Conducting an Effective Animal Feed Hazard Evaluation

How ready are you for compliance with Subpart C of the Preventive Controls for Animal Food rule (food safety plan requirement of FSMA)?

A. I am exempt from needing a food safety plan
B. I have not begun
C. I have a HACCP plan that needs to be converted to a food safety plan
D. I have a written food safety plan, but it needs cleaned up
E. I am ready for compliance

Conducting an Effective Animal Feed Hazard Evaluation

How familiar are you with the requirements of Subpart C of the Preventive Controls for Animal Food rule (food safety plan requirement of FSMA)?

A. I have limited knowledge of this topic
B. I have a base understanding, but don't understand how they apply to my facility
C. I have attended the FSPCA Preventive Controls for Animal Food course, but don't understand how to apply concepts to my facility
D. I have attended the FSPCA Preventive Controls for Animal Food course, and have a good understanding of how to apply concepts to my facility

Conducting an Effective Animal Feed Hazard Evaluation

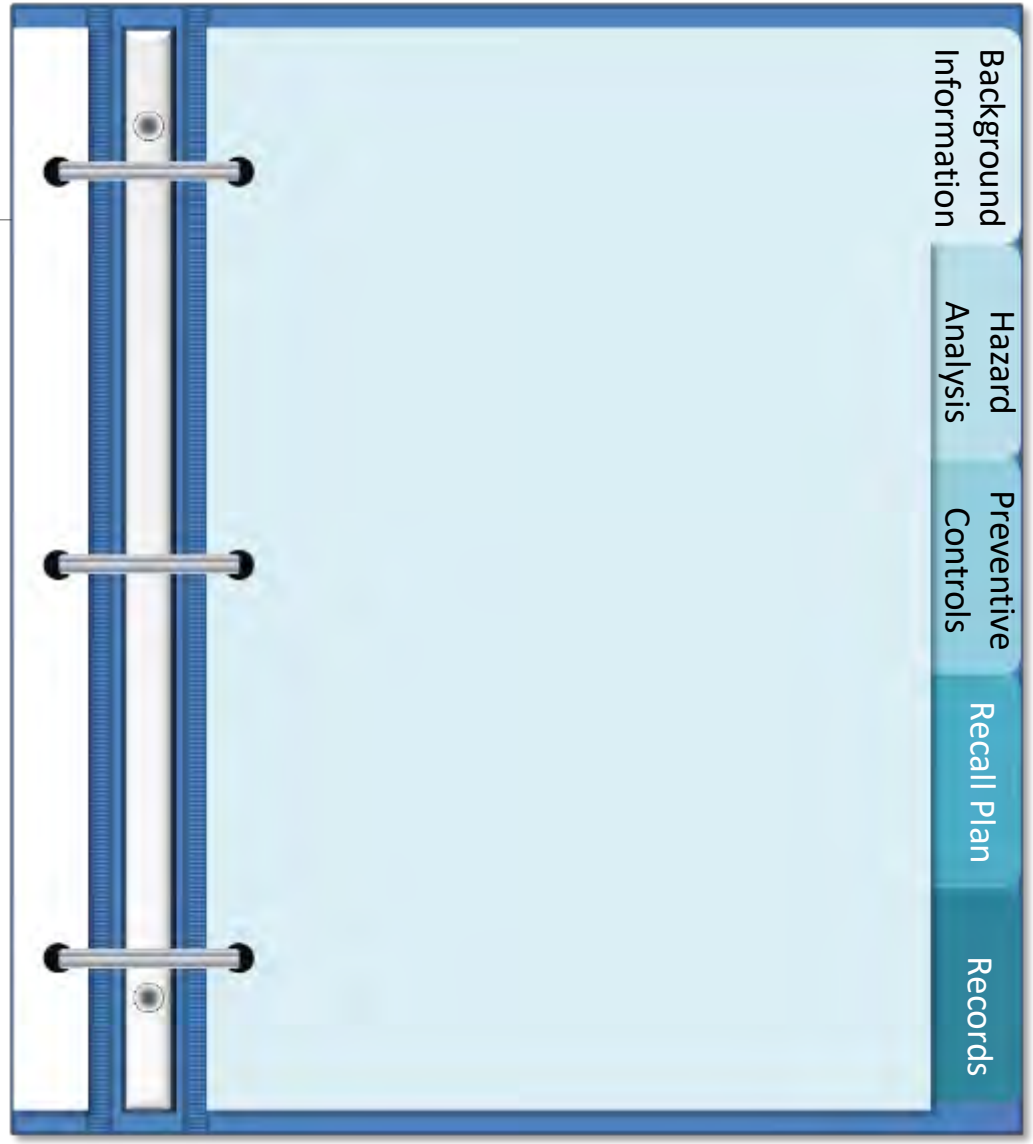
Assumptions for this session:

1. This example facility is already fully compliance with Subpart B (CGMP)
2. This example facility is not exempt from any Subpart C (food safety plan) requirements

Food Safety Plan

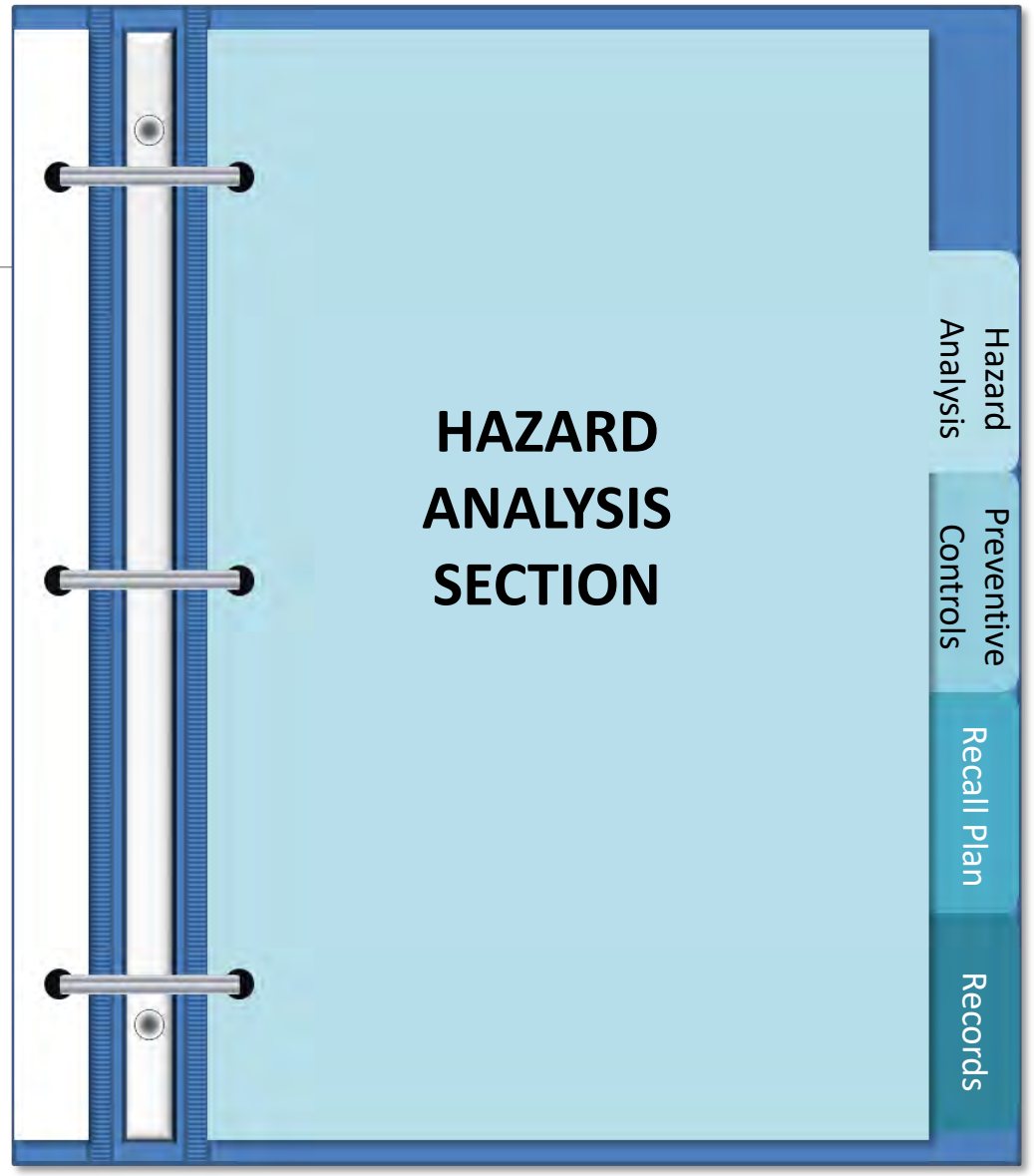
Food Safety Plan

1. Background information - optional
2. Hazard analysis and preventive controls determination
3. Preventive controls and their management components
4. Recall plan
5. Implementation records



Hazard Analysis

- Requirements:
  - Hazard analysis
  - Identification of the preventive controls
  - Justification for not establishing a preventive control



Regulatory Definitions 21 CFR 507.3

- Hazard
  - Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury in humans or animals.

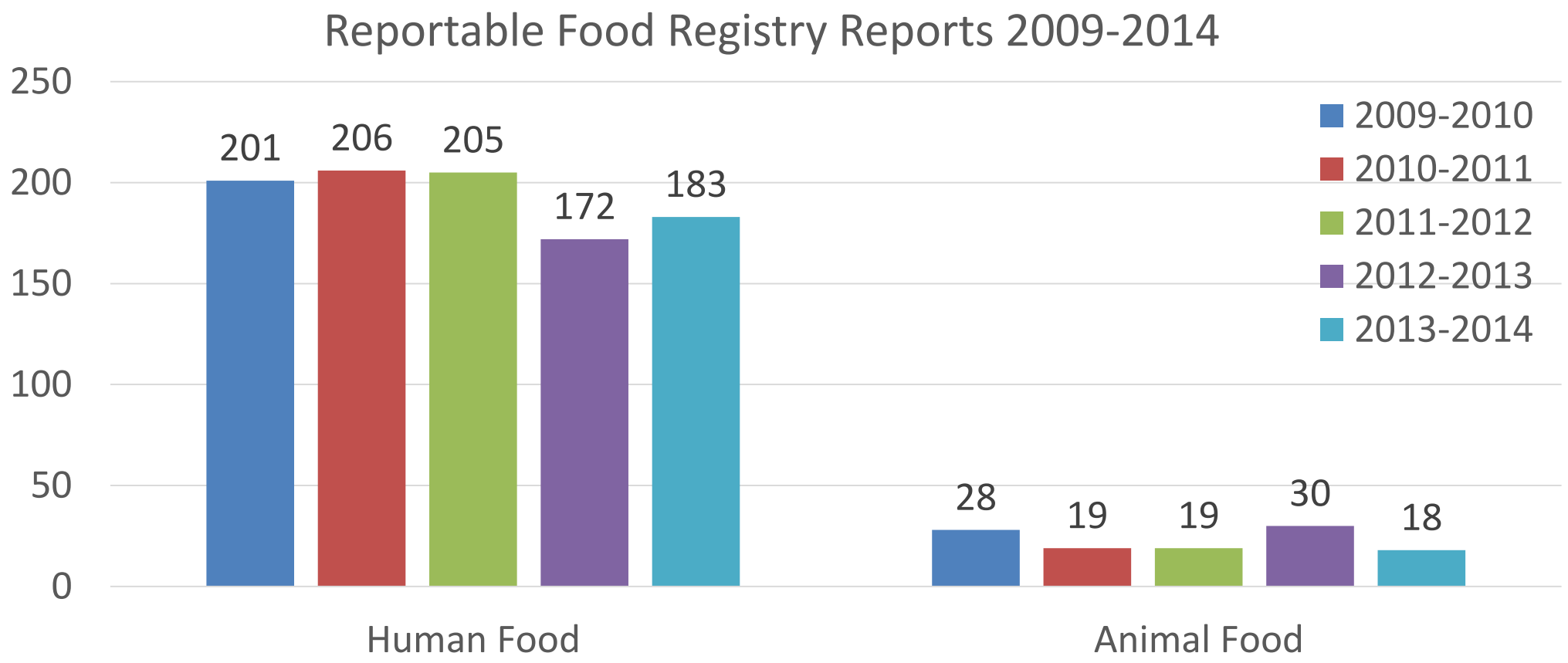
Regulatory Definitions 21 CFR 507.3

- Known or Reasonably Foreseeable Hazard
  - 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.

Regulatory Definitions 21 CFR 507.3

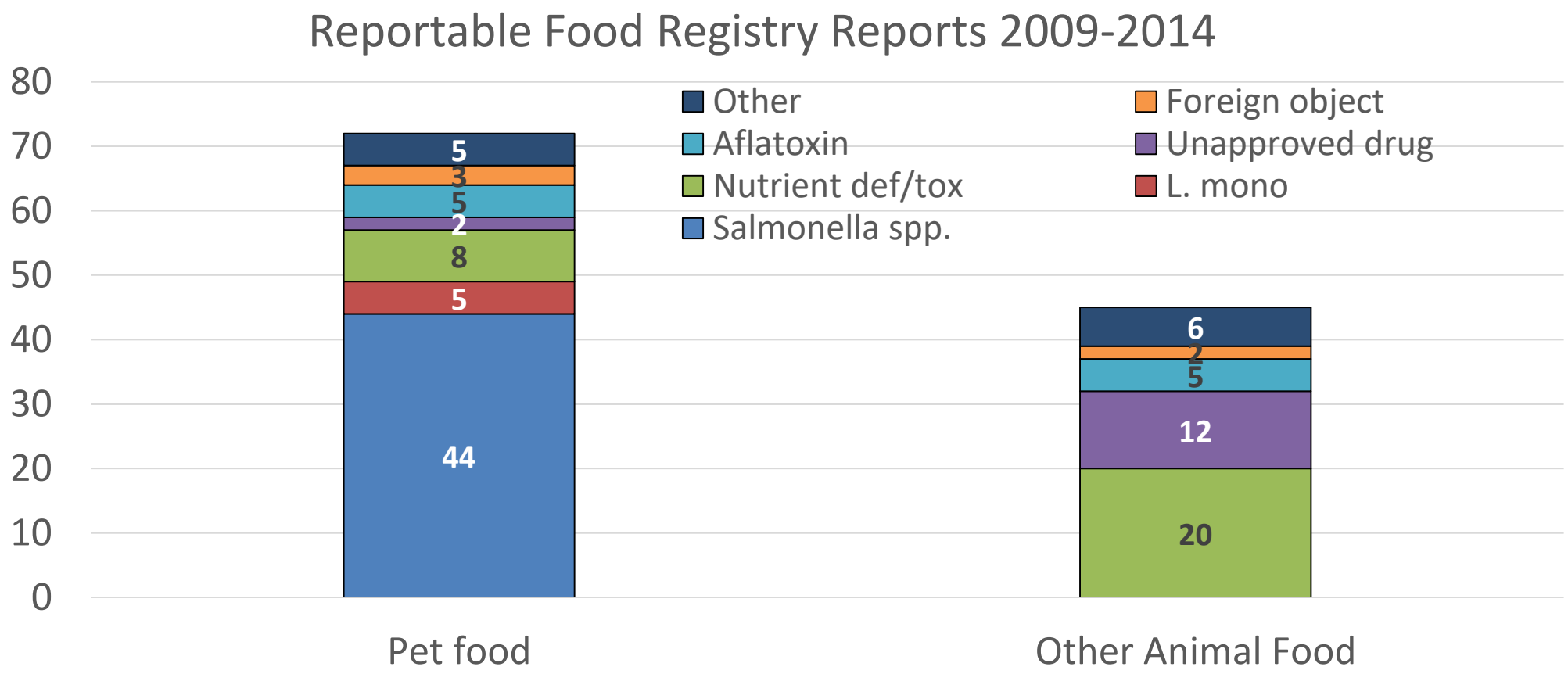
- Hazard Requiring a Preventive Control
  - A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness 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), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) 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.

Prevalence of Animal Food Hazards



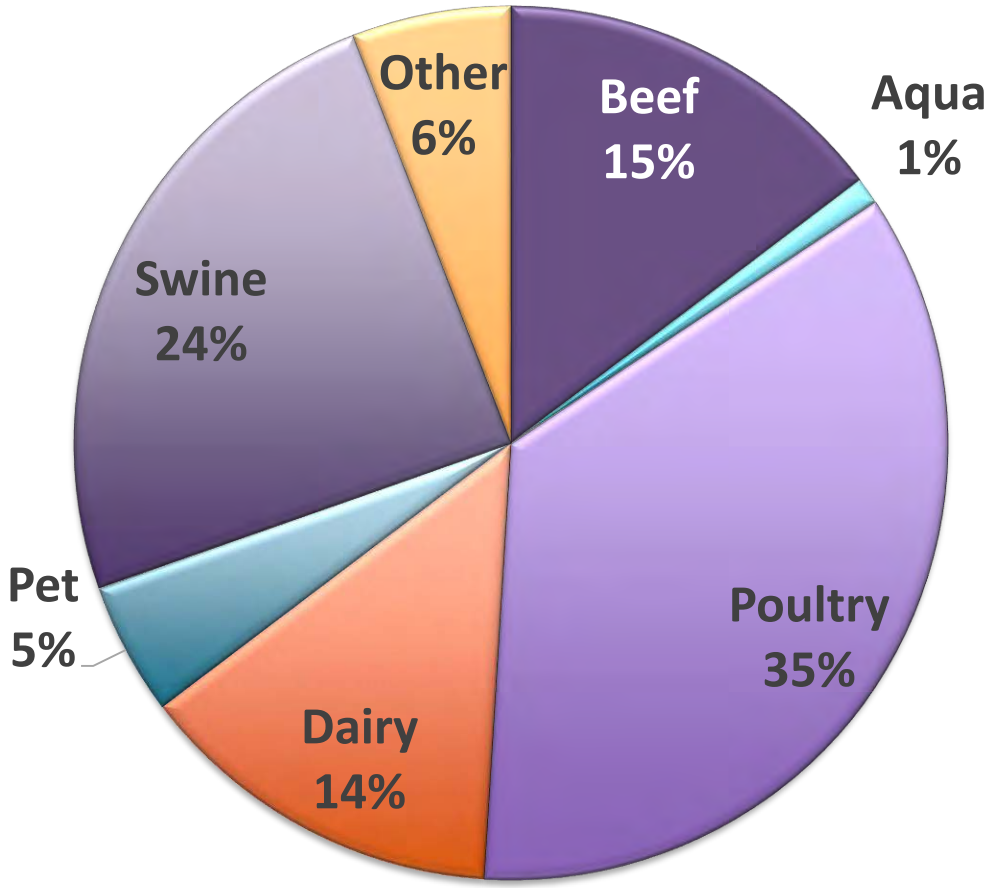
5th Reportable Food Registry Annual Report, FDA, 2016

Prevalence of Animal Food Hazards



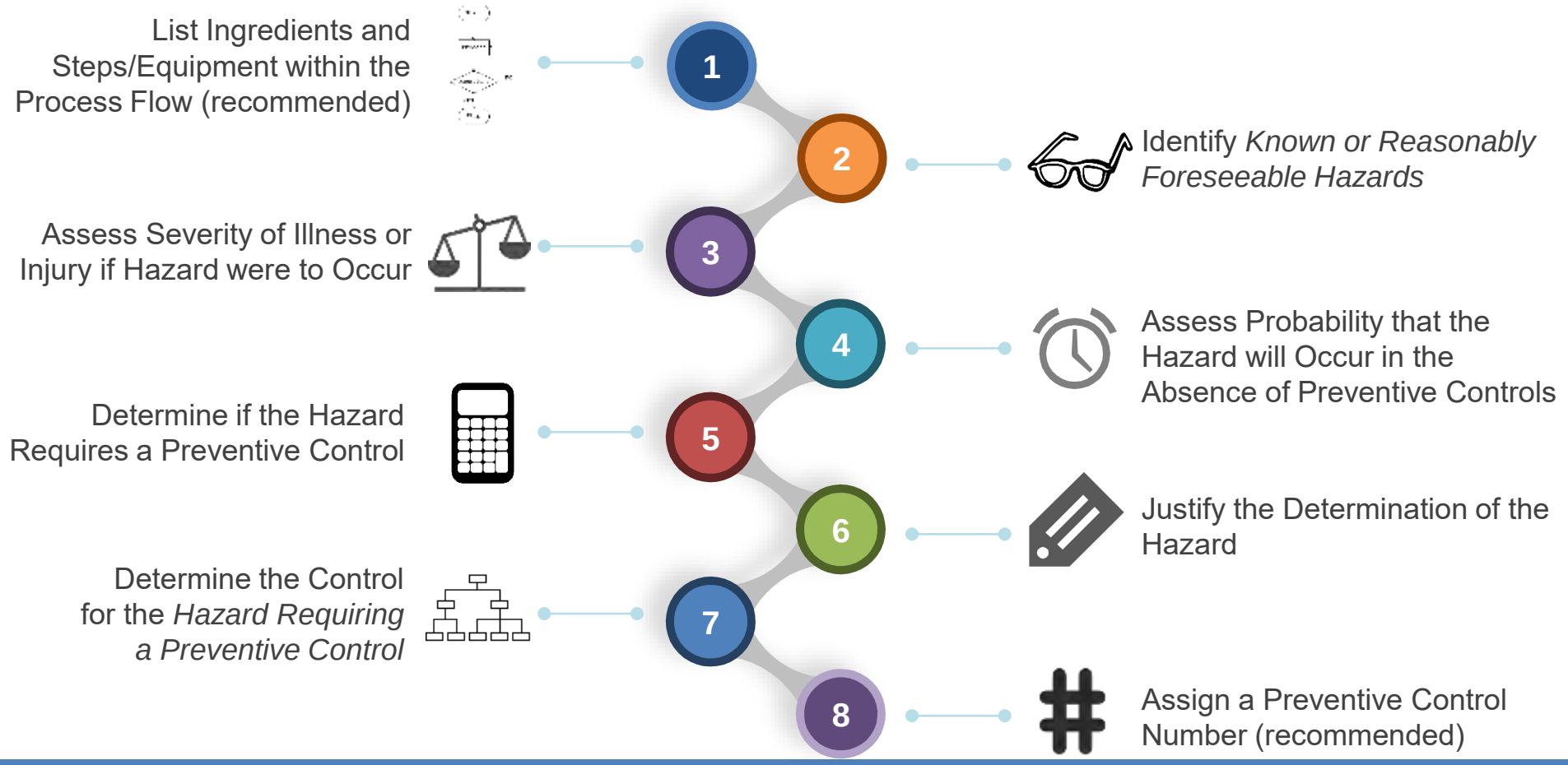
5th Reportable Food Registry Annual Report, FDA, 2016

US Animal Food Production by Species



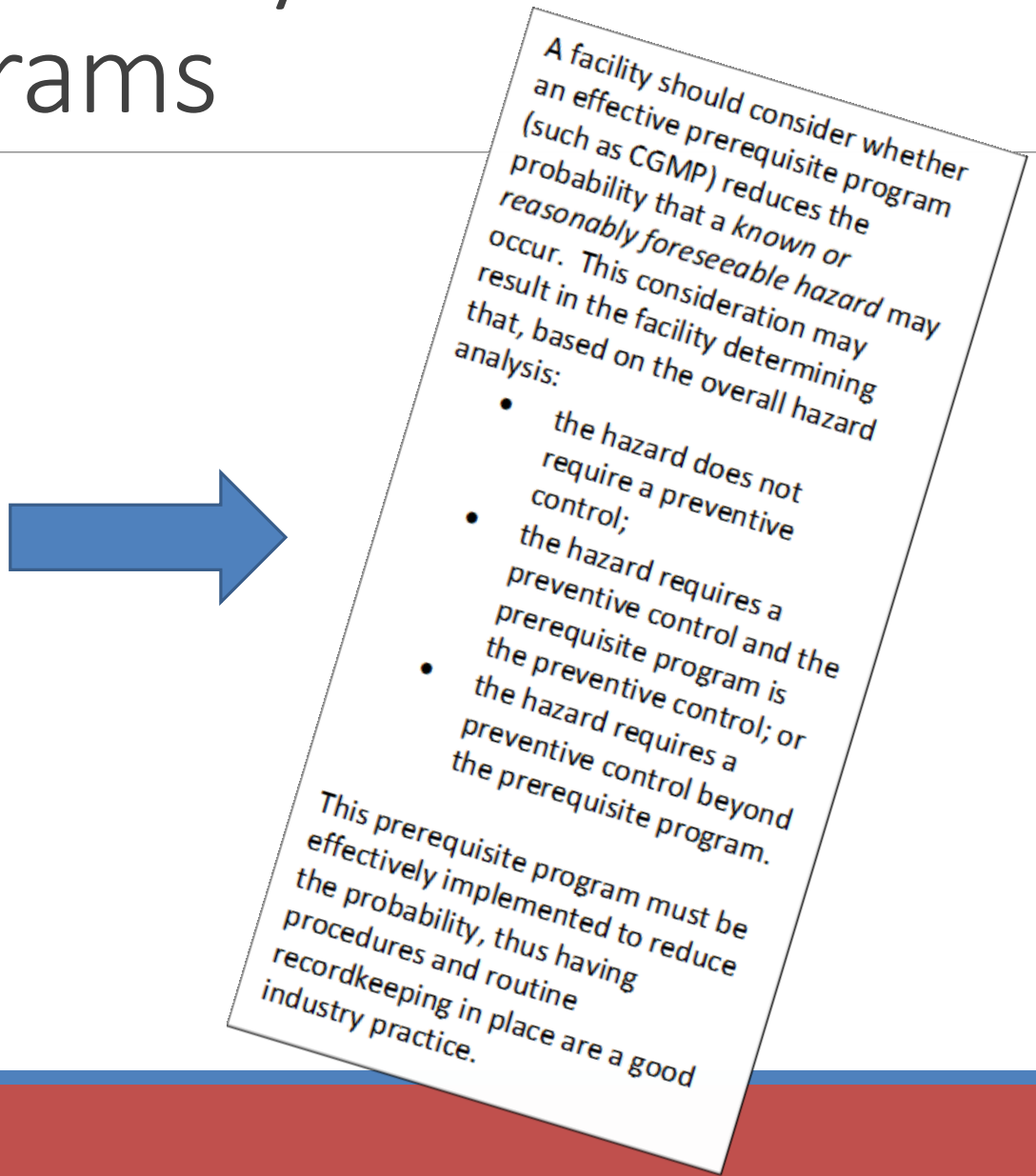
2017 Alltech Global Food Survey

Hazard Evaluation Steps



Remember – Probability CAN consider prerequisite programs

From FSPCA Preventive Controls for Animal Food Course Training Manual v1.1



A facility should consider whether an effective prerequisite program (such as CGMP) reduces the probability that a *known or reasonably foreseeable hazard* may occur. This consideration may result in the facility determining that, based on the overall hazard analysis:

- the hazard does not require a preventive control;
- the hazard requires a preventive control and the prerequisite program is the preventive control; or
- the hazard requires a preventive control beyond the prerequisite program.

This prerequisite program must be effectively implemented to reduce the probability, thus having procedures and routine recordkeeping in place are a good industry practice.

Regulatory Definitions 21 CFR 507.3

- Hazard Requiring a Preventive Control
  - A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes 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), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food ***and components to manage those controls*** (such as monitoring, corrections or corrective actions, verification, and records) 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.

Regulatory Definitions 21 CFR 507.3

	Process Preventive Control	Sanitation Preventive Control	Supply-Chain-Applied Control	Other Control
Monitoring	✓	✓		
Corrective Actions and Corrections	✓	✓	✓	
Validation	✓			
Verification of Monitoring, Corrective Actions, and Implementation and Effectiveness	✓	✓	✓	

As necessary to satisfy the requirements of Part 507.

Hazard Evaluation Steps

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

Example of Implementation

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	

Hazard Analysis Form Example -
other formats may be used

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

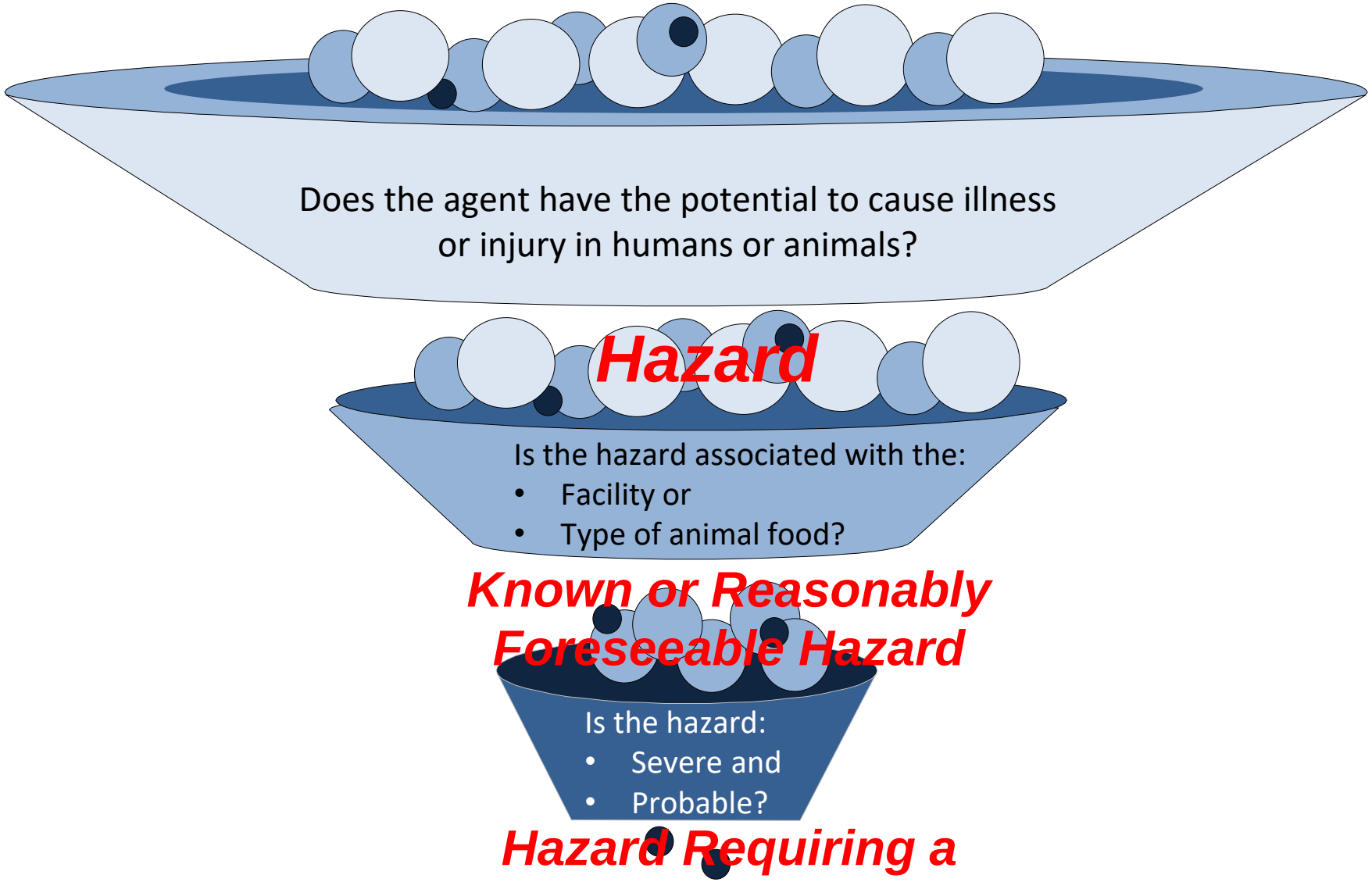
Evaluation			
(3)	(4)	(5)	(6)
Assess Severity of Illness or Injury to Humans or Animals if the Hazard Were to Occur	Assess Probability that the Hazard Will Occur in Absence of Preventive Controls	Determine if Hazard Requires a Preventive Control (Yes or No)	Justify the Classification for the Hazard in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

Hazard Analysis Form Example -
other formats may be used

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


Does the agent have the potential to cause illness or injury in humans or animals?
Hazard
Is the hazard associated with the:
• Facility or
• Type of animal food?
Known or Reasonably Foreseeable Hazard
Is the hazard:
• Severe and
• Probable?
Hazard Requiring a Preventive Control
Supplier
Self
Customer
Supply-Chain-Applied Controls
Process, Sanitation, Other Controls
21 CFR 507.36

What Type of Facility Should We Use?

This is an interactive session. Please participate by voting at:
http://asi318participoll.com

A. Grain elevator that rolls corn for local dairy
B. Grain processor
C. Integrated swine feed mill
D. Toll mill for swine and poultry feed
E. Multi-species commercial feed mill
F. Dog food extrusion facility

1 – List ingredients/Process Steps
2 – Identify Known or Reasonably Foreseeable Hazards

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	

What Is Your Classification of: *Salmonella* spp.

- Pathways to illness
  - Animal salmonellosis through direct consumption
  - Human salmonellosis through cross-contamination when stored in the home
- Regulatory perspective
  - Pet food is adulterated when contaminated with *Salmonella* and will not subsequently undergo a commercial heat step or other commercial process
  - Animal food is adulterated when contaminated with a *Salmonella* serotype that is considered to be pathogenic to the animal intended to consume the animal food and the animal food will not subsequently undergo a commercial heat step or other commercial process

FDA Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals

What Is Your Classification of: *Salmonella* spp.

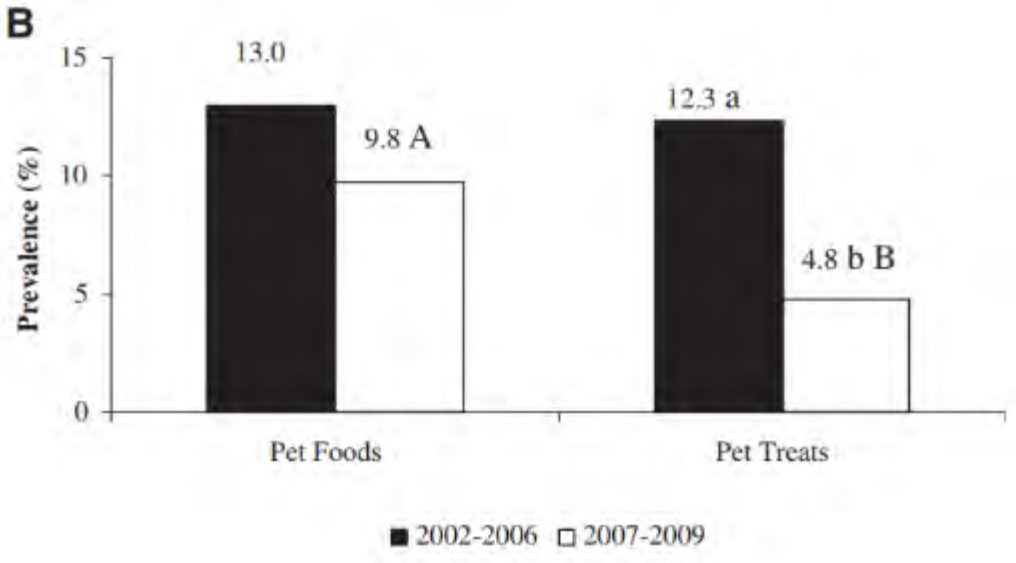
- Current examples of animal foods and the pathogenic Salmonella serotypes that have been associated with disease in the particular animal species consuming these foods:
  - Poultry food with *Salmonella* Pullorum, *Salmonella* Gallinarum, or *Salmonella* Enteritidis
  - Swine food with *Salmonella* Choleraesuis
  - Sheep food with *Salmonella* Abortusovis
  - Horse food with *Salmonella* Abortusequi
  - Dairy and beef food(s) with *Salmonella* Newport or *Salmonella* Dublin

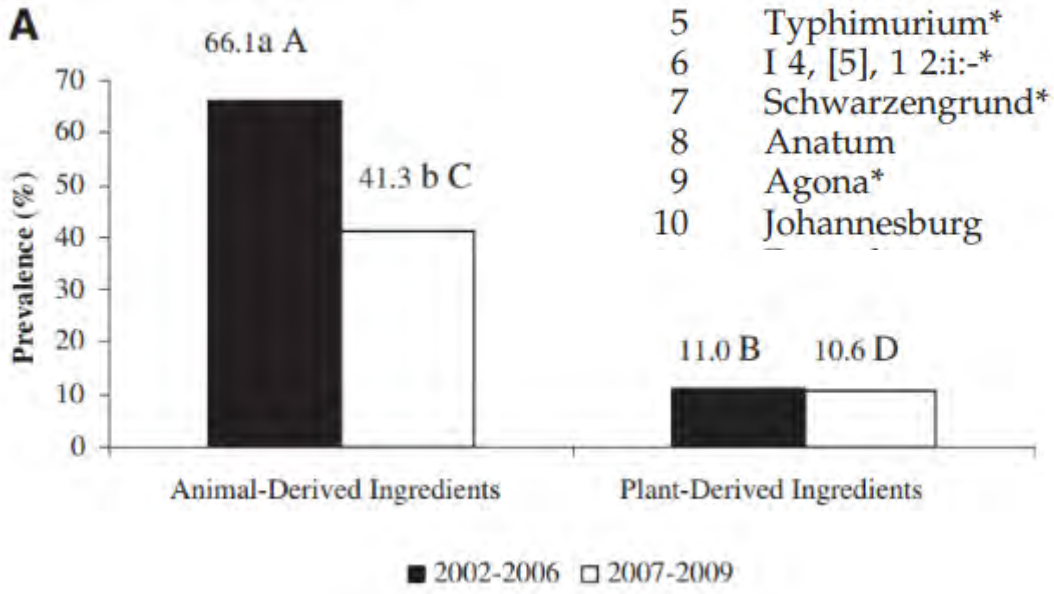
FDA Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals

3 – Assess Severity
4 – Assess Probability
5 – Determination if it Requires a Preventive Control
6 – Justification

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

WHAT IS YOUR CLASSIFICATION OF: *SALMONELLA* SPP.





Animal feeds (2002–2009)

Rank	*Serotype*	*%*
1	Senftenberg	8.9
2	Montevideo*,[b]	8.9
3	Mbandaka	8.6
4	Tennessee	6.2
5	Typhimurium*	5.4
6	I 4, [5], 1 2:i:-*	5.0
7	Schwarzengrund*	4.7
8	Anatum	4.3
9	Agona*	3.5
10	Johannesburg	3.5

Li et al., 2012

WHAT IS YOUR CLASSIFICATION OF: *SALMONELLA* SPP.

Feed type[a]	*No. of samples*	Salmonella
Animal derived	122	42 (34.4)
Meat and bone meal	72	28 (38.9)[A]
Poultry meal	17	3 (17.6)[A]
Blood meal	16	5 (31.3)[A]
Feather meal	10	1 (10)
Fish meal	5	4 (80)
Bone meal	2	1 (50)
Plant derived	79	4 (5.1)
Alfalfa meal	13	—
Oilseed byproducts	49	4 (8.2)
Soybean meal	31	3 (9.7)[a]
Cottonseed meal	8	1 (12.5)[a]
Sunflower meal	5	—
Linseed meal	3	—
Canola meal	2	—
Corn products	17	—
Corn gluten	10	—
Corn meal	5	—
Corn germ	1	—
Hominy	1	—
Total	201	46 (22.9)

Ge et al., 2013

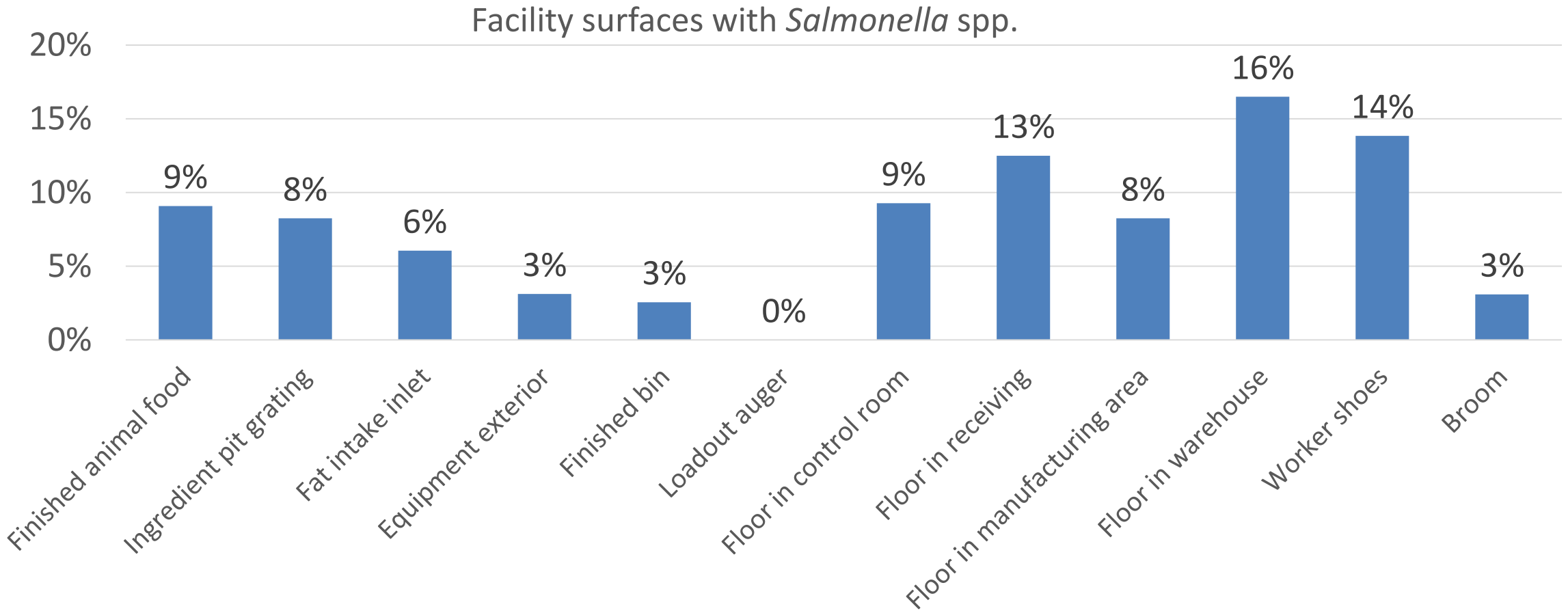
WHAT IS YOUR CLASSIFICATION OF: *SALMONELLA* SPP.

Results:

In the prevalence study, 42.0 % (21/50) of the 50 feed-ingredient piles were presumptive positive for *Salmonella*. By the culture method and Enterobacteriaceae Micro-ID system, 2.0 % (1/50) was confirmed as *Salmonella enteritidis* and serogrouped as poly Group B, Group C_1. In the repeated samples study, 60.0 % (6/10) of the piles were presumptive positive for *Salmonella*. By the culture method and the Enterobacteriaceae Micro-ID system, 20.0 % (2/10) were confirmed as *Salmonella enteritidis* and serogrouped as poly Group B, Group C1. Fifty bacterial isolates were tested for antimicrobial resistance. Sixty-two percent (31/50) of the isolates demonstrated ampicillin resistance while 10.0 % (5/50) displayed tetracycline resistance.

Kidd et al., 2002

What Is Your Classification of: *Salmonella* spp.



Boccatto et al., 2017

What Is Your Classification of: *Salmonella* spp.

A. Not a hazard
B. Hazard, but not known or reasonably foreseeable
C. Known or reasonably foreseeable, but does not require a preventive control
D. Hazard requiring a preventive control – control via supply-chain-applied control
E. Hazard requiring a preventive control – control via process control/other control
F. Hazard requiring a preventive control – control via 21 CFR 507.36

What is Your Justification?

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 we manufacture, its moderate severity (II – Medium) and probability (D – Very Low) determine that it is <u>not</u> a *hazard requiring a preventive control because:*

- 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* we must be concerned with include poultry: Pullorum, Gallinarum, or Enteritidis; swine: Choleraesuis; sheep: Abortusovis; equine: Abortusequi; and cattle: Newport or Dublin. 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.
- Probability: Scientific research reported the frequency with which different *Salmonella* serotypes were found in animal food and ingredients. Of the serotypes relevant to our facility and identified in the severity section above, none were within the top 10 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.

What is Your Justification?

§ 507.33 Hazard analysis.

(a)(1) 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

What is the Role of 'Experience' in Your Justification?

This is an interactive session. Please participate by voting at:
http://asi318participoll.com

A. I plan to use my experience and/or my facility's experience with a specific hazard as justification for probability.
B. I do not plan to use my experience and/or my facility's experience with a specific hazard as justification for probability.
C. I don't know yet.

7 – Determine the Appropriate Control
8 – Assign a Preventive Control Number

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

What Is Your Classification of: Aflatoxin

- Specific growing conditions (cool/wet or hot) in some grains encourage the growth of various mold species.
- Some molds, such as aspergillus and fusarium, occasionally produce mycotoxins during specific environmental conditions.
- Mycotoxins can cause serious illness in humans and animals at very low dosages.
  - Severity depends upon animal physiology, phase of production.

Source: Mycotoxins: Risks in Plant, Animal, and Human Systems. CAST Task Force Report 2003.

What Is Your Classification of: Aflatoxin

- Can be transmitted through milk, meat, eggs to humans
  - Highly carcinogenic.
- In animals, causes mortality, decreased weight gain and egg/milk production

FDA Action Limits for Aflatoxin		
Level	**Ingredient**	**Animal**
300 ppb	Corn or Peanut Products	Finishing Beef Cattle
300 ppb	Cotton Seed Meal	Beef Cattle, Swine, Poultry
200 ppb	Corn or Peanut Products	Finishing Swine (100 lb BW or greater)
100 ppb	Corn, Peanut Products, Other Animal Foods	Breeding Beef Cattle, Breeding Swine, Mature Poultry
20 ppb	Corn, Peanut Products, Other Animal Foods	Immature Animals and Others Not Listed

Source: FDA Compliance Policy Guide Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds

What Is Your Classification of: Aflatoxin

A. Not a hazard
B. Hazard, but not known or reasonably foreseeable
C. Known or reasonably foreseeable, but does not require a preventive control
D. Hazard requiring a preventive control – control via supply-chain-applied control
E. Hazard requiring a preventive control – control via process control/other control
F. Hazard requiring a preventive control – control via 21 CFR 507.36

What Is Your Classification of: Copper Toxicity in Sheep Feed

A. Not a hazard
B. Hazard, but not known or reasonably foreseeable
C. Known or reasonably foreseeable, but does not require a preventive control
D. Hazard requiring a preventive control – control via supply-chain-applied control
E. Hazard requiring a preventive control – control via process control/other control
F. Hazard requiring a preventive control – control via 21 CFR 507.36

What Is Your Classification of: **Monensin Sodium Carryover**

A. Not a hazard
B. Hazard, but not known or reasonably foreseeable
C. Known or reasonably foreseeable, but does not require a preventive control
D. Hazard requiring a preventive control – control via supply-chain-applied control
E. Hazard requiring a preventive control – control via process control/other control
F. Hazard requiring a preventive control – control via 21 CFR 507.36

What Is Your Classification of: Nicarbazin Carryover

A. Not a hazard
B. Hazard, but not known or reasonably foreseeable
C. Known or reasonably foreseeable, but does not require a preventive control
D. Hazard requiring a preventive control – control via supply-chain-applied control
E. Hazard requiring a preventive control – control via process control/other control
F. Hazard requiring a preventive control – control via 21 CFR 507.36

What Is Your Classification of: Ractopamine Carryover

A. Not a hazard
B. Hazard, but not known or reasonably foreseeable
C. Known or reasonably foreseeable, but does not require a preventive control
D. Hazard requiring a preventive control – control via supply-chain-applied control
E. Hazard requiring a preventive control – control via process control/other control
F. Hazard requiring a preventive control – control via 21 CFR 507.36

What Is Your Classification of: Metal

A. Not a hazard
B. Hazard, but not known or reasonably foreseeable
C. Known or reasonably foreseeable, but does not require a preventive control
D. Hazard requiring a preventive control – control via supply-chain-applied control
E. Hazard requiring a preventive control – control via process control/other control
F. Hazard requiring a preventive control – control via 21 CFR 507.36

SUMMARY

- Each facility is responsible for making appropriate decisions about hazard analysis.
- This can be challenging because there is substantial flexibility in the *Preventive Controls for Animal Food* rule with limited current guidance.
- Effective hazard analysis relies on "experience, illness data, scientific reports, and other information." This should be defendable.
- It is helpful to understand how others in similar industry segments are evaluating hazards because food safety is not a trade secret.