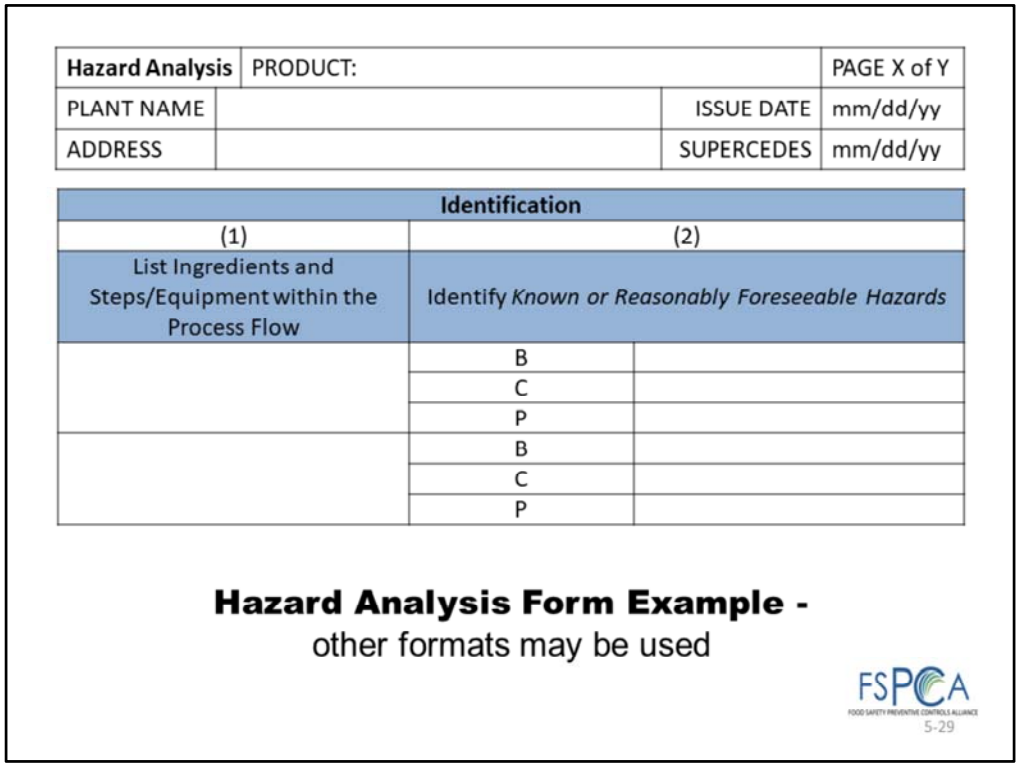
At that point, the type of control can vary. For example, the facility can ask a supplier to control the *Hazard Requiring a Preventive Control* by using a Supply-Chain-Applied Control, which will be described in the Supply Chain Program in Chapter 9. The facility could control the *Hazard Requiring a Preventive Control* itself using a Process Control, Sanitation Control, or Other Control. There are also circumstances when a facility may ask its customer or downstream user of the

animal food to control the *Hazard Requiring a Preventive Control*, at which the written assurances and disclosure statements described in Slides 5-24 and 5-25 would be utilized.



This next section is just one example of how a facility may choose to organize and document the hazard identification and evaluation process in the Food Safety Plan. As with all examples in this curriculum, the example is just one way to accomplish the required activities. First, a blank plan is shown to discuss the key components. To help emphasize when one step transitions to another, the identification steps have been outlined in blue (columns 1 and 2), the evaluation steps in red (columns 3 through 6), and the control steps in green (columns 7 and 8).

If this was printed in black and white or grey scale, the colors will not be visible in this manual but the column numbers can be referenced as listed above.



Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify *Known or Reasonably Foreseeable Hazards*	
	B	
	C	
	P	
	B	
	C	
	P	

The format of this slide is important to review because similar formats will be used for the rest of the chapter. The top has a table where product information, the facility name, and the facility address can be included. In addition, there is a place for a page number, an issue date, and a date documenting if one version supersedes another to track historical changes to the Food Safety Plan.

The middle of the slide shows a table that is formatted similarly to Table 1 in the example Food Safety Plans. The first section in blue (columns 1 and 2) is hazard identification, where the ingredients or processing steps from the flow diagram can be recorded (Step 1). Next, the *known or reasonably foreseeable hazards* can be listed within each ingredient or processing step and grouped by classification as biological denoted with a (B), chemical denoted with a (C), or physical denoted with a (P) (Step 2). Some facilities may choose to have an additional column here or elsewhere in their hazard analysis listing a number of hazards that may not be known or reasonably foreseeable as they go through the hazard identification process. That is acceptable, as is more specific or broader grouping of ingredient and process step categories.

Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Evaluation			
(3)	(4)	(5)	(6)
Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5

Hazard Analysis Form Example -
other formats may be used

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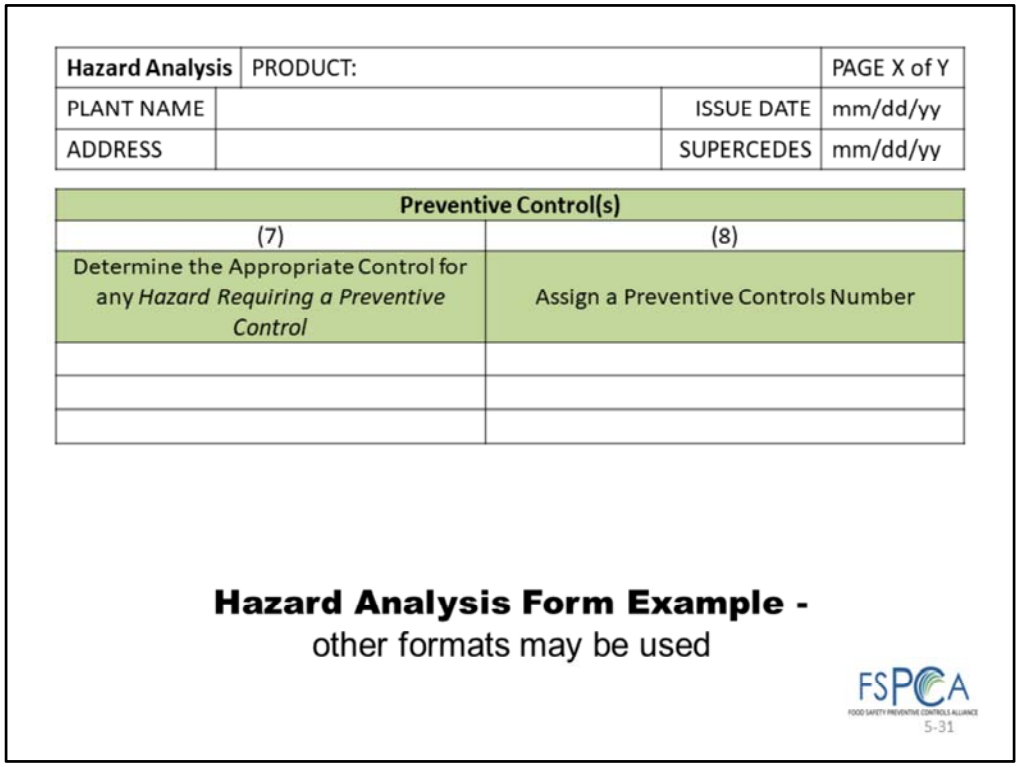
Next, columns 3 through 6 (in red) show the hazard evaluation steps. The hazard evaluation only needs to take place for those hazards that are known or reasonably foreseeable. The hazard analysis must include an assessment of severity of illness or injury to humans and animals if the hazard were to occur and the probability the hazard will occur in the absence of a preventive control. In this example, the severity and probability of the hazard are recorded in columns 3 and 4, respectively. Column 5 is used to record the determination of whether the hazard requires a preventive control and this can simply be done using a Yes or No designation. Lastly, column 6 is where the justification for that decision would be recorded. The justification may be longer than what can reasonably fit into a table. In those cases, the facility may choose to use appendices for lengthy explanations or maintain reference documents (such as scientific or technical articles) as part of its justification.



Hazard Analysis	PRODUCT:		PAGE X of Y
PLANT NAME		ISSUE DATE	mm/dd/yy
ADDRESS		SUPERCEDES	mm/dd/yy

Preventive Control(s)	
(7)	(8)
Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number

Hazard Analysis Form Example -
other formats may be used

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
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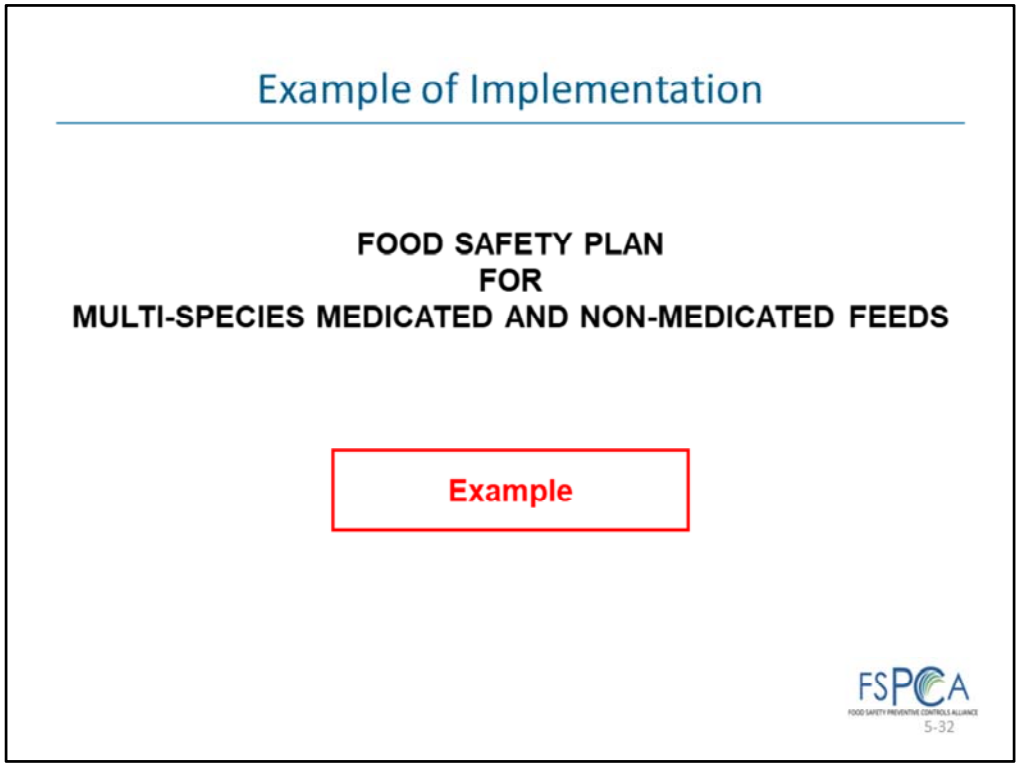
Finally, the preventive control that will be used to significantly minimize or prevent the hazard is shown in green (column 7). Column 8 is used to designate a preventive controls number that will be used to more clearly denote specific control measures and their management components, which are shown in Table 2 of the example Food Safety Plans and will be discussed in chapter 6. For now, that is the end of Table 1 and the example documentation for hazard identification and evaluation. The next section progresses through this table for both of the example Food Safety Plans.



The first implementation example for a hazard analysis and preventive control determination discussed is for the multi- species medicated and non-medicated feed manufacturing facility. To proceed with the example, start with the flow diagram that has been provided for this facility. Not every process step or ingredient will be listed in this example. To remain concise, the example has been limited to a single category of ingredients and shown a combination of process steps together. In a full Food Safety Plan, a more comprehensive consideration of process steps and/or ingredients may be necessary to conduct a thorough hazard analysis.

Livestock Feed Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feed		
PLANT NAME	ABC Feed Mill	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify *Known or Reasonably Foreseeable Hazards*	
Ingredients	B1	*Salmonella* spp.
	B2	BSE
	C1	Copper toxicity
	C2	Mycotoxins
	P	Stones, metal
Hand addition of ingredients	B	None
	C	Copper toxicity
	P	Foreign material: glass, metal, paper, plastic
Mixing	B	None
	C	Copper toxicity

This hazard analysis is for the multi-species medicated and non-medicated animal food from "ABC Feed Mill in Anywhere, USA." This is an abridged example; all ingredients were grouped together for hazard analysis and only two of the process steps are shown. The *known or reasonably foreseeable hazards* for each ingredient or process step category are listed by their classification as biological (B), chemical (C), or physical (P) hazards. In the ingredients category, *Salmonella* spp. and bovine spongiform encephalopathy (BSE) are biological hazards, and are identified because *Salmonella* spp. has been associated with some of the ingredients used by the feed mill and the facility feeds cattle. The facility manufactures food for sheep and also uses several ingredients that have high added copper levels, such as copper sulfate and beef and swine trace mineral premixes. Thus, copper toxicity in sheep resulting from an incorrectly labeled inbound ingredient may be a chemical hazard, particularly with sheep trace mineral premix. Another category of chemical hazards are mycotoxins that may be associated with different grains used by the facility. Stones and metal are also *known or reasonably foreseeable hazards* in the ingredients in this facility, and would be characterized as physical hazards.

There are also hazards listed for the hand addition of ingredients and mixing. Not all ingredients or process steps have biological, chemical, or physical hazards, such as there being no *known or reasonably foreseeable hazards* in the biological category for mixing. Meanwhile, some steps may have multiple hazards in a single category,

such as the hand addition of ingredients potentially having glass, metal, paper, or plastic physical hazards.

Livestock Feed Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify *Known or Reasonably Foreseeable Hazards*	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
Salmonella spp.	II - Medium	D – Very Low	No	FDA CPG 690.800; Li et al., 2012; see *Statement 1*
Copper toxicity in sheep	I – High	B - Medium	Yes	Multispecies premixes used by facility, copper toxic to sheep
Stones, metal	IV – Very Low	B - Medium	No	Grates employed over receiving pit, feed cleaner, magnets checked weekly for ferrous metal

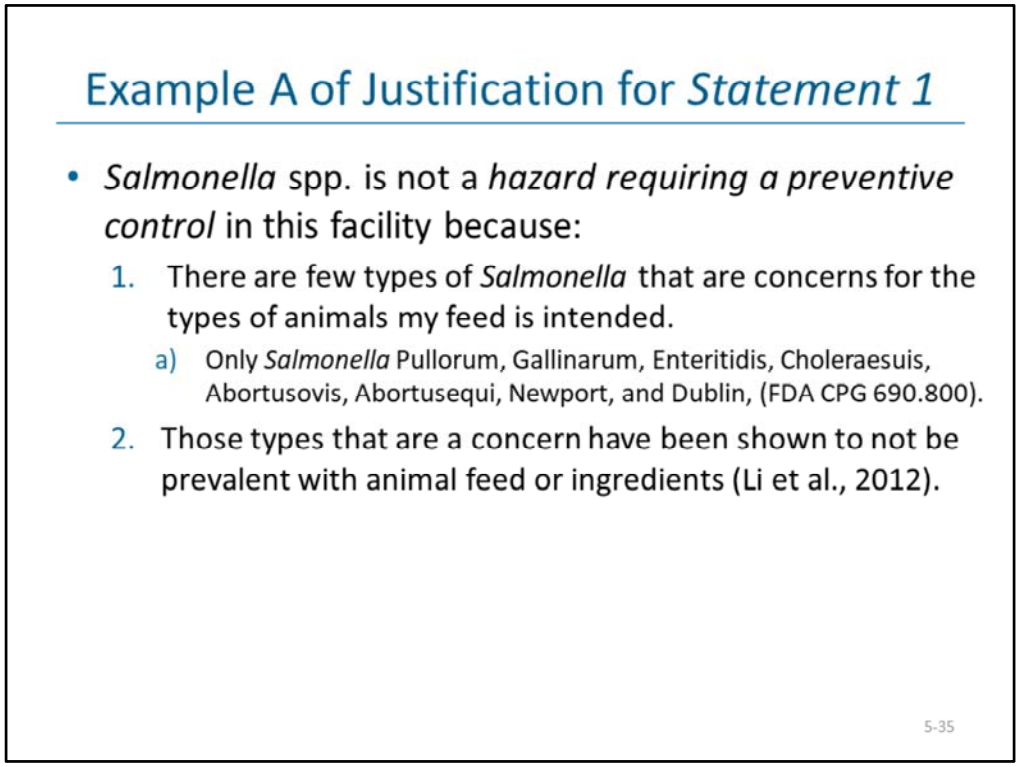
This slide is a continuation of the hazard analysis from slide 3-30. This slide focuses on only three of the hazards listed in the ingredients category: *Salmonella* spp., copper toxicity in sheep, and stones or metal. Because these are *known or reasonably foreseeable hazards*, the facility must assess severity of illness or injury to humans or animals if the hazard were to occur and the probability of occurrence in the absence of preventive controls in order to determine if the hazard is a *hazard requiring a preventive control*.

Salmonella spp.: In this example, the facility determined the severity of illness or injury from *Salmonella* spp. in the animals for which the food is intended was II - Medium. Next, the probability of occurrence of the hazard was evaluated as D - Very Low. Due to this combination, the facility determined *Salmonella* spp. was not a *hazard requiring a preventive control*. The brief justification for this determination is listed as FDA CPG 690.800; Li et al., 2012, but there is a note to see *Statement 1,* where there is a more thorough explanation.

Copper toxicity: During the severity assessment for copper toxicity, it was determined that the hazard in sheep was I - High. The probability of occurrence for the hazard was determined to be B - Medium because there are ingredients containing high levels of added copper utilized within the facility, such as copper sulfate and trace mineral premixes for other species. The facility determined this

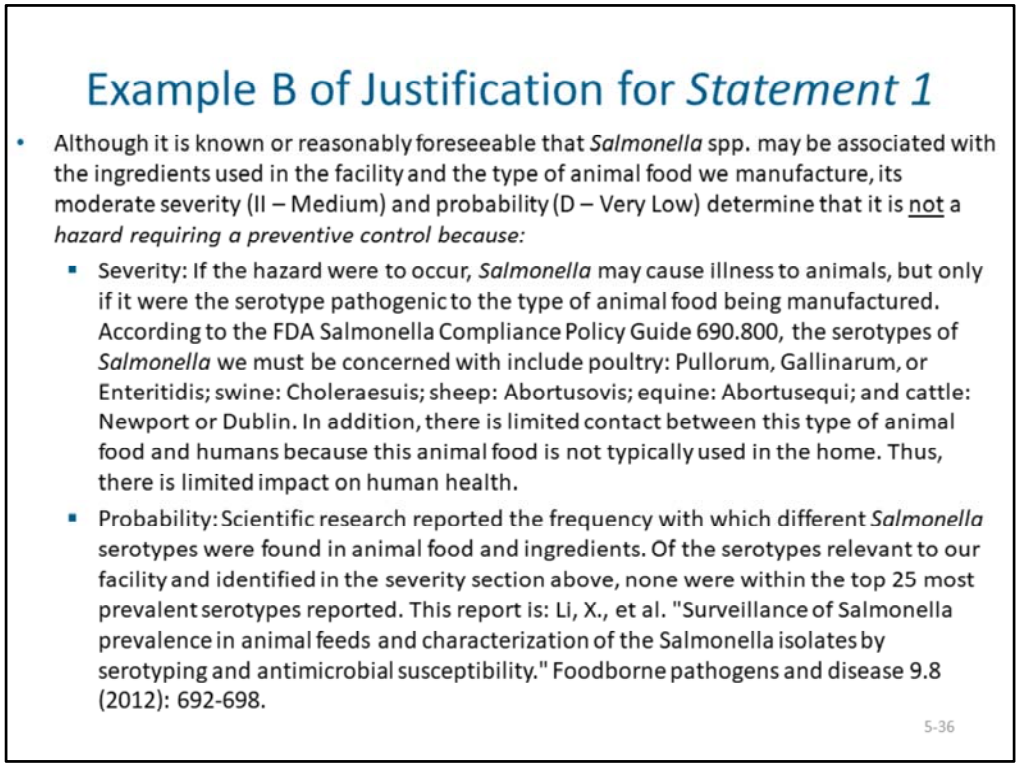
combination of a high severity and medium probability warranted a preventive control.

Metal: Finally, the severity assessment for metal was determined to be IV - Very Low. Its probability was B - medium because metal has been associated with inbound ingredients, but there are components in place to reduce its probability, such as grates over the receiving pit, a feed cleaner, and magnets for ferrous metal that are checked weekly. While the probability was medium, the severity was low enough that the facility determined that a preventive control was not necessary. Note the justification for this hazard is relatively short and can be embodied within the single cell.



This shows some example justification language that the facility included to further explain why *Salmonella spp.* was a *known or reasonably foreseeable hazard*, but was not a *hazard requiring a preventive control*. Additional justification outside the Table form may be helpful so facility personnel can explain the decisions made during hazard analysis, particularly in the absence of the PCQI. The justification is as follows:

- *Salmonella* spp. is not a *hazard requiring a preventive control* in this facility because:
    1. There are few types of Salmonella that are concerns for the types of animal food manufactured within this facility. Only select serotypes (Pullorum, Gallinarum, Enteritidis, Choleraesuis, Abortusovis, Abortusequi, Newport, and Dublin) are known to be pathogenic in the animal species for which feed is manufactured at this facility. This is according to the Salmonella Compliance Policy Guide 690.800.
    2. Those serotypes that are a concern have been shown to not be prevalent with animal feed or ingredients. This is according to a scientific paper, Li et al., 2012.



Another facility may choose to use the same reasoning for making this determination, but may choose to format their justification in a more thorough manner. For example, the facility may choose to format it in paragraph form and show as follows:

Although it is known or reasonably foreseeable that *Salmonella spp*. may be associated with the ingredients used in the facility and the type of animal food manufactured, its moderate severity (II – Medium) and probability (D – Very Low) determine that it does not require a preventive control.

- Severity: If the hazard were to occur, *Salmonella* may cause illness to animals, but only if it were the serotype pathogenic to the type of animal food being manufactured. According to the FDA Salmonella Compliance Policy Guide 690.800, the serotypes of *Salmonella* of concern to cattle include: Newport or Dublin; goats: none; poultry: Pullorum, Gallinarum, or Enteritidis; sheep: Abortusovis; equine: Abortusequi; and swine: Choleraesuis. In addition, there is limited contact between this type of animal food and humans because this animal food is not typically used in the home. Thus, there is limited impact on human health.

The justification goes on to discuss probability:

- Probability: Scientific research reported the frequency with which different *Salmonella* serotypes were found in animal food and ingredients. Of the serotypes relevant to this facility and identified in the severity section above, none were within the top 25 most prevalent serotypes reported. This report is: Li, X., et al. "Surveillance of Salmonella prevalence in animal feeds and characterization of the Salmonella isolates by serotyping and antimicrobial susceptibility." Foodborne pathogens and disease 9.8 (2012): 692-698.

Due to the medium severity and very low probability for the hazard in the type of animal food the facility manufactures, the determination was made that *Salmonella spp*. was not a *hazard requiring a preventive control*.

Livestock Feed Example

Hazard Analysis	PRODUCT: Multi-Species Medicated and Non-Medicated Feeds		PAGE X of Y
PLANT NAME	ABC Feed Mill	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify *Known or Reasonably Foreseeable Hazards*	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number
Salmonella spp.	n/a	n/a
Copper toxicity in sheep	Supply-Chain-Applied Control - Control of copper level in sheep mineral premix	1
	Process Control - Procedures for ensuring correct manual weighing and addition of sheep mineral premix	2
	Process Control - Procedures for mixing and sequencing of food for sheep	3
Stones, metal	n/a	n/a

FSPCA
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While the only *hazard requiring a preventive control* was copper toxicity, a total of 3 preventive controls were determined necessary to significantly minimize or prevent the hazard. First, the facility determined that the incoming copper level of sheep mineral premix must be known and controlled. Second, there must be standard procedures for ensuring correct manual weighing and addition of the sheep mineral premix, particularly to prevent incorrect addition or unintentional use of a mineral premix for a different species that may cause copper toxicity when manufacturing food for sheep. Third, there must be standard procedures for ensuring adequate mixing and mixer cleanout so carryover of other feeds does not cause copper toxicity in food for sheep. These preventive controls are numbered sequentially and their specific controls will be discussed more fully in later chapters.

Comparison of Hazard Evaluation

- Example: Copper toxicity in premix addition step in food for sheep

Hazard Evaluation	Facility 1	Facility 2
Is the hazard known or reasonably foreseeable?	Yes	Yes
Severity	I - High	I - High
Probability	C - Low	B - Medium
Does the hazard require a preventive control?	No	Yes
Justification	Single mineral premix used by facility, weighed by automation. Facility procedures used to ensure automation works properly.	Other mineral premixes with high copper levels. Premixes are weighed manually.
Preventive Control	None	Receiving of ingredients with added Cu; Hand-add of ingredients with added Cu; Mixing, sequencing of sheep feed
Preventive Control Management Requirements	None	Monitoring, Corrective Actions, Verification, Record Review, Recall Plan

This is a side-by-side example of two facilities that, due to differences in equipment and raw materials, are addressing the same hazard of copper toxicity in different ways. Facility 1 does not require a preventive control, while Facility 2 requires a preventive control at this step. Both of these facilities manufacture food for sheep, so in both cases, copper toxicity is listed and determined to be a *known or reasonably foreseeable hazard*. The severity is I - High for both facilities due to the severe implications of copper toxicity in sheep.

Facility 1 evaluated the hazard to have a C – Low probability, and therefore, the facility determined copper toxicity was not a hazard requiring a preventive control. Facility 1 made this determination because the facility does not have mineral premixes for other animal species that may contain a concerning level of copper, so the probability for copper toxicity by an employee unintentionally including the incorrect mineral premix is reduced. Furthermore, the premix is weighed out by an automation system from a microsystem and procedures ensure that the microingredient bins are accurate, precise, and calibrated, which further reduces the likelihood of hazard occurrence. Because the hazard does not require a preventive control in Facility 1, there are no required preventive control management components.

While Facility 2 had the same severity for the hazard, the facility evaluates that

copper toxicity in sheep has a probability of occurrence of B - Medium and requires a preventive control. This is because Facility 2 utilizes mineral premixes for other animal species that have high added copper levels, and their accidental use in food for sheep may result in toxicity. In addition, the mineral premixes are all weighed manually, which enhances the chance for weighing error. Because of the difference in probability assessment, Facility 2 determined copper toxicity was a *hazard requiring a preventive control*.

Because Facility 2 implements preventive controls for copper toxicity, Facility 2 requires the necessary preventive controls management components, such as monitoring, corrective actions, verification, record review, and a recall plan. Management components will be discussed in chapter 6, but this example illustrates how two facilities can assess probability of the same hazard in different ways, and may come to different conclusions about the necessity for a preventive control.

The second implementation example for a hazard analysis and preventive control determination discussed is the example Food Safety Plan for dry extruded dog and cat food. Participants should reference the flow diagram for this example plan during the discussion.

Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification		
(1)	(2)	
List Ingredients and Steps/Equipment within the Process Flow	Identify *Known or Reasonably Foreseeable Hazards*	
Ingredients	B	*Salmonella* spp.
	C	Thiamine deficiency
	P	Foreign material: metal, plastic, bone, glass, wood
Bulk receiving	B	*Salmonella* spp.
	C	None
	P	Foreign material: metal, plastic, glass, wood
Mixing	B	None
	C	Thiamine deficiency
	P	Metal

This is an abridged example; all ingredients were grouped together for hazard analysis and only two of the process steps are shown. The *known or reasonably foreseeable hazards* for each ingredient or process step category are listed by their classification as biological (B), chemical (C), or physical (P) hazards.

In the example for dry extruded dog and cat food from ABC Pet Food, incoming ingredients are sources of known or reasonably foreseeable hazards. *Salmonella* spp. is listed as a known or reasonably foreseeable hazard because the ingredients used by the pet food facility have been known to be a source of the pathogen. In fact, the facility knowingly purchases ingredients that may be contaminated with *Salmonella* because it plans to control the hazard during processing. In addition, metal, plastic, bone, glass, or wood are all physical hazards that may be associated with incoming ingredients.

Bulk receiving typically contains an open entry point into the manufacturing system, where a variety of foreign material may enter if it crosses the receiving pit grating. Examples of foreign material that may be in the bulk receiving area include metal, plastic, glass, or wood.

Finally, mixing is a manufacturing/processing step in which the facility identified a known or reasonably foreseeable hazard. Improper mixing may prevent the

thiamine premix from being fully incorporated in cat food and lead to thiamine deficiency. Mixers are also made of metal, and may introduce the hazard during the process.

Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification	Evaluation			
(2)	(3)	(4)	(5)	(6)
Identify *Known or Reasonably Foreseeable Hazards*	Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in Step 5
Salmonella spp.	I - High	A - High	Yes	FDA Salmonella CPG 690.800
Thiamine deficiency (cat)	II - Medium	C - Low	No	COA used by known supplier with historical data to confirm values.
Metal	II - Medium	B - Medium	Yes	Ingredients may include non-ferrous metal that may not be caught by a magnet

As with the livestock feed example, *known or reasonably foreseeable hazard*s must be evaluated for severity and probability to determine if they are *hazards requiring a preventive control*. Justification is required, particularly for those hazards that do not require a preventive control. In this example, only the assessment of *Salmonella* spp., thiamine deficiency in cats, and metal are described in the ingredients section.

Salmonella spp.

The facility assessed *Salmonella* to have I - High severity as it is known to potentially cause both human and animal illness. The hazard was determined to have A - High probability because it is likely present in some of the ingredients. This combination warranted the determination that *Salmonella* was a *hazard requiring a preventive control*, with several factors impacting this justification. First, there is data to support that *Salmonella* in pet food has been linked to illness in humans. Second, there are numerous recalls of pet food for *Salmonella* contamination. Finally, FDA's Salmonella Compliance Policy Guide states there is zero tolerance for *Salmonella* in pet food.

Thiamine deficiency

The facility determined the severity of thiamine deficiency in cats was II - Medium because the hazard may lead to serious illness or death in cats, but would not impact human health. The probability of hazard occurrence was evaluated as C –

Low because the facility requires certificates of analysis from its cat mineral premix supplier and has historical data demonstrating the supplier's compliance with declared values. This data will be provided upon official request.

Metal

Finally, the facility determined that the severity of metal is II-Medium because it could cause a more substantial impact based on the eating behavior and other factors, which will be described later. The probability was assessed as B - Medium because the ingredients may include non-ferrous metal that may not be caught by a magnet. The facility determined that this combination of severity and probability warranted a preventive control.

Pet Food Example

Hazard Analysis	PRODUCT: Dry Extruded Dog and Cat Food		PAGE X of Y
PLANT NAME	ABC Pet Food	ISSUE DATE	mm/dd/yy
ADDRESS	123 Street, Anywhere, USA	SUPERSEDES	mm/dd/yy

Table 1. Hazard Analysis

Identification	Preventive Control(s)	
(2)	(7)	(8)
Identify *Known or Reasonably Foreseeable Hazards*	Determine the Appropriate Control for any *Hazard Requiring a Preventive Control*	Assign a Preventive Controls Number
Salmonella spp.	Process Control - Extrusion temperature	1
	Sanitation Control - Post-extruder surface sanitizing	2
Thiamine deficiency (cat)	n/a	n/a
Metal	Process Control - Metal detection of finished pet foods	3

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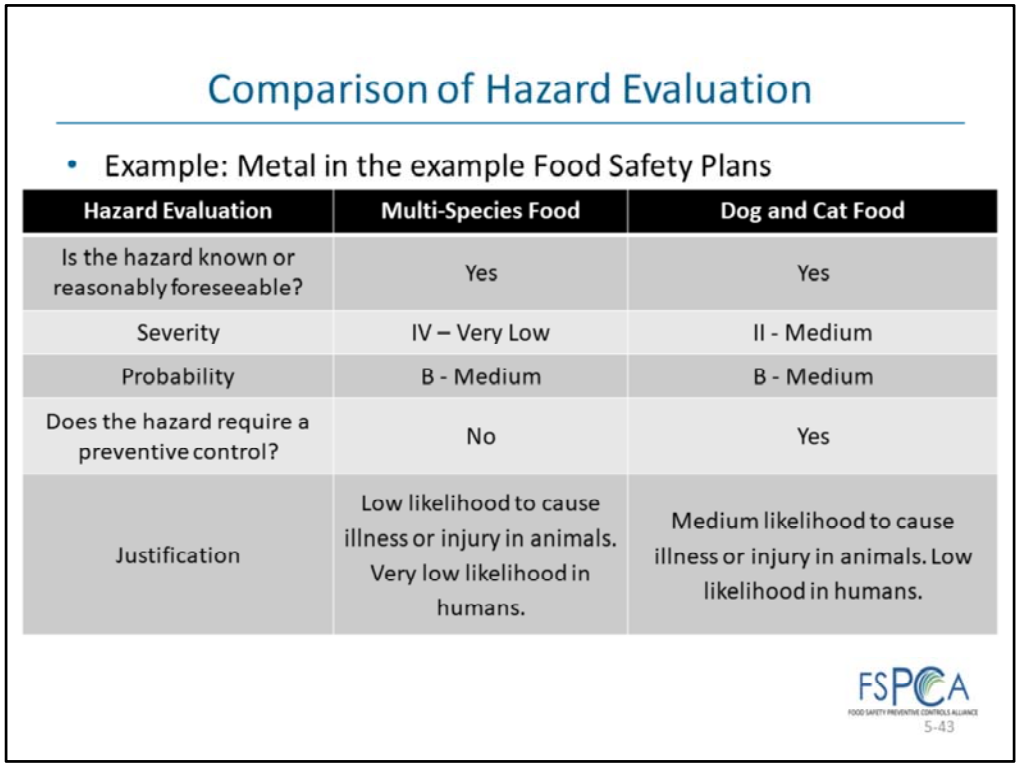
The facility determined that *Salmonella* should be controlled by two different preventive controls. The first preventive control is the application of a commercial heat step, which is a process control because there would be a minimum temperature required during extrusion. The commercial heat step, which is achieved through extrusion, is identified as preventive control number 1. The second preventive control would be the use of sanitation controls to prevent post-processing cross- contamination, and this preventive control has been assigned number 2.

Metal was determined to be controlled by metal detection of finished pet food, which would be a process control and preventive control number 3. Again, the control measures and their required management components will be described in coming chapters, but this describes the hazard analysis process for this example Food Safety Plan.

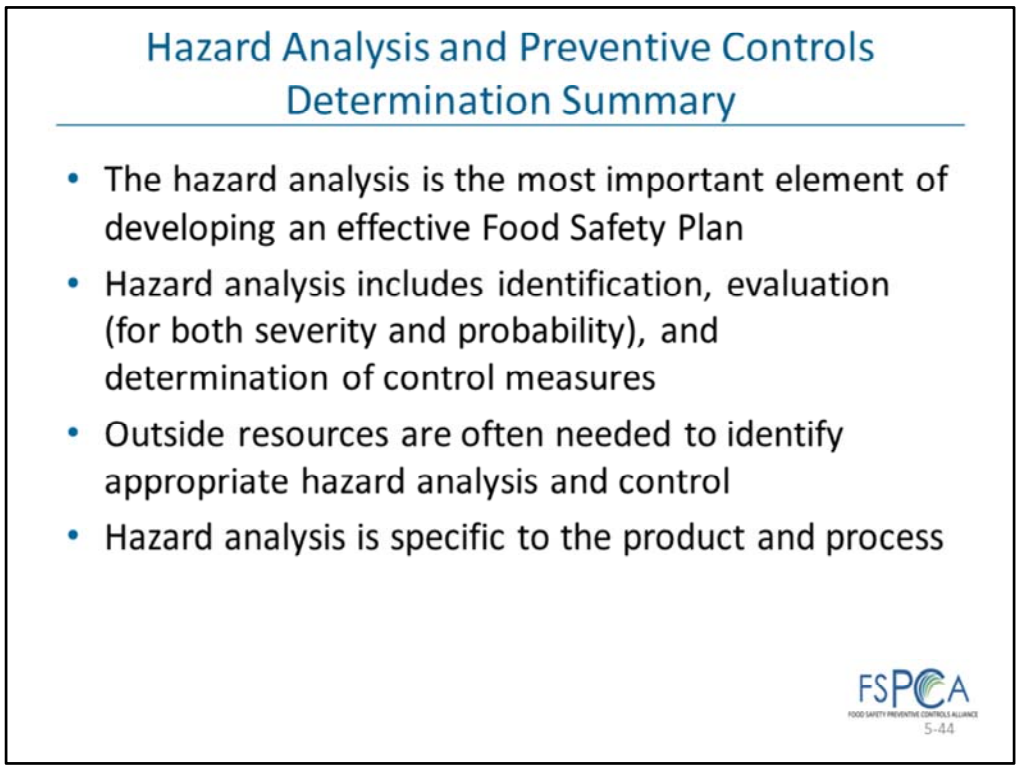


The multi-species medicated and non-medicated animal food example on slide 5-35 showed how two facilities making the same types of animal food were controlling the same copper toxicity hazard in different ways. In that example, discussion focused on why the probability for the hazard may be different in the two facilities. In this example, the probability for the hazard is held constant and the example instead illustrates how differences in severity may also affect the outcome of hazard evaluation. This example uses metal as the hazard.

Both example Food Safety Plans identified metal as a *known or reasonably foreseeable hazard*. Furthermore, the probability of hazard occurrence was similar (B – Medium) in both facilities. The difference comes when evaluating severity of illness or injury to an animal. The feed mill manufacturing multi-species medicated and non-medicated animal food determined that the severity of metal was IV – Very Low. The facility manufacturing dry extruded dog and cat food determined the hazard had a severity of II - Medium.

The difference in the determination is based on differences in the intended species for the animal food. For example, the livestock feed example had a lower severity because a 300-lb pig is unlikely to consume metal even if the hazard occurred in its food because of the way pigs sort their food while eating. If the animal food with metal was consumed, the resultant illness or injury to the 300- lb pig would likely be

minor due to the size of the pig's stomach. On the other hand, a small dog, such as a Chihuahua, is more likely to consume the metal hazard in its pet food due to its eating behavior by wolfing. If the small dog were to consume the same size metal hazard as the pig, the family pet is at greater risk to have severe injury, such as an intestinal blockage, than the 300-lb pig due to the Chihuahua's significantly smaller stomach. The difference in severity assessment was justification for the facility in each case to determine if a preventive control was or was not required. Again, these are just examples of ways that hazard identification and evaluation may be employed. Each facility is different, and it is the responsibility of the facility to consider a number of factors when identifying *known or reasonably foreseeable hazards* and then assessing their severity and probability to determine if they require a preventive control.



In summary, the hazard analysis is the most important element of developing an effective Food Safety Plan. The hazard analysis must include identification of known or reasonably foreseeable hazards, hazard evaluation (for both severity of illness or injury to humans or animals and the probability of occurrence), and the determination of appropriate preventive control measures to significantly minimize or prevent the hazard. Outside resources are often needed to conduct an effective hazard analysis and determine the appropriate preventive control(s). Finally, hazard analysis is specific to the product and process. The examples from this chapter are intended to demonstrate the complexities of the decision-making process and possible variations from one product to another and one facility to another. Hazard analysis and preventive controls determination is one of the key responsibilities of the preventive controls qualified individual. The next chapter will discuss the management components associated with preventive controls.

Exercise 5

- In small groups (5-10 individuals):
  - Draw a card of a type of facility and animal food it manufactures, processes, pack, or holds.
    1. Choose one ingredient and one process step from that facility.
    2. Complete the blank Table 1 from Exercise 5 in the Exercise Workbook for that ingredient and process step.
    3. When your group is complete, answer the reflection questions in the Exercise Workbook.

Exercise 5 Summary

- There are specific regulatory requirements that must be completed during hazard analysis. However, there is flexibility in how to apply those requirements.
- The outcome of a hazard analysis may vary. Not all hazards will be evaluated the same or controlled the same, even within the same type of facility.
- It is important to document your rationale (justification) so you remember your thinking at the time, have alignment with your team, and can support the scientific basis for decisions.

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