

**Qualitative Risk Assessment:  
Risk of Activity/Animal Food Combinations for Activities  
(Outside the Farm Definition) Conducted in a Facility  
Co-Located on a Farm**

**August 2015**

## EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) has conducted a qualitative risk assessment (RA) related to manufacturing, processing, packing, and holding activities for animal food when such activities are conducted on farms. The purpose of the RA is to provide a science-based risk analysis to determine those activity/animal food combinations that are considered low risk. FDA conducted this RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities involving specific animal food that FDA determines to be low risk from the requirements of sections 418 and 421 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or whether to modify such requirements for such facilities.

The RA identified the following as low-risk activity/animal food combinations:

- Chopping/shredding hay;
- Cracking/crimping/flaking/pearling/peeling/shelling/wafering grain (e.g., barley, sorghum, corn, oats, rice, rye, and wheat) or oilseed (e.g., beans, canola, cottonseed, linseed, soybeans, and sunflowers);
- Crushing/dry rolling/grinding/milling/pulverizing/ grain, oilseed, grain by-products and processed grain products (e.g., bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal), oilseed products (e.g., oil or meal of safflower, soybean, and sunflower), hay, ensiled material, culled fruits and vegetables, roughage (e.g. cobs, hulls, husks, and straws), or roughage products (e.g., alfalfa meal, entire plant meal, stem meal, pomace, pulp);
- Ensiling (including chopping/shredding/mixing/storing/fermenting), that is, making silage or haylage from forage (e.g., sorghum (milo), corn (maize), alfalfa, and grass), grain, or culled fruits and vegetables, or roughage;
- Extracting (mechanical)/wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;
- Labeling roughage products, plant protein meals (e.g., algae, coconut (copra), guar, and peanut), grain by-products and processed grain products, oilseed products, molasses (e.g., processed sugar cane, sugar beets, and citrus), animal protein meals (e.g., blood, feather, meat, meat and bone, and marine (e.g., crab, fish, shrimp)), milk products (e.g., casein, cheese rind, and lactalbumin), animal tissue-derived products, (e.g., fat), vitamins, minerals, concentrates, processing aids (e.g., enzymes, preservatives, and stabilizers), finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety;
- Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety;
- Packing/re-packing roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal

food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety;

- Storing/holding (ambient, cold, or controlled atmosphere), including activities incidental to holding (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety.

## TABLE OF CONTENTS

Executive Summary.....	2
Table of Contents.....	4
List of Tables .....	5
I. Background and Purpose.....	6
A. Statutory and Regulatory Framework of the FDA Food Safety Modernization Act (FSMA) .....	6
B. Approach to the Qualitative Risk Assessment .....	7
C. Activities on Animal Food That Are Out of Scope of the Qualitative Risk Assessment .....	8
D. Specific Questions to be Addressed in the RA .....	8
E. Definitions of Low-Risk Activity and Low-Risk Activity/Animal Food Combination .....	9
F. Data Limitations .....	10
II. Scope (Activity/Animal Food Combinations within the Scope of the RA).....	11
III. Hazard Identification .....	15
IV. Hazard Characterization .....	21
A. Biological Hazards .....	21
B. Chemical (including Radiological) Hazards .....	23
C. Nutrient Imbalance .....	25
D. Physical Hazards .....	26
V. Exposure Assessment .....	26
A. Approach .....	26
B. Factors That Impact the Frequency and Levels of Contamination of the Animal Food - Biological Hazards .....	28
1. Impact of water activity on growth of foodborne pathogens.....	28
2. Impact of pH on growth of foodborne pathogens.....	29
3. Impact of temperature on growth of foodborne pathogens .....	30
4. The impact of other factors on growth of foodborne pathogens .....	30
5. Interaction of factors that impact the growth of foodborne pathogens.....	31
6. Inherent Controls for Biological Hazards Relevant to This Risk Assessment .....	31
7. Interventions to Control the Biological Hazards Relevant to This Risk Assessment.....	31
8. Activities That Can Introduce, or Increase the Potential for, Biological Hazards Relevant to This Risk Assessment.....	32
C. Factors That Impact the Frequency and Levels of Contamination of the Animal Food - Chemical (including Radiological) Hazards .....	33
D. Factors That Impact the Frequency and Levels of Contamination of the Animal Food - Nutrient Imbalance (Deficiencies or Toxicities) Hazards.....	34
E. Factors That Impact the Frequency and Levels of Contamination of the Animal Food - Physical Hazards .....	35
G. Frequency of Consumption and Amount of Animal Food Consumed .....	35
VI. Risk Characterization .....	36
A. Approach .....	36
B. Qualitative Risk Characterization .....	36
C. Characterizing Interventions with Respect to the Definition of Low-Risk Activity.....	39
VII. Conclusions.....	43

A. Answers to the Questions to be Addressed in This Risk Assessment.....	43
B. Summary .....	47
VIII. References.....	48
Appendix 1. Definitions Relevant to Activities of Farms and Farm Mixed-Type Facilities .....	57
Appendix 2. A summary of key changes in the final risk assessment compared to the draft risk assessment .....	59
Appendix 3: Chronology of Technical and Scientific Reviews of the Qualitative Risk Assessment..	61
Appendix 4: Public Comments and FDA/CVM’s Responses.....	62
Appendix 5: Packing/Holding Activities.....	65
Appendix 6: Manufacturing/Processing Activities .....	66

## LIST OF TABLES

Table 1: Manufacturing, Processing, Packing, and Holding Activity/Animal Food Combinations That May Be Conducted by Farm Mixed-type Facilities on Foods for Animal Consumption, Excluding Those Always Within the Farm Definition.....	12
Table 2. Summary of Primary Reports Submitted to the RFR from the RFR Annual Reports 2010-2013 Used in Identifying Hazards in Animal Food.....	16
Table 3. Summary of Animal Food Recalls from the RES, Used in Identifying Hazards	17
Table 4. Potential Biological and Chemical Hazards That Are Reasonably Likely to Be Associated with the Animal Food Categories Manufactured, Processed, Packed, or Held on a Farm Mixed-Type Facility.....	19
Table 5. Interaction of Factors Operating as Controls for Biological Hazards in the Making of Silage .....	31
Table 6. Examples of Interventions to Control Biological Hazards.....	32
Table 7. Example of an Activity that Can Introduce, or Increase the Potential for, Biological Hazards .....	33
Table 8. Examples of Interventions and Activities that Can Affect Chemical Hazards ..	34
Table 9. Qualitative Risk Characterization of Representative Hazards That Are Likely Be Associated With Animal Food Manufactured/processed, Packed, or Held on a Farm Mixed-Type Facility.....	38
Table 10. Is an Activity/Animal Food Combination Low Risk?.....	40
Table 11. Why Certain Activity/Animal Food Combinations Are Not Low Risk.....	42
Table 12. Chronology of Technical and Scientific Reviews of the Qualitative Risk Assessment	61
Table 13. Summary of Public Comments Received to the Draft Preventive Control Rule for Animal Food or the Draft RA and FDA/CVM Responses .....	62
Table 14. Animal Food Categories That Are Included in the Exemption for On-Farm Low-Risk Packing and Holding Activities, Revised for Clarification as a Result in the Change of “Farm” Definition.....	65
Table 15. Animal Food Categories That Are Not Included in the Exemption for On-Farm Low-Risk Packing and Holding Activities in the Final RA That Were Included in the Draft RA	66
Table 16. Activity/Animal Food Combinations Included in the Exemption for On-Farm Low-Risk Manufacturing/Processing Activities That Are New in the Final RA.....	66
Table 17. Activity/Animal Food Combinations That Are Not Included in the Exemption for On-Farm Low-Risk Manufacturing/Processing Activities .....	67

## **I. BACKGROUND AND PURPOSE**

### **A. Statutory and Regulatory Framework of the FDA Food Safety Modernization Act (FSMA)**

On January 4, 2011, the FSMA (Public Law 111–353) was signed into law. Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418 with the same name. Among other things, Section 418 requires facilities to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, identify and implement preventive controls, monitor the performance of those controls, and maintain records of the monitoring. Section 418 is applicable to animal food facilities that are required to register under section 415 of the FD&C Act (Registration of Food Facilities). The registration requirement in section 415 of the FD&C Act does not apply to farms. However, it does apply to “farm mixed-type facilities,” which are establishments that are farms, but that also conduct activities outside the “farm” definition that require the establishment to be registered.

Section 103(c) of FSMA directs the Secretary of the Department of Health and Human Services (HHS) to conduct a science-based risk analysis to cover “(i) specific types of on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership, as such packing and holding relates to specific foods; and (ii) specific on-farm manufacturing and processing activities as such activities relate to specific foods that are not consumed on that farm or on another farm under common ownership.” We previously issued for public comment a document entitled “Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm” (Draft RA) (78 FR 64428, October 29, 2013; Docket No. FDA-2013-N-1043). The activities listed in the Draft RA were those on-farm activities that were outside the farm definition as it existed at the time FSMA became law. Therefore, at that time all such activities triggered the registration requirements of section 415 of the FD&C Act and, thus, would make an establishment subject to the new requirements of section 418 of the FD&C Act and the mandatory inspection frequencies in section 421 of the FD&C Act. FDA has since revised the farm definition to include some of the listed activities within the farm definition, thereby narrowing the scope of the activity/animal food combinations that need to be considered in this risk assessment. (See Appendix 1 for the revised definition of “farm,” harvesting, holding, packing, and manufacturing/processing.)

Section 103(c) of FSMA also requires that the Secretary of HHS consider the results of the science-based risk analysis and exempt certain facilities from the requirements in section 418 of the FD&C Act, and the mandatory inspection frequency in section 421 of the FD&C Act, or modify the requirements, as the Secretary determines appropriate, if such facilities are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities that the Secretary determines to be low risk involving specific animal food the Secretary determines to be low risk. The exemptions or modifications would apply only to small businesses and very small businesses (as would be defined in the regulation implementing section 418).

The purpose of this document is to satisfy these requirements of FSMA 103(c) for a science-based risk analysis covering certain manufacturing, processing, packing, and holding activities conducted on farms. Risk managers at FDA considered the results of the risk analysis presented in this RA in determining, in part, exemptions from, or modifications to, requirements that would otherwise apply to small or very small farm mixed-type facilities.

Since issuing the Draft RA, we have considered the following information with respect to its impact on the Draft RA:

- Revisions that FDA proposed to definitions that affect the regulatory status of activities that take place on farm in rulemaking entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,” (proposed animal food preventive controls rule; Docket No. FDA-2011-N-0922):
  - Proposed rule, 78 FR 64736, October 29, 2013;
  - Supplemental notice of proposed rulemaking (79 FR 58476, September 29, 2014).
- Comments submitted to Docket FDA-2013-N-1043 on the Draft RA; and
- Comments submitted to Docket FDA-2011-N-0922 on the proposed rule relevant to activities conducted on animal food on farms.

In general, to the extent relevant to animal food and, in particular, with respect to changes to the definition of farm, we also considered the dockets for the preventive controls rule for human food:

- Revisions that FDA proposed to definitions that affect the regulatory status of activities that take place on farm in rulemaking entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,” (proposed human preventive controls rule; Docket No. FDA-2011-N-0920):
  - Proposed rule, 78 FR 3646, January 16, 2013;
  - Supplemental notice of proposed rulemaking (79 FR 58524, September 29, 2014).
- Comments submitted to Docket FDA-2012-N-1258 on the Draft RA; and
- Comments submitted to Docket FDA-2011-N-0920 on the proposed rule relevant to activities conducted on foods on farms.

We revised the Draft RA as appropriate after considering all of this information. A summary of key changes in this final risk assessment compared to the draft risk assessment can be found in Appendix 2.

## **B. Approach to the Qualitative Risk Assessment**

We focused on activity/animal food combinations that we identified as being conducted on farms (and, thus, might be conducted by farm mixed-type facilities), but we did not consider activity/animal food combinations that would be solely within the farm definition (such as growing, harvesting, and storing grains and oilseeds on farm) and, thus, are not relevant to the requirements of section 103 of FSMA.

We focused on considering the risk of activity/animal food combinations rather than separately considering the risk of specific animal food categories because doing so would better enable us to focus on whether a specific manufacturing, processing, packing, or holding activity conducted on animal food by a farm mixed-type facility warranted an exemption from, or modified requirements for, the provisions of section 418 of the FD&C Act.

The decision before FDA was in part to determine the need for preventive controls required by section 418 of the FD&C Act for small and very small farm mixed-type facilities. Therefore, in this RA we assessed whether the types of controls that would be required by section 418 of the FD&C Act are needed to ensure the safety of the animal food manufactured, processed, packed, or held by small or very small farm mixed-type facilities in light of the regulatory framework that would apply to such facilities that would become exempt from, or subject to modified requirements for, the

requirements for hazard analysis and risk-based preventive controls that would be established under section 418 of the FD&C Act. Examples of the types of controls that facilities may implement under section 418 include process controls (where a process is used to significantly minimize or prevent a hazard), sanitation controls, and supply-chain controls. The regulatory framework that applies to small or very small farm mixed-type facilities includes the current good manufacturing practice (CGMP) requirements for manufacturing, processing, packing, or holding animal food (established as subpart B concurrently with the preventive controls requirements established as subpart C of the implementing regulations) and the adulteration provisions of section 402 of the FD&C Act. While small or very small mixed-typed facilities that conduct only activities designated as low risk are exempt from complying with subparts C and E of the implementing regulations, they are subject to the CGMP (subpart B) requirements and responsible for producing safe animal food.

### **C. Activities on Animal Food That Are Out of Scope of the Qualitative Risk Assessment**

Activities to produce animal protein meals, animal tissue-derived products, pet food (including treats), and milk products that require one or more preventive controls (e.g., heat treatment, or time/temperature control for safety) to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death to humans or animals are out of the scope of the risk assessment. See Chapter 2, “Current and Proposed Definitions of "Potentially Hazardous Foods" in Evaluation and Definition of Potentially Hazardous Foods for additional discussion regarding food requiring time/temperature control for safety (Institute of Food Technologists, 2001). Thus, activities to produce animal protein meals, animal tissue-derived products and milk products for animal consumption, and to produce pet food, including pet treats, could not be considered low-risk activity/animal food combinations. We eliminated activities (e.g., rendering, extruding, churning) used to make the above animal food products from the scope of the RA because they are not low-risk by virtue of requiring temperature controls. While activities to manufacture these products are outside the scope of the risk assessment, processed animal protein meals, animal tissue-derived products, and milk products processed into a form that does not require time/temperature control for safety and brought onto farm to be combined with other animal food are within the scope of the risk assessment. That is, on-farm activities performed to make animal food for distribution into commerce using animal protein meals, animal tissue-derived products, or milk products produced off-farm are within the scope of the risk assessment.

In addition, based on the statutory framework of FSMA, activities related to low-acid<sup>1</sup> canned foods are within the scope of the RA only with respect to chemical (including radiological) and physical hazards. However, for animal food, we understand that low-acid canning is an activity used only in the production of pet food which is out of the scope of the animal food RA for the reasons noted above.

### **D. Specific Questions to be Addressed in the RA**

**Question 1:** What animal food would be manufactured, processed, packed, or held by a farm mixed-type facility?

---

<sup>1</sup> Low-acid foods have a pH greater than 4.6; acid foods are those that have a natural pH of 4.6 or below. This pH has long been used to separate foods that may support growth of *C. botulinum* from those that do not. However, other pathogens are capable of growing at pH values of 4.6 or below, e.g., *Salmonella* have been shown to grow at pH 4.0 in laboratory media under certain conditions (Chung and Goepfert, 1970).

**Question 2:** What are the activities that might be conducted by farm mixed-type facilities on that animal food?

**Question 3:** What are the known or reasonably foreseeable hazards<sup>2</sup> associated with the animal food manufactured, processed, packed, or held by a farm mixed-type facility?

**Question 4:** For the purpose of determining whether an activity/animal food combination is low risk, which hazards should be considered to have a reasonable probability of causing serious adverse health consequences or death to humans or animals?

**Question 5:** For the purpose of determining whether an activity/animal food combination is low risk, what animal food has inherent controls that significantly minimize or prevent in the animal food a hazard that is a known or reasonably foreseeable biological hazard and that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

**Question 6:** What interventions significantly minimize or prevent in the animal food a hazard that is a known or reasonably foreseeable hazard and that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

**Question 7:** Which of these activities are reasonably likely to introduce into animal food, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals and what are these hazards?

**Question 8:** Which of these activities are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals from consumption of the animal food?

**Question 9:** Which activity/animal food combinations are low risk?

## **E. Definitions of Low-Risk Activity and Low-Risk Activity/Animal Food Combination**

For the purpose of the analysis required by section 103(c)(1)(C) of FSMA, we are defining “low-risk activity” and “low-risk activity/animal food combinations” as follows.

- We are defining “low-risk activity” to mean an activity that:
  1. Is performed on, or during production of, an animal food that has inherent controls for foodborne pathogens, provided that the animal food does not require preventive controls to significantly minimize or prevent other types of hazards (e.g., a chemical hazard such as mycotoxins); or
  2. Satisfies both of the following criteria:
    - a) Is not reasonably likely to introduce (or increase the potential for) a hazard for which there is a reasonable probability that use of, or exposure to, the animal food will cause serious adverse health consequences or death to humans or animals (a SAHCODHA hazard); and

---

<sup>2</sup> A known or reasonably foreseeable hazard is a biological, chemical (including radiological), nutrient deficiencies or toxicities, or physical hazard that is known to be, or has the potential to be, associated with the facility or the animal food.

- b) Does not significantly minimize or prevent a SAHCODHA hazard.
- We are defining “low-risk activity/animal food combination” to mean a low-risk activity that applies to a specific animal food.

For the purpose of this analysis, we:

- Refer to the above three parts of the definition of “low-risk activity” as:
  - #1 (inherent controls);
  - #2a (activity not likely to introduce, or increase the potential for, a SAHCODHA hazard; and
  - #2b (activity does not significantly minimize or prevent a SAHCODHA hazard).
- Use the term “inherent controls” to mean that in making the animal food the hazard is controlled, and it is highly unlikely that the animal food will be made in a way that the hazard is not adequately addressed.
- Use the phrase “reasonably likely to cause serious adverse health consequences or death to humans or animals” to mean that there is a reasonable probability that use of, or exposure to, an animal food containing a hazard will cause serious adverse health consequences or death to humans or animals. It is important to note that our conclusions in this document with respect to whether there is a reasonable probability that use of, or exposure to, an animal food containing a hazard will cause serious adverse health consequences or death to humans or animals are limited to the purposes of this document. In this document, we are considering such hazards and animal food in general terms, on a forward-looking basis, and not in reference to a particular animal food contamination incident or foodborne illness outbreak. Determinations of whether there is such a reasonable probability in specific situations may be different from the conclusions made for the limited purposes of this document.

Importantly, under the definition of low-risk activity animal food combination, to be low risk the activity/animal food combination must either:

- Satisfy part #1; or
- Satisfy both part #2a and part #2b.

## **F. Data Limitations**

There are many limitations to the data used in this analysis:

- We have limited data on the types of activity/animal food combinations associated with small and very small farm mixed-type facilities, especially for foreign facilities.
- We have limited data on the frequency and levels of contamination of animal food in general.
- We have no data on the frequency and levels of contamination of animal food manufactured, processed, packed, or held by small and very small farm mixed-type facilities in particular.
- We have limited data on the occurrence of serious adverse health consequences or death from hazards associated with manufacturing, processing, packing, or holding activities conducted on animal food. We receive reports of sporadic incidences of illness in animals associated with animal food consumption or illness in humans from handling animal food and several outbreaks have been recorded. However, there is no surveillance system established for consistent reporting of information on foodborne illnesses in animals. Many of the hazards in animal food are discovered by the responsible party and reported to the Reportable Food Registry prior to distribution of the animal food, avoiding exposure and health consequences. In addition, farms that produce animal food fed only to animals on that farm remain within the

farm definition and are not required to report into the Reportable Food Registry described below in Section III, Hazard Identification. Thus, we relied in large part on our existing understanding of hazards and processes in order to characterize risk.

- We have no data on serious adverse health consequences or death in humans or animals from hazards associated with manufacturing, processing, packing, or holding activities conducted on animal food by small and very small farm mixed-type facilities specifically.
- We lack data to conduct a dose-response assessment for hazard characterization for animal food for many hazards.
- There is little data linking human foodborne illness to hazards in animal food. Information on the extent to which presence of a hazard in food fed to animals influences the presence of the hazard in human food is limited to a few instances. One known example is the presence of aflatoxin in animal food for dairy cattle resulting in detectable levels of aflatoxin in milk (FDA, 2013a).
- Limited data are available on the human health impacts of direct contact with animal food. Instances of human cases of salmonellosis associated with contact with pet food have been reported to the Reportable Food Registry (FDA, 2013b) and the U.S. Centers for Disease Control and Prevention (CDC, 2008; CDC, 2010; CDC 2014) and have been the subject of joint FDA-CDC outbreak investigations (FDA, 2012a; CDC, 2014a).

The lack of evidence associating occurrences of serious adverse health consequences or death with biological, chemical (including radiological), and physical hazards associated with manufacturing, processing, packing, or holding activities conducted on animal food by small and very small farm mixed-type facilities, along with the other data limitations noted above, are significant limitations of this RA.

## **II. SCOPE (ACTIVITY/ANIMAL FOOD COMBINATIONS WITHIN THE SCOPE OF THE RA)**

The scope of the RA is limited to an assessment of the risk of serious adverse health consequences or death in humans or animals from hazards associated with manufacturing, processing, packing, or holding activities conducted on animal food by small and very small farm mixed-type facilities, including both domestic and foreign facilities, to determine which activity/animal food combinations conducted by such facilities are low risk.

The activity/animal food combinations considered within the scope of this RA are those that we identified that might be conducted by farm mixed-type facilities by forming a cross-tabulation with activities as rows and individual animal foods as columns using animal foods and activities conducted on animal food found in animal food trade publications (FDA, 2013c; FDA, 2013d). We solicited input from animal food safety and processing experts within the FDA Center for Veterinary Medicine and from outside experts in the animal food industry and academia about whether the activity and animal food pairs represented by the cells of the table were feasible activity/animal food combinations and whether they were likely to be conducted by small or very small farm mixed-type facilities. We do not have data on activity/animal food combinations likely to be conducted by foreign farm mixed-type facilities, which may include activity/animal food combinations not considered here.

FDA requested comment on the activity/animal food combinations considered within the scope of the risk assessment (Docket FDA-2013-N-1043, 78 FR 64428 at 64429; Docket FDA-2011-N-0992, 78 FR 64736 at 64753). We did not receive comments requesting us to modify our list of activity/animal food combinations.

If an expert or a reference identified an activity/animal food combination that is outside the scope of this RA (i.e., activities to produce animal tissue-derived products, pet food, and milk products), we did not include that activity/animal food combination in the list. We also did not include activity/animal food combinations or activity/animal food combinations that are always within the farm definition (e.g., growing grain and related activities such as applying pesticides prior to harvest and field cutting and drying grasses to harvest hay).

Table 1 lists the resulting activity/animal food combinations that we identified as likely to be conducted by farm mixed-type facilities, taking into consideration the revised definition of farm. Most notable of these changes is that packing and holding (storing) of raw agricultural commodities (RACs) by farms which was within the farm definition only if done on RACs grown on the farm (or a farm under the same ownership) where they are packed now remains within the farm definition regardless of where the RACs are grown. See the definition of holding in Appendix 1 for an explanation of the activities included. As a result, there are no RACs listed in combination with packing or holding activities. Table 1 includes activities that may encompass multiple steps (e.g., ensiling or making silage may involve steps such as chopping, shredding, mixing, storing and fermenting) and groups these steps to better identify the end product. Since fermenting as an on-farm animal food processing activity is specific to making silage, fermenting does not appear as a separate entry. Examples of animal foods within the categories used in the table are described in more detail following the table.

**Table 1: Manufacturing, Processing, Packing, and Holding Activity/Animal Food Combinations That May Be Conducted by Farm Mixed-type Facilities on Foods for Animal Consumption, Excluding Those Always Within the Farm Definition**

Activity	Animal Food
Chopping/shredding	Hay
Cracking/crimping/flaking/pearling/peeling/shelling/wafering	Grain; oilseed
Crushing/dry rolling/grinding/milling/pulverizing/	Grain; oilseed; grain by-products and processed grain products; oilseed products; hay; ensiled material; culled fruits and vegetables; roughage, roughage products
Ensiling (including chopping/shredding/mixing/storing/fermenting), that is, making silage or haylage	Forage; grain; culled fruits and vegetables; roughage
Extracting (mechanical)/wet rolling	Grain, oilseed, brewers grain by-products, or distillers grain by-products

Activity	Animal Food
Labeling	Roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids; finished animal food, including animal food ready for consumption; any other processed food that does not require time/temperature control for safety
Making complete animal food (including processing activities such as mixing/extruding/pelleting and other activities such as sifting/separating/weighing/labeling/packaging)	Grain; oilseed; roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids
Making mineral and vitamin mixes and concentrates for feeding to animals without further processing (including weighing/mixing/packaging/labeling)	Grain; oilseed; roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids
Packing/re-packing (including activities performed for safe or effective packing of that animal food)	Roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids; finished animal food, including animal food ready for consumption; any other processed food that does not require time/temperature control for safety

Activity	Animal Food
Packaging	Roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids; finished animal food, including animal food ready for consumption; any other processed food that does not require time/temperature control for safety
Storing/holding (ambient, cold, or controlled atmosphere) including activities incidental to holding (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that animal food	Roughage products, plant protein meals, grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, and any other processed food that does not require time/temperature control for safety

Based on the fact that we received no comments requesting revisions to the activity/animal food combinations considered within the scope of our draft risk assessment (Docket FDA-2013-N-1043, 78 FR 64428 at 64429; Docket FDA-2011-N-0992, 78 FR 64736 at 64753), FDA believes that Table 1 includes most of the activity/animal food combinations (except for those always within the farm definition) that are potentially conducted by farm mixed-type facilities on animal food that are within the scope of the RA. However, the list of activity/animal food combinations likely to be conducted at farm mixed-type facilities has been re-structured in light of revisions to the farm definition. Compared with the draft RA, RACs such as grain, oilseed, and forage are no longer listed in combination with packing/holding activities performed by farms because these activity/animal food combinations fall within the new farm definition. RACs are not listed in combination with packaging and labeling because these combinations also fall within the farm definition, while other manufacturing/processing activities related to animal food RACs are not within the farm definition and are included in the table. See Appendix 1 for relevant definitions. We grouped the animal food categories into three classes to assist in aligning them with the activities according to the new farm definition: RACs, manufactured/processed animal food, and manufactured animal food ready for consumption.

- 1) RACs. As they apply to animal food, these may include:
  - a. Grain such as barley, grain sorghum (milo), corn (maize), oats, rice, and wheat;
  - b. Oilseed such as beans, canola, cottonseed, linseed, safflower, soybeans, and sunflowers;
  - c. Forage such as sorghum (milo), corn (maize), alfalfa, grass and hay; and

- d. Culled fruits and vegetables, and roughage such as cobs, hulls, husks, and straws.
- 2) Manufactured/processed animal food. This class is further divided into two subclasses.
  - a. Processed RACs that may have been processed at the farm-mixed facility or acquired from off farm. These include, for example:
    - i. Roughage products such as alfalfa meal, entire plant meal, stem meal, pomace, and pulp;
    - ii. Plant protein meals such as algae meal, coconut meal (copra), guar meal, and peanut meal;
    - iii. Grain by-products and processed grain products such as brans, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal;
    - iv. Oilseed products such as oil or meal of, safflower, soybean, and sunflower; and
    - v. Molasses such as processed sugar cane, sugar beets, and citrus.
  - b. Manufactured/processed animal food acquired from off farm. This includes, for example:
    - i. Animal protein meals such as blood meal, feather meal, meat meal, meat and bone meal, and marine (crab, fish, shrimp) meal;
    - ii. Milk products such as casein, cheese rind, and lactalbumin;
    - iii. Animal tissue-derived products such as fat;
    - iv. Vitamins, minerals, and concentrates;
    - v. Processing aids such as enzymes, preservatives, and stabilizers; and
    - vi. Any other processed animal food that does not require time/temperature control for safety.
- 3) Finished animal food. This includes, for example:
  - a. Animal food ready for consumption;
  - b. Mineral and vitamin mixes and blocks;
  - c. Concentrates; and
  - d. Silage, haylage.

For the purpose of this document, a fruit is the edible reproductive body of a seed plant or tree nut (such as orange and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. For the purpose of this document, a vegetable is the edible part of an herbaceous plant (such as potato) or fleshy fruiting body of a fungus (such as white button or shiitake mushrooms) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as animal food and includes mushrooms, sprouts, and herbs (such as basil or cilantro).

For the purposes of this document, grain means the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds. For the purposes of this document, oilseed means the small, hard fruits or seeds of arable crops (that is, grain), that are grown and processed mainly for the oil that is extracted from them.

### **III. HAZARD IDENTIFICATION**

The purpose of the Hazard Identification step of a food safety risk assessment is to identify the hazards of concern. The scope of this RA requires consideration of the broad range of biological,

chemical (including nutrient deficiencies and nutrient toxicities, and radiological hazards), and physical hazards in animal food that are relevant to a farm mixed-type facility under section 418 of the FD&C Act. Although there is a National Animal Health Monitoring System (NAHMS) maintained by the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), the animal disease cases reportable to the monitoring program are chiefly cases with communicable diseases such as tuberculosis and brucellosis in cattle rather than cases experiencing adverse health outcomes following consumption of a suspect animal food (USDA APHIS, 2012). In contrast to CDC's FoodNet data that serves to identify and estimate numbers of cases affected by microbial hazards in human food, there are no monitoring data to estimate numbers of animals affected by hazards of concern for animal food (CDC, 2014b). As a result, we relied more heavily upon information available from the FDA's Reportable Food Registry (RFR) and Recall Enterprise System (RES) and identified biological, chemical, and physical hazards associated with animal food (FDA, 2013b; FDA, 2015a). The RFR was established by section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L.110-085) and requires a responsible party to file a report through the RFR electronic portal 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. The RES is a component of the FDA Office of Regulatory Affairs (ORA) Mission Accomplishments and Regulatory Compliance Services (MARCS) database.

Many of the hazards reported to the RFR and to the RES are common to food for humans and food for animals. However, nutrient deficiency and nutrient toxicities are not described as hazards for human food but are frequently reported hazards of animal food and very important ones because often animals depend entirely on the same daily ration offered for their consumption and they often consume the ration *ad libitum* (Gries and Scott, 1971; Johnson and Storts, 1988; National Research Council, 1994; National Research Council, 2000; National Research Council, 2005). For the purposes of this RA, nutrient deficiency and nutrient toxicity are considered chemical hazards associated with animal food with potential to harm only animals, while chemical contamination is a form of chemical hazard associated with animal food with potential to harm both humans and animals.

The information in the RFR and in the RES is not limited to reports of SAHCODHA events. In fact, the recalls in the RES do not consistently have observed health outcomes associated with them because the animal food contamination is usually detected by the responsible party at the animal food manufacturer facility before there are adverse health outcomes.

**Table 2. Summary of Primary Reports Submitted to the RFR from the RFR Annual Reports 2010-2013 (FDA, 2011a; FDA, 2012b; FDA, 2013e; FDA, 2015b), Used in Identifying Hazards in Animal Food**

<b>Hazard</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>	<b>Serious adverse consequences or deaths reported</b>
Salmonella	13	13	5	18	No
Chemical contaminants (e.g., mycotoxins, dioxin, botulinum toxin, drug contamination, etc.)	-	-	4	4	Yes

<b>Hazard</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>	<b>FY 2013</b>	<b>Serious adverse consequences or deaths reported</b>
Nutrient imbalance (deficiencies or toxicities (e.g., excessive copper, excessive urea, inadequate thiamine, vitamin D)	-	2	8	6	Yes
Other <sup>3</sup>	12	10	1	1	
Physical hazards (listed as foreign objects e.g., metal, glass, plastic)	3	3	1	1	No

<sup>3</sup>Listings changed between the 2011 and 2012 annual reports such that the “Other” category was refined to specify categories for chemical contaminants and nutrient imbalances.

**Table 3. Summary of Animal Food Recalls from the RES, Used in Identifying Hazards**

<b>Hazard</b>	<b>Number of Class I Recalls (Fiscal Years 2006-2012)<sup>4</sup></b>	<b>Number of Class I Recalls (Fiscal Year 2013 – July, 2015)</b>	<b>Types of Animal Food(s) Recalled</b>
Microbiological-Salmonella	58	51	
Microbiological-Listeria monocytogenes	1	4 <sup>5</sup>	
Microbiological-Total	59	55	Pet Food; Livestock Food
Chemical Contaminants - Melamine	17	0	
Chemical Contaminants - All others (e.g., Mycotoxins, Botulinum toxin, Pesticides)	20	22 <sup>6</sup>	
Chemical: contaminants - Total	37	22	Pet Food; Horse Food; Livestock Food
Nutrient Imbalance	26	25	Pet Food; Livestock Food
Physical hazards (e.g., Metal, Glass, Plastic)	1	1	Pet Food

<sup>4</sup> In the draft RA, the numbers reported were substantially higher because they were the numbers of products recalled rather than the numbers of distinct recalls. For example, a firm may have one recall during which they recall many different products. The current values are the numbers of distinct recalls.

5 *Listeria monocytogenes* found only in raw pet food products. As the process to make these products is out of the scope of the RA, *Listeria monocytogenes* is not evaluated as a hazard in this RA.

6 Contains eleven recalls for grease contaminated with Lasalocid.

Human cases of salmonellosis that were linked to handling pet food containing *Salmonella* are found both in the FDA RFR reports and in reports by the CDC (CDC, 2008; CDC, 2010; CDC, 2014b). Pet food production is beyond the scope of this RA on the basis of requiring temperature controls to control this hazard. Mycotoxins can adversely affect human health (CDC, 2014c) Residue of mycotoxins in human food (e.g., milk, eggs, and meat) from food-producing animals that consumed animal food containing mycotoxins is a possible mechanism for mycotoxin transfer from animal food to humans. However, most human exposure is attributed to contaminated grains and cereals (Orriss, 1997). In comparison to human diets, animal diets are much less varied and, except for companion animal food, are comprised chiefly of grains and oilseeds so that animals have much more opportunity for exposure to hazards such as mycotoxins (Brendemuhl and Myer, 2012; National Research Council, 1994; National Research Council, 2000).

No human illness cases associated with nutrient deficiencies or nutrient toxicities hazards, physical hazards, or chemical radiological hazards in animal food have been reported.

Severe animal health consequences, including death, have been associated with biological, chemical (including nutrient deficiencies or nutrient toxicities), and physical hazards in animal food, but no animal health consequences associated with radiological hazards in animal food were found.

Table 4 provides information about the association of biological and chemical hazards that are the subject of reports of illness or injury to FDA's RFR and RES with the animal food categories that we identified in section II of this document as likely to be manufactured, processed, packed, or held on a farm mixed-type facility. The biological and chemical hazards identified in Table 4 as associated with specific animal food categories are representative of the types of biological and chemical hazards that could be associated with the manufacturing, processing, packing, or holding of animal food by a farm mixed-type facility. Table 4 is not intended to be exhaustive. We provide information about the severity of each of the hazards identified in Table 4 in the Hazard Characterization section of this document.

Table 4 does not include physical hazards, which could be a contaminant in virtually any animal food category. Table 4 does not include radiological hazards because they are too rare in animal food to be considered associated with any animal food category. Table 4 includes nutrient deficiencies or nutrient toxicities as hazards only for complete animal food because nutrient balance is a property of a finished animal food. There is no expectation that single animal food ingredients would be nutritionally balanced.

**Table 4. Potential Biological and Chemical Hazards That Are Reasonably Likely to Be Associated with the Animal Food Categories Manufactured, Processed, Packed, or Held on a Farm Mixed-Type Facility**

<b>Animal Food Category</b>	<b>Associated Biological Hazards</b>	<b>Associated Chemical Hazards</b>	<b>References/Notes</b>
Grain	<i>Salmonella</i>	Mycotoxins (aflatoxin and deoxynivalenol); pesticide residues	(D'Mello and Macdonald, 1997);(International Commission on Microbiological Specifications for Foods, 2005a)
Oilseed	<i>Salmonella</i>	Mycotoxins (aflatoxin and deoxynivalenol); pesticide residues	(International Commission on Microbiological Specifications for Foods, 2005b);(Morita et al., 2006)
Forage	<i>Salmonella</i>	Mycotoxins (e.g., aflatoxin, fumonisin)	(Cavallarin et al., 2011);(D'Mello and Macdonald, 1997)
Culled fruits and vegetables; roughage	<i>Salmonella</i> and <i>Clostridium botulinum</i>	Pesticide residues; botulinum toxin	(Institute of Food Technologists, 2001a);(Jones, 2011); (FDA, 2010)
Roughage products		Pesticide residues	(FDA, 2010)
Plant protein meals	<i>Salmonella</i>	Mycotoxins (e.g., aflatoxin)	(Calhoun et al., 2013);(International Commission on Microbiological Specifications for Foods, 2005b); (Wu et al., 2013)
Grain by-products and processed grain products	<i>Salmonella</i>	Mycotoxins (e.g., aflatoxin and deoxynivalenol); pesticide residues	(International Commission on Microbiological Specifications for Foods, 2005a); (D'Mello and Macdonald, 1997);(Morita et al., 2006)
Oilseed products	<i>Salmonella</i>	Mycotoxins (e.g., aflatoxin and deoxynivalenol); pesticide residues	(International Commission on Microbiological Specifications for Foods, 2005a); (D'Mello and Macdonald, 1997);(Morita et al., 2006)

<b>Animal Food Category</b>	<b>Associated Biological Hazards</b>	<b>Associated Chemical Hazards</b>	<b>References/Notes</b>
Molasses	N/A	N/A	Molasses is the by-product of the refining of sugarcane or sugar beets into sugar. No significant foodborne pathogens are associated with the sugar made from sugarcane and sugar beets (International Commission on Microbiological Specifications for Foods, 2005e).
Animal protein meals acquired from off-farm to be further processed	N/A	N/A	Hazards for these products controlled by manufacturer prior to farm purchase
Milk products acquired from off-farm to be further processed	N/A	N/A	Hazards for these products controlled by manufacturer prior to farm purchase
Animal tissue-derived products acquired from off-farm to be further processed	N/A	N/A	Hazards for these products controlled by manufacturer prior to farm purchase
Vitamins, minerals, and concentrates acquired from off-farm to be further processed	N/A	N/A	Hazards for these products controlled by manufacturer prior to farm purchase
Processing aids acquired from off-farm to be further processed	N/A	N/A	Hazards for these products controlled by manufacturer prior to farm purchase

Animal Food Category	Associated Biological Hazards	Associated Chemical Hazards	References/Notes
Any other processed animal food that does not require time/temperature control for safety.	N/A	N/A	Hazards for these products controlled by manufacturer prior to farm purchase
Finished animal food including animal food ready for consumption other than silage, haylage.	<i>Salmonella</i> , depending upon which of the above animal foods are included in the finished animal food.	Nutrient deficiencies and nutrient toxicities	(Jones, 2011);(FDA, 2015a); (FDA, 2013b); see Tables 2- 3.
Ensiled material	<i>Salmonella</i> ; <i>Clostridium botulinum</i>	Mycotoxins (e.g., aflatoxin and deoxynivalenol); botulinum toxin; pesticide residues	(Agriculture and Agri-Food Canada Food Production Direction Inspection Branch, 1993);(Myllykosk et al., 2009)

#### IV. HAZARD CHARACTERIZATION

The Hazard Characterization step describes the nature, severity, and duration of adverse effects that may result from ingestion of the hazard applicable to an animal food category. These will depend on the host, the agent and the environment, and there is generally a range of adverse effects (i.e., there is a high degree of variability) that occurs in a population ingesting a contaminated animal food.

##### A. Biological Hazards

In the Hazard Identification section of this RA, we identified *Salmonella*, as representative of the biological (microbial) hazards of concern for animal food categories that are likely to be manufactured, processed, packed, or held on a farm mixed-type facility and within the scope of this RA. Adverse effects associated with biological hazards may occur as a result of a single exposure through animal consumption of or human contact with a contaminated animal food. Reports of *Salmonella*-contaminated animal food and illnesses associated with animal consumption of, or human contact with, a contaminated animal food are found in the RFR and RES.

*Salmonella* is a bacterium that causes the illness salmonellosis (FDA, 2012c). Symptoms of salmonellosis in people include diarrhea, fever, abdominal cramps, headache, nausea, and vomiting (FDA, 2012c). Acute symptoms may persist for 1 to 2 days or may be prolonged, depending on

host factors, ingested dose, and characteristics of the specific bacterial strain (FDA, 2012c). Most healthy people recover, but the infection can spread to the bloodstream, and then to other areas of the body, leading to severe or fatal illness, which is more likely to occur in children, the elderly, or persons with weakened immune systems (FDA, 2012c). The infective dose can be as few as 15-20 cells, depending on age and health of the victim and strain differences among the members of the genus (FDA, 2012c). *S. Typhi* and *S. Paratyphi* A, B, and C produce typhoid and typhoid-like fever in humans, infecting various organs and leading to lesions. The fatality rate for most forms of salmonellosis is less than 1 percent, although it is usually higher for typhoid fever (FDA, 2012c). However, a number of strains can cause severe disease, e.g., the fatality rate of *S. Dublin* is 15 percent when septicemic in the elderly, and the fatality rate of *S. Enteritidis* is approximately a 3.6 percent in hospital/nursing home outbreaks, with the elderly being particularly affected (FDA, 2012c). Reactive arthritis may occur in about two percent of culture-confirmed cases (FDA, 2012c). Septic arthritis, subsequent to or coincident with septicemia, also occurs and can be difficult to treat (FDA, 2012c).

Salmonellosis symptoms in animals include septicemia, acute enteritis, and chronic enteritis. Salmonellosis in cattle occurs as sporadic outbreaks, while individual horses tend to contract the illness following a period of stress (Merck Sharp & Dohme Corp, 2012a). Different animal species are susceptible to different serotypes of *Salmonella*. As examples, pigs are susceptible to *S. Choleraesuis*; cattle are susceptible to *S. Newport* and *S. Dublin*; and poultry are susceptible to *S. Enteritidis* and *S. Pullorum* (Merck Sharp & Dohme Corp, 2012a);(Uzzau et al., 2000). Young livestock are more likely to develop the septicemic form of the disease with depression and fever, often culminating in death (Merck Sharp & Dohme Corp, 2012a). Adult cattle, sheep, and horses tend to develop the acute form, experiencing fever and severe watery diarrhea and often tenesmus (Merck Sharp & Dohme Corp, 2012a). Horses also become dehydrated and develop leucopenia and neutropenia, and may die within 24 hours of onset of diarrhea (Merck Sharp & Dohme Corp, 2012a). Growing pigs and some adult cattle develop the chronic enteritis form of disease with persistent diarrhea, anorexia, and weight loss to the point of emaciation (Merck Sharp & Dohme Corp, 2012a). Spontaneous abortion is possible in pregnant animals with salmonellosis (Merck Sharp & Dohme Corp, 2012a). In dogs and cats, symptoms of salmonellosis are acute diarrhea with or without septicemia (Merck Sharp & Dohme Corp, 2012a).

*Clostridium botulinum* is a spore-forming anaerobic bacterium that causes botulism, a rare but serious paralytic illness caused by a nerve toxin that is produced by the bacterium (CDC, 2011). While botulinum toxin is the hazard responsible for adverse health consequences, *C. botulinum* is considered under microbial hazards because control measures to prevent the toxin from being present in animal food are exercised against the bacterium that produces the toxin. Symptoms of botulism in humans include double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, dry mouth, and muscle weakness, which, if untreated, may progress to paralysis of the respiratory muscles, arms, legs, and trunk (CDC, 2011). Death due to respiratory failure can occur. A patient with severe botulism may require a breathing machine as well as intensive medical and nursing care for several months, and some patients die from infections or other problems related to remaining paralyzed for weeks or months. Patients who survive an episode of botulism poisoning may have fatigue and shortness of breath for years and long-term therapy may be needed to aid recovery (CDC, 2011).

Botulism incidence in animals is relatively low, with birds, including chickens, thought to be more susceptible than cattle or horses (Merck Sharp & Dohme Corp, 2012b). There are different strains

of *C. botulinum* and animal species differ with respect to which strains predominantly affect them (Merck Sharp & Dohme Corp, 2012b). Clinical symptoms are similar to those in humans: disturbed vision, difficulty chewing and swallowing, and progressive motor paralysis which may terminate with respiratory and cardiac paralysis. When treated early with antitoxin there is possibility of survival (Merck Sharp & Dohme Corp, 2012b). Adverse consequences in the horses exposed to *C. botulinum* reported to FDA's district offices and recorded in the RES included illness and at least one death (Table 4).

## **B. Chemical (including Radiological) Hazards**

The Hazard Identification section of this RA identified mycotoxins (e.g., aflatoxins, ochratoxin A, deoxynivalenol, fumonisin), pesticides, and dioxin as representative of the chemical hazards associated with animal food categories (e.g., grain, oilseed, other plants or plant byproducts) that are likely to be manufactured, processed, packed, or held on a farm mixed-type facility and within the scope of this RA. The adverse reactions due to mycotoxin hazards depend upon the type of mycotoxin and the amount which a person or animal ingests, and may be acute or chronic. The effects of mycotoxins on humans are still not well understood, and much information on adverse effects is based on animal models. Currently, in developed countries such as the United States and those of the European Union, significant investments in production, storage and drying facilities, coupled with the country's regulatory system, now result in low concentrations of mycotoxins in foods, including animal food (Williams et al., 2004). Acute adverse effects of mycotoxins currently are more common in developing countries (Pestka and Smolinski, 2005);(Williams et al., 2004). In humans, adverse effects associated with chemical hazards such as mycotoxins tend to be the result of chronic exposure rather than manifesting as an acute illness (Williams et al., 2004).

Large doses of aflatoxin can result in acute illness and death in humans, usually through liver cirrhosis; reports of serious illness and death usually originate in the zone of risk for mycotoxin production (at latitudes between 40 degrees North and South of the equator) and occur infrequently(Williams et al., 2004). Adult humans usually have a high tolerance for aflatoxin, and some ingested aflatoxin is detoxified (Williams et al., 2004). Long-term, cumulative exposure to aflatoxin can result in liver cancer (Shephard, 2008);(Williams et al., 2004). Ochratoxins, which have been identified in barley, wheat, rye, corn, rice and coffee, are classified as human carcinogens and have been associated with nephrotoxicity in animals but have not been associated with acute illnesses (Bayman and Baker, 2006). In contrast, deoxynivalenol which may be found in wheat, corn and barley, has been associated with acute gastroenteritis similar to staphylococcal food poisoning (vomiting, abdominal pain, diarrhea, headache, dizziness and fever) in humans, although not in the United States (Pestka and Smolinski, 2005). Although mycotoxins have been associated with a number of diseases, the Food and Agricultural Organization of the United Nations (FAO) has noted that in most instances conclusive evidence for the role of mycotoxins is lacking (Bhat and Miller, 1991).

Mycotoxin effects on animals similarly vary according to the type of mycotoxin and the levels to which the animal is exposed, with acute effects being associated with high level exposures and chronic effects being associated with long-term, low-level exposure. High level exposure to aflatoxins in mammals may result in loss of appetite, lethargy, ataxia, rough hair coat, and pale, enlarged livers. Liver failure and death was observed in 100 dogs consuming dog food contaminated with aflatoxin at high levels (Lang, 2006). Signs of long-term, low-level exposure

include decreased appetite and reduced feed efficiency and milk production. Aflatoxin is also responsible for suppression of immunity and lowered resistance to disease in species such as turkeys, chickens, pigs, mice, guinea pigs, and rabbits (Whitlow and Hagler, 2005).

Fumonisin can be found mostly in corn and cause toxicity in animals primarily through disruption of lipid metabolism (Tsunoda et al., 1998). Equine leukoencephalomalacia (ELEM) has been identified as being an effect of fumonisin exposure unique to horses and it is typically secondary to cardiovascular effects (USDA, 2000). Effects of lower levels of exposure to fumonisin in swine have been associated with slowly progressive hepatic necrosis while exposure to higher levels also results in pulmonary edema (Merck Sharp & Dohme Corp, 2012c). RES contains a report about horse silage that contained fumonisin and all 14 of the horses exposed died (Table 3).

Swine are the most sensitive species with respect to deoxynivalenol, followed by rodents, dog, cat, poultry, and ruminants with low doses resulting in an emetic response, in some species. Chronic exposures may affect growth, immune function and result in reduced litter size (Pestka and Smolinski, 2005). Ochratoxin A is associated with nephropathy in swine and avian species (Rutqvist et al., 1978). In cattle, the rumen degrades ochratoxin making them less susceptible to toxic effects; nonetheless, surveys of some European dairies detected ochratoxin in milk (Battacone et al., 2010).

Table 4 in the Hazard Identification section of this RA identifies pesticide residues as a chemical hazard that can be associated with grains, oilseeds, culled fruits and vegetables, roughage products, grain by-product, oilseed products, and ensiled material. Whether a pesticide is safe for a particular use, in a particular animal food, at a particular level, depends on factors such as the amount of the animal food that is consumed and, if the pesticide is ingested by a living animal before slaughter, how the product is metabolized in that animal. Pesticide chemical residues in or on food in the absence of or in excess of a tolerance established by the United States Environmental Protection Agency (EPA) are deemed by the FD&C Act to be unsafe for the purpose of determining whether the food is adulterated (see sections 402 and 408 of the FD&C Act). Reports from FDA's pesticide monitoring program consistently demonstrate that levels of pesticide chemical residues in the U.S. food supply are overwhelmingly in compliance with EPA's permitted pesticide uses and tolerances (FDA, 2010).

Most of the population, both human and animal, has low-level exposure to dioxins. Although dioxins are environmental contaminants, most dioxin exposure occurs through the diet, with over 95% in humans coming through dietary intake of animal fats. Small amounts come from breathing air containing trace amounts of dioxins on particles and in vapor form, from inadvertent ingestion of soil containing dioxins, and from absorption through the skin that is in contact with air, soil, or water containing minute levels of dioxins (CDC ATSDR, 1999; FDA, 2011b).

The most common health effect in people exposed short term to large amounts of dioxin is chloracne. Altered liver function is also possible. Chloracne is a severe skin disease with acne-like lesions that occur mainly on the face and upper body. Chloracne cases have typically been the result of accidents or significant contamination events (CDC ATSDR, 1999; FDA, 2011b). Long term exposure can cause impaired immune function and affect the developing nervous system, endocrine and reproductive systems. (WHO, 2014).

Effects of dioxin consumption on animals vary considerably by animal species and by dose. In toxicological studies, death resulted from a single high dose exposure in rodents and dogs (CDC ATSDR, 1999). At low doses, as are typically seen in animal food, chronic exposure is required to observe effects such as weight loss, liver damage, disruption of the endocrine system, weakening of the immune system, and reproductive damage and birth defects (CDC ATSDR, 1999).

The scope of this RA requires consideration of radiological hazards that are relevant to a farm mixed-type facility under section 418 of the FD&C Act. Tables 2 and 3 in the Hazard Identification section of this document do not include radiological hazards because no incidents involving radiological hazards in animal food have been reported through RES or RFR. The health effect from radiological hazards depends upon the type of radionuclide and the amount to which an animal or a person is exposed. Consuming food contaminated with radioactive material will increase the amount of radioactivity a person is exposed to and could increase the health risks (e.g., increased risk of cancer) associated with exposure to radiation (WHO, 2011). For instance, exposure to certain levels of radioactive iodine is associated with increased risk of thyroid cancer (WHO, 2011). However, contaminated food would have to be consumed over prolonged periods to represent a risk to human health (WHO, 2011) and, therefore presumably, to animal health as well. When animals consume animal food contaminated with a radiological hazard, there is some transfer of the hazard to animal tissue and to milk. But, as was seen following release of iodine-131 from a foreign nuclear plant after a natural disaster, the amount transferred to the milk was orders of magnitude lower than levels that would trigger action to remove the milk from market (FDA and EPA, 2011).

### **C. Nutrient Imbalance**

The Hazard Identification section of this RA identified nutrient imbalance of essential nutrients (nutrient deficiency which results from too little of the required nutrients being in the animal food and nutrient toxicity which results from too much of certain required nutrients being in the animal food) as hazardous to animals. The existence and content of the National Research Council publications on nutrient requirements for all species of food animals indicates the importance of balanced nutrition for animals dependent on the rations supplied to them every day (National Research Council, 1994; National Research Council, 2000).

More incidences of nutrient toxicity in animal food are reported through the RFR or received in the RES than complaints concerning nutrient deficiency in animal food. Nutrient toxicity in animal food can trigger an acute toxicity response which is likely to be pronounced and detected, whereas nutrient deficiencies in animal food require more than a single exposure to elicit response. When a response to nutrient deficiency in animal food for food animals occurs, it is likely to be considered unthriftiness at first. Continued exposure to nutrient deficiency in animal food will eventually lead to profound effects and can result in death over time (Merck Sharp & Dohme, 2015).

An example of a nutrient toxicity is copper poisoning in sheep consuming food with excessive levels of copper. An example of a nutrient deficiency that compromises the health of animals is riboflavin deficiency in diets fed to chickens that leads to curled toe disease (Johnson and Storts, 1988; Merck Sharp & Dohme, 2015). Nutrient toxicities reported to the RFR and RES include elevated copper, urea, zinc, and salt levels that were reported to have been associated with illness and death in ewes and goats, cows, calves, and pigs, respectively. Neurological and muscular, gastrointestinal, behavioral, and reproductive adverse health consequences were seen in pigs exposed to animal food containing high levels of selenium while weight loss and dehydration were

associated with high levels of manganese sulfate in animal food fed to pigs. On the other hand, deaths were reported among pigs fed swine food or given a swine vitamin supplement found to have inadequately low levels of vitamin D. Thiamine deficiency in food for cats has also been reported. Cats experiencing thiamine deficiency will at first exhibit signs that may include decreased appetite, salivation, vomiting, and weight loss. In advanced cases, neurologic signs can develop, which may include ventriflexion (bending towards the floor) of the neck, wobbly walking, circling, falling, and seizures (FDA, 2015c).

Nutrient deficiency and nutrient toxicity can occur simultaneously from diets containing inappropriate proportions of essential nutrients. For example, an animal's calcium needs cannot be considered independently of phosphorus. Calcium, an essential mineral, may be adequate in forage (especially legumes) for grazing cattle. Phosphorus, however, can be deficient in the forages, and since calcium and phosphorus work hand in hand for the animal's muscle and metabolic functions, respectively, supplemental phosphorus at an appropriate level would be needed for cattle on forage-based diets. Calcium and phosphorus are also the major mineral constituents of bone. The calcium to phosphorus ratio in the animal food for cattle would need to be maintained in the desired range to prevent negative health effects (e.g., rickets in young animals, osteomalacia in adult animals, reduced resistance to disease, overall reduced productivity including reduced food intake, reduced conception rates, or reduced milk production in cattle) (National Research Council, 2005).

Proper nutrient balance is particularly important for animal food because often one animal food type is the sole source of an animal's diet. Nutrient deficiency and nutrient toxicity are therefore hazardous in a finished animal food and pose a greater risk to the health of animals fed a sole source diet than to the health of animals receiving a varied diet similar to that consumed by humans. No human health consequences as a result of nutrient deficiency or nutrient toxicity in animal food were identified.

#### **D. Physical Hazards**

The scope of this RA requires consideration of physical hazards that are relevant to a farm mixed-type facility under section 418 of the FD&C Act. Physical hazards can be contaminants in virtually any food category. Reports to the RFR included animal food exposures of horses to plastic and metal resulting in stomach ulcers and blood in the urine to injuries resulting in the need for euthanasia at the extreme. The literature contains reports of cow deaths following consumption of animal food containing metal. Hardware disease is the common name given to this condition and death may follow puncture of the pericardium (Braun, 2009; Ward and Ducharme, 1994).

There are not likely to be any serious injuries to humans associated with physical hazards in animal food as the physical contaminant is not assimilated into edible tissues.

### **V. EXPOSURE ASSESSMENT**

#### **A. Approach**

Exposure assessment for foodborne hazards includes an evaluation of the actual or anticipated animal exposure to the hazards from consumption of contaminated animal food. For animal food,

exposure assessment also includes an evaluation of the actual or anticipated human exposure to hazards either by handling an animal food or through consumption of food of animal origin that contains residues of a hazard that was in animal food consumed by the animal and transferred to the human food of animal origin. Factors that have a direct effect on exposure to hazards in animal food include:

- Frequency and levels of contamination of the animal food;
- Frequency of consumption of the animal food by the animals;
- Transfer potential of the animal food hazard to human food of animal origin;
- Frequency of consumption of the human food of animal origin; and
- Frequency with which humans handle the animal food.

For the purposes of this qualitative RA, we used the frequency of reporting, as reflected in reports to the RFR (see Table 2) and in RES data (see Table 3) as an overall indicator of exposure to hazards: biological; chemical (including nutrient deficiency and nutrient toxicity); and physical hazards. We took this approach because most of the available data and information address the presence, but not the level, of these hazards. For example, RFR reports and RES data generally would provide some information about the level of chemicals, including nutrients in animal food, because the level is needed to determine whether a food meets the definition of a reportable food and to classify a recall. However, RFR reports and RES data generally do not provide information about the level of biologic hazards because the presence of a bacterial pathogen is reportable due to the potential for bacterial growth. Levels are generally not reported for physical hazards because a single foreign object may cause injury. The use of the RFR reports as an overall indicator to exposure to hazards has limitations - e.g., the RFR reports and RES data are not limited to the animal food categories addressed by this RA. In addition, we did not attempt to include the frequency of consumption of animal food contaminated with biologic hazards, chemical hazards (including nutrient deficiencies and nutrient toxicities), or physical hazards, and the amount of animal food consumed, for animal food manufactured, processed, packed, or held by farm mixed-type facilities in light of the difficulty in obtaining meaningful values.

For the purpose of this RA, we considered exposure to radiological hazards to be low because we have received no reports to the RFR or RES concerning radiological hazards in animal foods.

For the purpose of this RA, the factors that are relevant to likelihood that hazards would contaminate the animal food when consumed include:

- Potential for growth of biological hazards in the animal food;
- Inherent controls for biological hazards (e.g., low water activity ( $a_w$ ) preventing growth);
- Interventions (e.g., preventive control measures applied to significantly minimize or prevent a hazard that is reasonably likely to cause serious adverse health consequences or death (e.g., acidification during ensiling)); and
- Activities that can introduce hazards into food (e.g., storing moist grain products).

## **B. Factors That Impact the Frequency and Levels of Contamination of the Animal Food - Biological Hazards**

The presence of *Salmonella* in animal food may present a significant risk to animals even when the animals are exposed to low numbers of the bacteria because the bacteria can multiply in the intestine (Merck Sharp & Dohme Corp, 2012a). In still other cases, the presence of high numbers of certain serotypes of *Salmonella* adapted to specific animal species in food may present a risk of only mild illness to the general population of those species while the presence of fewer organisms may present a risk of serious adverse health consequences or death to susceptible populations, such as young animals, that have limited immunity and lack stable intestinal flora (Merck Sharp & Dohme Corp, 2012a).

Importantly, the risk of illness to humans or animals from foodborne pathogens that cause illness from consumption of only a few cells significantly increases if growth occurs. Thus, if the animal food containing a foodborne pathogen supports growth of that pathogen, and the animal food may be subject to conditions that allow growth, the risk for illness increases. The primary factors impacting the risk of illness from most foodborne pathogens in an animal food, therefore, are intrinsic factors and extrinsic factors that influence growth (Jay, 2000; Montville and Matthews, 2007). Intrinsic factors are chemical and physical factors that are inherent to the animal food (e.g., pH and  $a_w$ ). Extrinsic factors are those that refer to the environment surrounding the animal food (e.g., storage temperature).

Below, we discuss key intrinsic and extrinsic factors that can influence growth of bacterial pathogens. We also describe inherent controls for the representative biological hazards relevant to this RA, interventions to control these representative biological hazards, and activities that can introduce these representative biological hazards into the animal food categories relevant to this RA.

### *1. Impact of water activity on growth of foodborne pathogens*

The  $a_w$  of animal food is a key intrinsic factor affecting the growth of foodborne pathogens. Water activity relates to the amount of unbound water that a microorganism needs to grow. As moisture is removed from an animal food or bound by solutes such as salt or sugar,  $a_w$  decreases. All microorganisms require a certain  $a_w$  for growth to occur, and when  $a_w$  is reduced below that point, the organism stops growing. For example, *Salmonella* does not grow below an  $a_w$  of 0.94 (International Commission on Microbiological Specifications for Foods, 1996a), *S. aureus* does not grow below an  $a_w$  of 0.83 (International Commission on Microbiological Specifications for Foods, 1996b), and *C. botulinum* does not grow below an  $a_w$  of 0.935 (International Commission on Microbiological Specifications for Foods, 1996c).

Generally, the  $a_w$  of raw plant material used for animal food (e.g., freshly cut forage) is greater than 0.99, which supports the growth of bacterial foodborne pathogens (Jay, 2000). Food such as dried cereal grains has very low water activities (e.g., 0.60 and below) and do not support growth of bacterial foodborne pathogens (Scott et al., 2001). Some animal food may be dried to a moisture level at which foodborne pathogens will not grow (e.g., hay). However, many foodborne pathogens will survive for extended periods of time under dry conditions, including *Salmonella* spp. (D'Aoust and Maurer, 2007; Scott et al., 2009). Overall, moist animal food with  $a_w$  of 0.85 and above (e.g., chopped corn stover forage) usually require other processes (e.g., ensiling) as an intervention to control growth of foodborne pathogens for long term storage, while animal food with lower  $a_w$  (e.g.,

hay, dried whole cereal grains) does not necessarily require additional processing to control growth of pathogens (although in some cases the food might have limited shelf life as a result of spoilage due primarily to yeasts and molds).

Intervention measures that rely on  $a_w$  to prevent the growth of foodborne pathogens require strict control. Lack of such control can result in growth of foodborne pathogens, leading to serious adverse health consequences or death to humans or animals.

## 2. Impact of pH on growth of foodborne pathogens

The pH of an animal food product is a key intrinsic factor affecting the growth of foodborne pathogens. Most bacterial pathogens grow best at pH values near neutral (i.e., 6.6-7.5) (Jay, 2000). Low pH inhibits the growth of bacterial foodborne pathogens and in some cases can kill such pathogens. Some types of animal food are naturally acidic (i.e. have a low pH) (e.g., many culled fruits, including citrus fruits, apples and grapes) and do not support growth of bacterial foodborne pathogens. Other the other hand, culled melons have pH values that support growth of bacterial foodborne pathogens. Byproducts of vegetable processing (e.g., vegetable trimmings) have pH values above 5.0 and support growth of bacterial foodborne pathogens when the natural protective barriers are cut. Some animal food types may be fermented by bacteria to produce products with a reduced pH (e.g., haylage). While many strains of foodborne pathogens die off under conditions of low pH, other strains, including strains of *E. coli* O157:H7 and *Salmonella*, can survive under conditions of low pH for a long time, even though their growth might be inhibited (Conner and Kotrola, 1995; Leyer and Johnson, 1992). Therefore, the effectiveness of pH as an intervention measure to kill, or prevent the growth of, bacterial foodborne pathogens is variable. Such intervention measures require strict control throughout manufacturing or processing. Lack of such control can result in the survival and growth of foodborne pathogens.

Controls to avoid botulinum toxin in animal food involve controlling the growth of *Clostridium botulinum* bacteria in food. *C. botulinum* grows under anaerobic conditions and produces toxins while in a vegetative state; it also forms spores which are resistant to environmental extremes. Botulinum toxin contamination of animal food is a rare event usually associated with the presence of rotting animal or plant matter. For example, hay is periodically contaminated as the result of a small animal being caught up into the baling process as part of harvesting. In making silage, the fermenting forage is a good substrate for growth of bacteria including *C. botulinum* which, if present, would thrive in the anaerobic conditions if it were not for the acidification process serving as an intervention that reduces the likelihood of growth of *C. botulinum* (Leibensperger and Pitt, 1987; Ruoho, 2007). The proper processing of animal food such as haylage and silage requires an understanding of the principles of making silage and the microbiology of ensiling including, creating anaerobic conditions, chopping animal food product to the appropriate particle size, selecting raw materials of appropriate moisture content, and providing appropriate containment for the ensiled animal food product. When one or more of these factors is not as it should be, the product that results may contain ammonia and be refused by the animals. High heat for over 15 minutes used as an intervention in canning processes to kill spores of *C. botulinum* is not practical for animal food such as hay and silage.

### 3. *Impact of temperature on growth of foodborne pathogens*

Temperature is a key extrinsic parameter affecting growth of foodborne pathogens. As temperature decreases, the growth of microorganisms slows; all microorganisms have a temperature below which growth cannot occur. Some foodborne pathogens do not grow, or grow very slowly, at refrigeration temperatures, e.g., most strains of *Salmonella* (International Commission on Microbiological Specifications for Foods, 1996a). Foodborne pathogens cannot grow when a food is frozen (Jay, 2000). Intervention measures that use reduced temperatures to minimize growth of foodborne pathogens require strict, ongoing control (often referred to as “maintaining the cold chain”). Lack of such control can result in the growth of foodborne pathogens, leading to serious adverse health consequences or death.

The growth of foodborne pathogens can also be controlled by maintaining the temperature of animal food products above a temperature that permits growth of those pathogens (e.g., heated holding tanks for oils and fats used to make animal food). Increasing the temperature high enough will kill some foodborne pathogens. Intervention measures that use high temperatures to kill foodborne pathogens require expert knowledge of the heat resistance of the specific pathogen in the specific animal food product, the delivery of heat via the animal food matrix to inactivate pathogens, and the parameters that impact the heat process. Improper application of such interventions can result in survival and growth of foodborne pathogens, leading to serious adverse health consequences or death in animals consuming the food or humans handling the animal food products, e.g., pet food.

### 4. *The impact of other factors on growth of foodborne pathogens*

Raw food from plant and animal origins often has physical barriers that provide very good protection against entry and growth of foodborne pathogens. These physical barriers are biological structures that act as natural coverings for the food. Examples of such physical barriers include the outer coverings of grains. Activities that break or remove these barriers can result in contamination of the food product by allowing invasion and growth of pathogens and molds in the tissues (Whitlow and Hagler, 2005). For example, an intact kernel of corn is unlikely to support growth of molds that produce aflatoxin. Once the grain's outer covering is broken, the protective barrier of the grain is compromised, allowing microorganisms to access parts of the grain that can support growth of microorganisms. When whole grain corn used to make corn silage, the intact corn kernel does not support growth of molds such as *Aspergillus* spp. However, once the grain is cracked and mixed with other portions of the corn stalk to produce silage, the cracked corn kernel may support growth of molds such as *Aspergillus* spp, unless there is an intervention such as ensiling in order to control the growth of molds (Whitlow and Hagler, 2005). Preservatives (e.g., organic acids, salts of organic acids, and formaldehyde) can minimize growth of foodborne pathogens, and in some cases aid in killing them. If preservatives that are used to control pathogens are not added properly (e.g., at the correct concentration and at the proper pH of the animal food), pathogens can survive and grow, leading to serious adverse health consequences or death. Thus, intervention measures that use preservatives to control foodborne pathogens require specialized expertise to understand the conditions under which the preservatives are effective in controlling pathogens.

### 5. Interaction of factors that impact the growth of foodborne pathogens

Factors such as  $a_w$ , pH, temperature, and preservatives, can interact to affect growth of foodborne pathogens (Jay, 2000). As temperature decreases, the minimum  $a_w$  for growth increases (Koutsoumanis et al., 2004). For example a pathogen that would grow at room temperature if the  $a_w$  is 0.95 or above may need an  $a_w$  of 0.97 to grow under refrigeration temperatures. These interactions are complex and have been discussed in scientific reviews (Institute of Food Technologists, 2009) and in regulatory references such as FDA's Food Code (FDA, 2012d). Using combinations of factors to control foodborne pathogens requires specialized expertise. Improper application of interventions involving the interaction of intrinsic and extrinsic factors can result in the growth of foodborne pathogens.

Ensiling is an anaerobic fermentation process used to preserve immature green corn, legumes, grasses, and grain plants; the crop is chopped while at about 70-80% moisture and put into silos or other containers to exclude air (McGraw-Hill, 2003). Acid and heat that develop during the fermentation process act as inherent controls for bacteria. Acidification of silage significantly minimizes or prevents the hazard of botulinum toxin production by *C. botulinum* (Ito and Chen, 1978; Townsend et al., 1954).

The product listed in Table 5 is made under conditions using interactions of factors that impact the growth of microorganisms responsible for biological and chemical hazards relevant to this RA.

**Table 5. Interaction of Factors Operating as Controls for Biological Hazards in the Making of Silage**

Animal Food	Inherent Control	Comments
Silage	Acidification and heat retard growth of microorganisms	This process follows the cutting of forage and mitigates the tendency of development of bacterial growth in the cut material.

### 6. Inherent Controls for Biological Hazards Relevant to This Risk Assessment

Processing steps involving high heat and pressure, such as those used in making animal protein meals and animal tissue-derived products such as hydrolyzed feathers, calcined bones, or rendered animal fats, serve as inherent controls for biological hazards. These activities require time/temperature controls and were considered out of the scope of the RA.

### 7. Interventions to Control the Biological Hazards Relevant to This Risk Assessment

As discussed in sections V.B.1 through V.B.5 of this document, there are a number of interventions that may reduce the risk of the biological hazards relevant to this RA. If an intervention is not

properly conducted, the applicable hazard is reasonably likely to occur. Moreover, some interventions may require special expertise to ensure they are conducted properly.

Table 6 provides examples of interventions to control the representative biological hazards relevant to this RA. Other interventions could be preventive controls that facilities may implement under section 418 of the FD&C Act, such as treatment of animal food to inactivate foodborne pathogens.

**Table 6. Examples of Interventions to Control Biological Hazards**

<b>Hazard</b>	<b>Examples of Interventions to Control Hazards</b>	<b>Comments</b>
<i>Salmonella</i> ; <i>Clostridium</i> <i>botulinum</i>	<ul style="list-style-type: none"> <li>• Killing the organism - e.g., through:               <ul style="list-style-type: none"> <li>○ Reducing the pH in combination with specific conditions (e.g., type and concentration of acid, time of exposure, and temperature).</li> </ul> </li> <li>• Preventing the growth of the organism - e.g., by:               <ul style="list-style-type: none"> <li>○ Reducing the pH;</li> <li>○ Reducing <math>a_w</math>;</li> <li>○ Adding preservatives.</li> </ul> </li> </ul>	When a kill step is applied the food must be protected from recontamination. The organisms can survive for extended periods of time under some conditions that prevent the growth but do not kill the organism (Ruoho, 2007).

*8. Activities That Can Introduce, or Increase the Potential for, Biological Hazards Relevant to This Risk Assessment*

Conducting some activities on an animal food may increase the risk from a biological hazard. These are often specific to the animal food in which the hazard occurs. For example, chopping intact corn stalks and other forage can transfer microorganisms, including pathogens, from the exterior to the interior of the plants; in many cases this allows growth, thereby increasing the risk of illness (FDA, 2012c; Institute of Food Technologists, 2009). Table 7 provides an example of an activity that can introduce, or increase the potential for, biological hazards.

**Table 7. Example of an Activity that Can Introduce, or Increase the Potential for, Biological Hazards**

<b>Hazard</b>	<b>Example of an Activity That Are Reasonably Likely to Introduce or Increase the Potential for the Hazard</b>	<b>Comments</b>
<i>Salmonella</i>	Cutting of plants can transfer the organism from the low-moisture exterior (where it cannot grow) to the high-moisture interior and release juices from tissues, providing conditions that enhance microbial growth	Mitigation step that may follow cutting is ensiling.

### **C. Factors That Impact the Frequency and Levels of Contamination of the Animal Food - Chemical (including Radiological) Hazards**

The presence and levels of mycotoxins in foods in the United States is low (Williams et al., 2004). The presence and levels of mycotoxins in animal food is dependent in large part on growing conditions and harvesting activities. The type of mold, weather conditions, soil types, insect activity, and commodity type, along with timely harvest and rapid and adequate drying before storage, are important in determining the likelihood of contamination (Williams et al., 2004). Insect activity and condensation can result in pockets of moisture that can result in production of mycotoxins (Williams et al., 2004). There are no effective methods to remove mycotoxins once they have formed in animal food ingredients. Knowledge of mycotoxin levels in ingredients is essential for avoiding unsafe levels of mycotoxin in the production of finished animal food.

Pesticide residue contamination of RACs can be reduced by timing the application of the pesticides appropriately which is facilitated by accurate record keeping of pesticide applications (USDA Agricultural Marketing Service, 2010). Pesticide residues are likely to be concentrated on the outer surface of the commodities so that any process that removes that outer surface serves as a means of reduction of the hazard level. Heavy metals and other chemical contaminants, on the other hand, are more likely to be incorporated into the plants from the soil. Processing steps which remove moisture will tend to concentrate the levels of these chemical contaminants in the animal food.

The presence of detectable radiological hazards in animal food is rare and derives from plants grown in certain types of mineral soil or from water in similar areas. Use of water that contains a radionuclide to manufacture an animal food is not reasonably likely when using water from a domestic municipal source subject to regulation by 40 CFR 141.66 (see 65 FR 76708, December 7, 2000). Exposure of humans to radionuclide hazards as a result of contact with contaminated animal food or consumption of human food of animal origin from animals that have consumed contaminated animal food as a result of naturally occurring radioactive material is very low. When events (such as accidents or natural disasters) occur that could result in radiological contamination of water sources, there is generally much publicity that would alert a farm mixed-type facility to a risk in using a potentially contaminated water source, and we expect that government agencies,

including FDA, would likely take specific actions based on the circumstances to prevent consumer exposure.

Table 8 provides examples of interventions to control the representative chemical hazards relevant to this RA. Other interventions could be preventive controls that facilities may implement under section 418 of the FD&C Act.

**Table 8. Examples of Interventions and Activities that Can Affect Chemical Hazards**

<b>Hazard</b>	<b>Examples of Interventions to Control Hazards</b>	<b>Examples of Activities That Are Reasonably Likely to Introduce or Increase the Potential for the Hazard</b>	<b>References</b>
Mycotoxins	<ul style="list-style-type: none"> <li>• Preventing mold growth and toxin formation by controlling moisture for storage</li> <li>• Pest control</li> </ul>	<ul style="list-style-type: none"> <li>• Accepting and storing incompletely dried product</li> <li>• Lack of pest control</li> </ul>	(Williams et al., 2004)
Pesticide chemical residues	<ul style="list-style-type: none"> <li>• Preventing contamination by timing pesticide application well before harvest</li> <li>• Removing contamination by excluding the outer layers of plant</li> </ul>	<ul style="list-style-type: none"> <li>• Applying pesticide near time of harvest</li> <li>• Using outer plant layers such as husks in animal food</li> </ul>	(Agriculture and Agri-Food Canada Food Production Direction Inspection Branch, 1993);(FDA, 2010)
Other chemicals	<ul style="list-style-type: none"> <li>• Testing for presence of a hazard and excluding contaminated product from the animal food supply</li> </ul>	<ul style="list-style-type: none"> <li>• Drying increases the concentration of a chemical</li> </ul>	(FDA, 2013a)

#### **D. Factors That Impact the Frequency and Levels of Contamination of the Animal Food – Nutrient Imbalance (Deficiencies or Toxicities) Hazards**

Manufacture of animal food with adequate nutrition requires blending of the appropriate mix of food ingredients and augmenting the mix with additional ingredients, such as vitamins, minerals, amino acids, proteins or fatty acids, to compensate for deficiencies in the ingredients. Knowledge of the nutritional requirements of the animals to be fed and knowledge of the composition of the ingredients is necessary. Following established ration formulation and supplementation

recommendations, care in calculating the ingredient amounts, and weighing additives on accurate scales are of primary importance in assuring that nutrient levels in the animal food are appropriate for the species and life stage of the animals being fed. Thorough mixing is necessary to ensure uniform distribution of ingredients throughout the animal food to avoid a pocket of highly concentrated additives that might be consumed by a single animal.

### **E. Factors That Impact the Frequency and Levels of Contamination of the Animal Food – Physical Hazards**

The potential presence of physical hazards depends on the activities performed on the animal food, including activities that can remove foreign objects (e.g., sorting, inline use of magnets to remove ferrous material) and those that can introduce them (e.g., shredding, cutting). Adherence to good manufacturing practices minimizes the potential for physical hazards to be present in animal food products to which animals are exposed (Jantschke and Elliott, 2006).

### **G. Frequency of Consumption and Amount of Animal Food Consumed**

For any given prevalence of contamination in animal food, the likelihood of animals becoming sick increases as the amount of food consumed increases. The USDA National Agricultural Statistics Service 2012 census reports that there were about 90 million cattle and calves in the US and another 9 million dairy cows; 66 million hogs; 4.6 million sheep and lambs; 2.6 million goats; and 3.6 million horses and ponies. The poultry inventory included 350 million laying chickens; nearly 9 billion broiler and other meat-type chickens; 110 million pullets for laying flock replacement; over 100 million turkeys; and another 25 million other poultry, including ducks, geese, pheasants, quail, squab, emus and ostriches (USDA National Agricultural Statistics Service, 2014).

In total according to the summary “Feed Marketing & Distribution” in the 2015 Feedstuffs Reference Issue & Buyers Guide, in 2013, there were 116 million tons of primary animal food produced, with 40.3 million tons produced for broiler chickens and 17.3 million tons for hogs (Lundeen, 2014). As defined in the summary, “Primary feed is feed mixed with individual feed ingredients, sometimes with the addition of a premix at the rate of up to 100 lb. per ton of finished feed.” The National Agricultural Statistics Service in its report for 2010, estimates that the annual consumption per animal on a beef feedlot is about 9,200 pounds of animal food while that of a dairy cow is around 12,600 pounds (USDA, 2010). The estimates are 89 and 10.6 pounds, per turkey and per broiler chicken, respectively (USDA, 2010).

Information supplied through reporting systems such as the RFR and the RES is useful in identifying the kinds of hazards being found and in what animal food they are being found but it does not provide a means to know what fraction of the animal food supply contains hazards. First, the instances of contaminated animal food are likely to be under-reported because they might not all be identified. Secondly, unless the animal food is a product with lot numbers, the full extent of a contamination issue may be unknown. Information upon which to estimate the prevalence of hazards in animal food comes from surveys and studies that sample animal food and offer a snapshot in time to provide an estimate of the fraction of animal food containing the hazards under study. Results from surveys indicate considerable variability from sample to sample. One example of a survey of aflatoxin contamination in corn illustrates how difficult it is to determine either the prevalence (with a range from 2-3% in some regions to 13-32% in others) or level of contamination

(with a range from no more than 20 ppb from some locations to 8% of samples with more than 100 ppb from others) (Shotwell, 1977).

We do not have data to determine how much of a particular animal food produced by small or very small farm mixed-type facilities is consumed in order to assess the risk of serious adverse health consequences or death to humans and animals from consumption of the animal food from these facilities. We have an estimate, based on the Food Processing Sector Study (Muth et al., 2011), that the proportion of all food, human and animal, establishments co-located on farms is somewhere between 2% and 7% and that about 66% of animal food (not pet food) establishments in the study had under 20 employees. Based on these values, small or very small farm mixed-type facilities manufacturing animal food (not pet food) are likely to represent fewer than 5% of all animal food establishments. Thus, on a relative basis, the overall exposure of the animal population to all animal foods produced at small or very small farm mixed-type facilities is low and consequently the exposure to animal food containing hazards from small or very small farm mixed-type facilities would be even lower.

## **VI. RISK CHARACTERIZATION**

### **A. Approach**

In this section, we qualitatively characterize the risk from hazards and activity/animal food combinations based on the available information in the Hazard Identification, Hazard Characterization, and Exposure Assessment sections of this RA. There is uncertainty associated with each of these components of this RA, which leads to uncertainty in the Risk Characterization. The outcome of this risk characterization of hazards is a determination of whether, for the limited purposes of this RA, a hazard presents a reasonable probability of causing serious adverse health consequences or death to humans or animals in the absence of preventive controls that would be required under section 418 of the FD&C Act. In this RA, we are considering such hazards and animal food in general terms, on a forward-looking basis, and not in reference to a particular animal food contamination incident or foodborne illness outbreak. Determinations of whether there is such a reasonable probability in specific situations may be different from the conclusions made for the limited purposes of this document. The characterization of exposure to the hazard, the severity of adverse health consequences or death to humans or animals resulting from use of, or exposure to, an animal food containing the hazard, and the conclusions with respect to “reasonable probability of serious adverse health consequences or death” are made in relative terms.

### **B. Qualitative Risk Characterization**

Table 9 presents a qualitative risk characterization of representative hazards that may be associated with animal food manufactured, processed, packed, or held on a farm mixed-type facility. Table 9 draws from information presented in Tables 2 and 3 of this RA and from discussions in the Hazard Identification, Hazard Characterization, and Exposure Assessment sections of this RA.

As discussed in the Hazard Characterization section, adverse effects associated with biological hazards and with physical hazards may occur as a result of consumption of a contaminated food during a single eating occasion or a single human contact with animal food.

Table 9 characterizes the relative frequency of the various hazards in terms of numbers of cases reported to the RFR as well as the relative frequency of Class I recalls of animal food containing the various hazards in RES as follows:

- Low = No reports or recalls;
- Medium = Between 1 and 30 reports or recalls; and
- High = Greater than 30 reports or recalls.

Table 9 characterizes the severity of the hazards in terms of whether serious health outcomes or death have been reported as follows:

- Low = No serious health outcomes or deaths were reported; and
- Medium to high = Serious health outcomes or death;

Table 9 also shows whether adverse reactions from a single eating occasion are serious and are likely to include death as follows:

- Low = Cumulative exposure typically required to elicit serious health consequences or death; and
- High = Single-Eating Occasion may elicit serious health consequences or death.

**Table 9. Qualitative Risk Characterization of Representative Hazards That Are Likely Be Associated With Animal Food Manufactured/processed, Packed, or Held on a Farm Mixed-Type Facility**

Hazard	Frequency	Severity	Single Eating Occasion or Cumulative Exposure?	Reasonable Probability of Causing Serious Adverse health Consequences or Death	Comments
Biological ( <i>Salmonella</i> ) Effects on Animals	High	Low	Low	No	Animals are frequently carriers without symptoms depending on serotype and animal species (FDA, 2013b);(FDA, 2015a)( Merck Sharp & Dohme Corp, 2012a)
Biological ( <i>Salmonella</i> ) Effects on Humans	Medium	High	NA	Yes	Most reports are of human contact with pet food (not consumption)
Chemical contaminants (mycotoxins, dioxin, pesticides) ) Effects on Animals	High	High	Low	Yes	Grain and oil seed comprise about 75% of animal diets (Brendemuhl and Myer, 2012);(National Reasearch Council, 1994)
Chemical contaminants (mycotoxins, dioxin, pesticides) Effects on Humans	Low	High	Low	No	Most likely route of exposure of humans is through consumption of grains. Transfer through animal tissue and milk is not common and typically at very low levels when it occurs (Williams et al., 2004); (WHO, 2014)

Hazard	Frequency	Severity	Single Eating Occasion or Cumulative Exposure?	Reasonable Probability of Causing Serious Adverse health Consequences or Death	Comments
Chemical (nutrient imbalance)	High	High	Low	Yes	Animal food with nutrient deficiency typically requires multiple exposures. Animal food with nutrient toxicity may require only a single eating occasion
Physical hazards	Medium	High	High	Yes	Typically not widely dispersed across the animal food supply.

### C. Characterizing Interventions with Respect to the Definition of Low-Risk Activity

We characterized the interventions described in Table 6 and Table 8 under part #2b of the definition of low-risk activity (see section I.E of this document). Our task in this RA is in part to determine whether controls that would be required by section 418 of the FD&C Act are needed to ensure the safety of the product in light of the existing regulatory framework.

### D. Characterizing Activity/Animal Food Combinations

Table 10 presents a matrix of activity/animal food combinations. Activities and animal foods are taken from Table 1, and activity/animal food combinations are evaluated to determine if they are or are not low-risk. Animal food groups were described in Section II immediately following Table 1.

As discussed in section I.E of this document, there are three parts of the definition of low-risk activity/animal food combination. Importantly, under the definition of low-risk activity/animal food combination, to be low risk the activity/food combination must either:

- Satisfy part #1 (inherent controls); or
- Satisfy both part #2a (activity not likely to introduce, or increase the potential for, a SAHCODHA hazard) and part #2b (activity does not significantly minimize or prevent a SAHCODHA hazard).

For each row of Table 10, we ask whether an activity/animal food combination would be low risk (as defined in section I.E of this document). In answering this question, we:

- Answer the question “Yes” if the activity satisfies the definition of low-risk activity/animal food combination;

- Answer the question “No” if the activity does not satisfy the definition of low-risk activity/animal food combination.

In addressing the rationale:

For each activity/animal food combination that has a “Yes” answer, we provide the part of the definition of low-risk activity governing the classification of low-risk:

- #1 (inherent controls); or
- #2 (if the activity satisfies both part #2a and part #2b of the definition of low-risk activity).

For each activity/animal food combination that has a “No” answer, we provide the part of the definition of low-risk activity governing the conclusion that the activity/food combination is NOT low risk:

- #2a (if the activity introduces, or increases the potential for, a SAHCODHA hazard); or
- #2b (if the activity significantly minimizes or prevents a SAHCODHA hazard)

For those activity/food combinations that are not low risk, Table 11 explains the specific reasons why.

**Table 10. Is an Activity/Animal Food Combination Low Risk?**

<b>Activity</b>	<b>Animal Food</b>	<b>Low risk (Y/N)</b>	<b>Rationale</b>
Chopping/shredding	Hay	Yes	#2
Cracking/crimping/flaking/pearling/peeling/shelling/wafering	Grain; oilseed	Yes	#2
Crushing/dry rolling/grinding/milling/pulverizing	Grain; oilseed; grain by-products and processed grain products; oilseed products; hay; ensiled material; culled fruits and vegetables; roughage products	Yes	#2
Ensiling (including chopping/shredding/mixing/storing/fermenting), that is, making silage or haylage	Forage; grain; culled fruits and vegetables; roughage products	Yes	#1
Extracting (mechanical)/wet rolling	Grain; oilseed; brewers grain by-products; distillers grain by-products	Yes	#2

<b>Activity</b>	<b>Animal Food</b>	<b>Low risk (Y/N)</b>	<b>Rationale</b>
Labeling	Roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids; finished animal food, including animal food ready for consumption; any other processed food that does not require time/temperature control for safety	Yes	#2
Making complete animal food (including processing activities such as mixing/extruding/pelleting and other activities such as sifting/separating/weighing/labeling/pack aging)	Grain; oilseed; roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids	No	#2a and 2b
Making mineral and vitamin mixes and concentrates for feeding to animals without further processing (including weighing/mixing/packaging/labeling)	Grain; oilseed; roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids	No	#2a and 2b
Packing/re-packing (including activities performed for safe or effective packing of that animal food)	Roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids; finished animal food, including animal food ready for consumption; any other processed food that does not require time/temperature control for safety	Yes	#2

<b>Activity</b>	<b>Animal Food</b>	<b>Low risk (Y/N)</b>	<b>Rationale</b>
Storing (ambient, cold, or controlled atmosphere), including activities performed for the safe or effective storage performed as a practical necessity for the distribution of that animal food	Roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, and any other processed food that does not require time/temperature control for safety	Yes	#2

**Table 11. Why Certain Activity/Animal Food Combinations Are Not Low Risk**

<b>Activity</b>	<b>Animal Food</b>	<b>Activity Introduces, or Increases the Potential for, a SAHCODHA Hazard (#2a)</b>	<b>Activity Significantly Minimizes or Prevents a SAHCODHA Hazard (#2b)</b>
Making complete animal food (including processing activities such as mixing/extruding/pelleting and other activities such as sifting/separating/weighing/labeling/packaging)	Grain; oilseed; roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids	If done incorrectly, the activity could increase the potential for nutrient imbalance which could cause SAHCOD to animals.	If done correctly, the activity prevents nutrient imbalance which could cause a SAHCOD to animals.
Making mineral and vitamin mixes and concentrates for feeding to animals without further processing (including weighing/mixing/packaging/labeling)	Grain; oilseed; roughage products; plant protein meals; grain by-products and processed grain products; oilseed products; molasses; animal protein meals; milk products; animal tissue-derived products; vitamins; minerals; concentrates; processing aids	If done incorrectly, the activity could increase the potential for nutrient imbalance which could cause SAHCOD to animals.	If done correctly, the activity prevents nutrient imbalance which could cause a SAHCOD to animals.

## VII. CONCLUSIONS

### A. Answers to the Questions to be Addressed in This Risk Assessment

**Question 1:** What animal food would be manufactured, processed, packed, or held by a farm mixed-type facility?

**Response:** The RA identified the following animal food categories that are within the scope of the RA and that would be manufactured, processed, packed, or held by a farm mixed-type facility:

- Raw agricultural commodities (RACs). As they apply to animal food, these may include:
  - Grain such as barley, grain sorghum (milo), corn (maize), oats, rice, and wheat;
  - Oilseed such as beans, canola, cottonseed, linseed, safflower, soybeans, and sunflowers;
  - Forage such as sorghum (milo), corn (maize), alfalfa, grass and hay; and
  - Culled fruits and vegetables, and roughage such as cobs, hulls, husks, and straws.
- Manufactured/processed animal food. This class is further divided into two subclasses.
  - Processed RACs that may have been processed at the farm-mixed facility or acquired from off farm. These include, for example:
    - Roughage products such as alfalfa meal, entire plant meal, stem meal, pomace, and pulp;
    - Plant protein meals such as algae meal, coconut meal (copra), guar meal, and peanut meal;
    - Grain by-products and processed grain products such as brans, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal;
    - Oilseed products such as oil or meal of, safflower, soybean, and sunflower; and
    - Molasses such as processed sugar cane, sugar beets, and citrus.
  - Manufactured/processed animal food acquired from off farm. This includes, for example:
    - Animal protein meals such as blood meal, feather meal, meat meal, meat and bone meal, and marine (crab, fish, shrimp) meal;
    - Milk products such as casein, cheese rind, and lactalbumin;
    - Animal tissue-derived products such as fat;
    - Vitamins, minerals, and concentrates;
    - Processing aids such as enzymes, preservatives, and stabilizers; and
    - Any other processed animal food that does not require time/temperature control for safety.
- Finished animal food. This includes, for example:
  - Animal food ready for consumption;
  - Mineral and vitamin mixes and blocks;
  - Concentrates; and
  - Silage, haylage.

**Question 2:** What are the activities that might be conducted by farm mixed-type facilities on that animal food?

**Response:** Table 1 in section II of this document lists the activities that might be conducted by farm mixed-type facilities on that animal food.

**Question 3:** What are the known or reasonably foreseeable hazards associated with the animal food manufactured, processed, packed, or held by a farm mixed-type facility?

**Response:** The RA identified the following hazards as representative of the hazards of concern for animal food categories that are likely to be manufactured, processed, packed, or held on a farm mixed-type facility and within the scope of this RA:

- Salmonella;
- Botulinum toxin;
- Mycotoxins such as aflatoxins, deoxynivalenol, fumonisins, and ochratoxins;
- Other chemical hazards such as pesticides;
- Nutrient deficiencies and nutrient toxicities;
- Physical hazards.

**Question 4:** For the purpose of determining whether an activity/animal food combination is low risk, which hazards should be considered to have a reasonable probability of causing serious adverse health consequences or death to humans or animals?

**Response:** For the purpose of determining whether an activity/animal food combination is low risk, the RA identified the following hazards as having a reasonable probability of causing serious adverse health consequences or death:

- The biological hazard *Salmonella*;
- The chemical hazards mycotoxins and botulinum; and
- The chemical hazard nutrient deficiencies and nutrient toxicities.

**Question 5:** For the purpose of determining whether an activity/animal food combination is low risk, what animal food has inherent controls that significantly minimize or prevent in the animal food a biological hazard that is a known or reasonably foreseeable biological hazard and that is reasonably likely to cause serious adverse health consequences or death?

**Response:** For the purpose of determining whether an activity/animal food combination is low risk, the RA identified that processing steps involving high heat and pressure, such as those used in making hydrolyzed feathers, calcined bones, or rendered animal fats, serve as inherent controls for biological hazards. However, these activities are outside of the scope of the RA.

**Question 6:** What interventions significantly minimize or prevent in the animal food a hazard that is a known or reasonably foreseeable hazard and that is reasonably likely to cause serious adverse health consequences or death to humans or animals?

**Response:** The RA identified the following examples of interventions to significantly minimize or prevent in the animal food a known or reasonably foreseeable hazard that, for purposes of this RA, is considered reasonably likely to cause serious adverse health consequences or death to humans or animals:

- For the bacteria *Salmonella* and *Clostridium botulinum*:

- Killing the organism - e.g., through:
  - Reducing the pH in combination with specific conditions (e.g., type and concentration of acid, time of exposure and temperature);
- Preventing the growth of the organism - e.g., by:
  - Reducing the pH or  $a_w$ ;
  - Adding preservatives.
- For chemical contaminants (mycotoxins, pesticide residues, and dioxins) :
  - Preventing mold growth and toxin formation by controlling moisture during storage;
  - Preventing pesticide chemical residue by excluding the outer layers of plants from animal food;
  - Preventing the introduction of contaminated product by testing for presence of hazard in incoming ingredients and excluding contaminated product from the animal food supply.
- For nutrient imbalances, preventing deficiencies or toxicities by:
  - Following ration formulation and supplementation recommendations for targeted animal species and life stage;
  - Sequencing production and cleaning out between production lots for different species and age classes;
  - Maintaining accurate scales for weighing ingredients;
  - Mixing thoroughly.

**Question 7:** Which of these activities are reasonably likely to introduce into animal food, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals and what are these hazards?

**Response:** The RA identified the following examples of activities that are reasonably likely to introduce, or increase the potential for occurrence of, hazards that are reasonably likely to cause serious adverse health consequences or death:

- Cutting fresh plants is reasonably likely to introduce biological hazards;
- Storing grain that is incompletely dried is reasonably likely to increase the potential for growth of mold that could produce mycotoxins;
- Applying pesticides close to the time of harvest and using outer layers of treated plants in animal food;
- Drying moist animal food containing a chemical hazard is reasonably likely to increase the concentration of the chemical in the animal food;
- Using shredding and cutting equipment on animal food can introduce physical hazards; and
- Disregarding established ration formulations or miscalculating ingredient amounts, using inaccurate scales to weigh ingredients and additives, or failure to properly clean out a formulation for one species and age class prior to processing a formulation for another species or age class is likely increase the occurrence of nutrient imbalance in complete animal food.

**Question 8:** Which of these activities are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death from consumption of this animal food?

**Response:** The RA identified the following examples of activities that are interventions to significantly minimize or prevent hazards that are reasonably likely to cause serious adverse health consequences or death from consumption of this animal food:

- Reducing the pH or  $a_w$  of animal food (e.g., by drying, fermenting, adding preservatives)
- Controlling moisture in stored grains (e.g., by drying);
- Controlling introduction of biological hazards by controlling pests;
- Timing pesticide applications on animal food crops;
- Excluding outer layers of treated plants before using the plants as animal food;
- Testing for the presence of chemical hazards and excluding contaminated food;
- Using established ration formulations and supplement recommendations appropriate for species and life stages of animals;
- Adequate cleanout of product for a specific species and age class prior to mixing animal food for another specific species or age class.
- Using accurate scales to weigh animal food ingredients;
- Mixing animal food ingredients thoroughly.

**Question 9:** Which activity/animal food combinations are low risk, i.e., what on-farm activity/animal food combinations are not reasonably likely to introduce hazards that are reasonably likely to cause serious adverse health consequences or death to humans or animals or serve as preventive controls (interventions) to significantly minimize or prevent a hazard that could cause serious adverse health consequences or death?

**Response:** Based on the information in Table 11 for the purposes of the analysis required by section 103(c)(1)(C) of FSMA, the RA identified the following low-risk activity/animal food combinations.

- Chopping/shredding hay;
- Cracking/crimping/flaking/pearling/peeling/shelling/wafering grain (e.g., barley, sorghum, corn, oats, rice, rye, and wheat) or oilseed (e.g., beans, canola, cottonseed, linseed, soybeans, and sunflowers);
- Crushing/dry rolling/grinding/milling/pulverizing/ grain, oilseed, grain by-products and processed grain products (e.g., bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal), oilseed products (e.g., oil or meal of safflower, soybean, and sunflower), hay, ensiled material, culled fruits and vegetables, roughage (e.g. cobs, hulls, husks, and straws), or roughage products (e.g., alfalfa meal, entire plant meal, stem meal, pomace, pulp);
- Ensiling (including chopping/shredding/mixing/storing/fermenting), that is, making silage or haylage from forage (e.g., sorghum (milo), corn (maize), alfalfa, and grass), grain, or culled fruits and vegetables, or roughage;
- Extracting (mechanical)/wet rolling grain, oilseed, brewers grain by-products, or distillers grain by-products;
- Labeling roughage products, plant protein meals (e.g., algae, coconut (copra), guar, and peanut), grain by-products and processed grain products, oilseed products, molasses (e.g., processed sugar cane, sugar beets, and citrus), animal protein meals (e.g., blood, feather, meat, meat and bone, and marine (e.g., crab, fish, shrimp)), milk products (e.g., casein, cheese rind, and lactalbumin), animal tissue-derived products, (e.g., fat), vitamins, minerals, concentrates, processing aids (e.g., enzymes, preservatives, and stabilizers), finished animal

food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety;

- Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety;
- Packing/re-packing roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety;
- Storing/holding (ambient, cold, or controlled atmosphere), including activities incidental to holding (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety.

## **B. Summary**

This RA assesses the risk of activities conducted on animal food by farm mixed-type facilities to determine low-risk activity/animal food combinations. It advances our ability to describe our current state of knowledge about known or reasonably foreseeable hazards for animal food and activities on-farm and to assess which activities are low risk. It provides a framework for integrating and evaluating the scientific knowledge related to public health as applied to on-farm activities and can be used in support of regulatory decisions in the implementation of FSMA.

## VIII. REFERENCES

Agriculture and Agri-Food Canada Food Production Direction Inspection Branch, "Regulatory Directive: Pre-Harvest Intervals for Grazing and Cutting for Hay of Immature Crops Treated With Pesticides," <http://www.hc-sc.gc.ca/cps-spc/pubs/pest/pol-guide/dir93-18/index-eng.php>, October 28, 1993. Accessed on August 24, 2013. See Reference 30 to the 2013 Draft Risk Assessment.

Battacone, G; Anna Nudda, Giuseppe Pulina. "Effects of Ochratoxin A on Livestock Production" *Toxins* 2010 Vol 2:1796-1824.

Bayman, P. and J. L. Baker, "Ochratoxins: a Global Perspective," *Mycopathologia*, 162:215-223, 2006. See Reference 42 to the 2013 Draft Risk Assessment.

Bhat, R. V. and J. D. Miller, "Mycotoxins and Food Supply," <http://www.fao.org/docrep/U3550t/u3550t0e.htm>, 1991. Accessed on August 24, 2013. See Reference 43 to the 2013 Draft Risk Assessment.

Braun, U., "Traumatic Pericarditis in Cattle: Clinical, Radiographic and Ultrasonographic Findings," *The Veterinary Journal*, 182:176-786, 2009. See Reference 52 to the 2013 Draft Risk Assessment.

Brendemuhl, J. and B. Myer, "Types of Swine Diets," <http://edis.ifas.ufl.edu/pdffiles/AN/AN03600.pdf>, 2009 revision. Accessed on August 25, 2015. See Reference 23 to the 2013 Draft Risk Assessment.

Calhoun, S. et.al. "Prevalence and Concentration of Salmonella on Raw Shelled Peanuts in the United States," *Journal of Food Protection*, 76:575-579, 2012.

Caloni, F. and C. Cortinovis, "Toxicological Effects of Aflatoxins in Horses," *The Veterinary Journal*, 188:270-273, 2011. See Reference 2 to the 2013 Draft Risk Assessment.

Cavallarin, L., E. Tabacco, S. Antoniazzi, and G. Borreani, "Aflatoxin Accumulation in Whole Cropmaize Silage As a Result of Aerobic Exposure," *Journal of the Science of Food and Agriculture*, 91:2419-2425, 2011. See Reference 29 to the 2013 Draft Risk Assessment.

Centers for Disease Control and Prevention (CDC), "Botulism General Information," <http://www.cdc.gov/nczved/divisions/dfbmd/diseases/botulism/>, July 26, 2011. Accessed on August 24, 2013 See Reference 37 to the 2013 Draft Risk Assessment.

Centers for Disease Control and Prevention (CDC), "Foodborne Diseases Active Surveillance Network(FoodNet): FoodNet Surveillance Report for 2012 (Final Report)," 2014b.

Centers for Disease Control and Prevention (CDC), "Multistate Outbreak of Human *Salmonella* I 4,[5],12:i:-Infections Associated With Frozen Rodents (Final Update),"

(<http://www.cdc.gov/salmonella/frozenrodents/index.html>), August 2, 2010. Accessed June 17, 2015.

Centers for Disease Control and Prevention, "Multistate Outbreak of Human Salmonella Typhimurium Infections Linked to Frozen Feeder Rodents (Final Update)," (<http://www.cdc.gov/salmonella/typhimurium-rodents-05-14/index.html>), August 1, 2014. Accessed June 17, 2015. 2014a

Centers for Disease Control and Prevention (CDC), "Surveillance for Foodborne Disease Outbreaks - United States, 2012," <http://www.cdc.gov/foodsafety/pdfs/foodborne-disease-outbreaks-annual-report-2012-508c.pdf>. Accessed on August 31, 2015. 2014c.

Centers for Disease Control and Prevention (CDC), "Update: Recall of Dry Dog and Cat Food Products Associated With Human Salmonella Schwarzengrund Infections --- United States, 2008," <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5744a2.htm>, November 7, 2008. Accessed on August 24, 2013. See Reference 9 to the 2013 Draft Risk Assessment.

Centers for Disease Control and Prevention (CDC) ATSDR, "Chlorinated Dibenzo-p-Dioxins (CDDs) ," <http://www.atsdr.cdc.gov/tfacts104.pdf>, February, 1999. Accessed on August 24, 2013. See Reference 48 to the 2013 Draft Risk Assessment.

Chung, K.C. and J.M. Goepfert, "Growth of *Salmonella* at Low pH," Journal of Food Science, 35:326-328, 1970.

Conner, D. E. and J. S. Kotrola, "Growth and Survival of *Escherichia Coli* O157:H7 Under Acidic Conditions," Applied and Environmental Microbiology, 61:382-385, 1995. See Reference 64 to the 2013 Draft Risk Assessment.

D'Aoust, J. Y. and J. Maurer, "*Salmonella* Species," In: Food Microbiology: Fundamentals and Frontiers, edited by M. P. Doyle and L. R. Beuchat, 3rd, Washington, DC, Chapter 10, pp. 187-236, ASM Press, 2007. See Reference 62 to the 2013 Draft Risk Assessment.

D'Mello, J. P. F. and A. M. C. Macdonald, "Mycotoxins," Animal Feed Science Technology, 69:155-166, 1997. See Reference 25 to the 2013 Draft Risk Assessment.

FDA, "AAFCO Ingredient Definitions: Setting the Standards," <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm109972.htm>, April 16, 2013. Accessed on August 24, 2013. See Reference 11 to the 2013 Draft Risk Assessment. 2013d.

FDA, "Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook. *Salmonella* Spp.," Second Edition, 2012. See Reference 34 to the 2013 Draft Risk Assessment. 2012c.

FDA, "Dioxin,"  
<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/Contaminants/ucm050430.htm>,  
February 16, 2011. Accessed on August 24, 2013. See Reference 49 to the 2013 Draft Risk  
Assessment. 2011b.

FDA, "FDA Foods and Veterinary Medicine Program, The Reportable Food Registry: A New  
Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration. First Annual  
Report: September 8, 2009 - September 7, 2010,"  
<http://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM291297.pdf>, April, 2011.  
Accessed August 28, 2015. 2011a.

FDA, "FDA Foods and Veterinary Medicine Program, The Reportable Food Registry: Targeting  
Inspection Resources and Identifying Patterns of Adulteration. Second Annual Report: September 8,  
2010 - September 7, 2011,"  
<http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM301013.pdf>,  
April, 2012. Accessed August 28, 2015. See Reference 7 to the 2013 Draft Risk Assessment. 2012b.

FDA, "FDA Foods and Veterinary Medicine Program, The Reportable Food Registry: Targeting  
Inspection Resources and Identifying Patterns of Adulteration. Third Annual Report: September 8,  
2011 - September 7, 2012,"  
<http://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM349856.pdf>, April, 2013.  
Accessed August 28, 2015. 2013e.

FDA, "FDA Foods and Veterinary Medicine Program, The Reportable Food Registry: Targeting  
Inspection Resources and Identifying Patterns of Adulteration. Fourth Annual Report: September 8,  
2012 - September 7, 2013,"  
<http://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM395684.pdf>, April, 2015.  
Accessed August 28, 2015. 2015b.

FDA, "Food Code 2009,"  
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm>,  
February 28, 2012d.

FDA, "Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human  
Food and Animal Feed," 2013. See Reference 8 to the 2013 Draft Risk Assessment. 2013a

FDA, "Ingredients and Additives,"  
<http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/IngredientsAdditives/default.htm>,  
June 27, 2013. Accessed on August 24, 2013. See Reference 10 to the 2013 Draft Risk  
Assessment. 2013c.

FDA, Investigation of Multistate Outbreak of Human Infections Linked to Dry Dog Food,  
<http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm302904.htm>  
.Last updated July 21, 2014. Last accessed 6/16/2015. 2012a.

FDA, "Pesticide Monitoring Program - FY 2008," <http://www.fda.gov/downloads/Food/FoodSafety/FoodContaminantsAdulteration/Pesticides/ResidueMonitoringReports/UCM230537.pdf>, June 19, 2010. Accessed on August 24, 2013. See Reference 47 to the 2013 Draft Risk Assessment. 2010.

FDA, "Primal Pet Foods Voluntarily Recalls A Single Lot of Raw Frozen Cat Food." (Thiamine Deficiency). <http://www.fda.gov/safety/recalls/ucm438183.htm>. Last accessed 6/18/2015. 2015c.

FDA, "7-4 Recall Enterprise System," (<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177308.htm>), June 19, 2015. Accessed on August 28, 2015. 2015a.

FDA, "Reportable Food Registry (RFR) at a Glance," <http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM181885.pdf>, April, 2013. Accessed August 24, 2013. See Reference 15 to the 2013 Draft Risk Assessment. 2013b.

FDA and EPA, "Joint EPA/FDA Statement: Update on Ongoing Monitoring," <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249146.htm>, March 30, 2011. Accessed August 24, 2013 See Reference 55 to the 2013 Draft Risk Assessment.

Gries, C. L. and M. L. Scott, "The Pathology of Thiamin, Riboflavin, Pantothenic Acid and Niacin Deficiencies in the Chick," *The Journal of Nutrition*, 102:1269-1286, 1971. See Reference 17 to the 2013 Draft Risk Assessment.

Institute of Food Technologists, "Analysis and Evaluation of Preventive Control Measure for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce," 2001.

Institute of Food Technologists, "Chapter 2 Current and Proposed Definitions of 'Potentially Hazardous Foods,'" In: *Evaluation and Definition of Potentially Hazardous Foods*; <http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm094143.htm>, December 31, 2001. (page updated 11/26/2014) Accessed August 24, 2015.

Institute of Food Technologists, "Evaluation and Definition of Potentially Hazardous Foods," (June 18, 2009. See Reference 5 to the 2013 Draft Risk Assessment.

International Commission on Microbiological Specifications for Foods, "Cereals and Cereal Products," In: *Microorganisms in Foods 6. Microbial Ecology of Food Commodities*, edited by T. A. Roberts, J.-L. Cordier, L. Gram, R. B. Tompkin, J. I. Pitt, L. G. M. Gorris, and K. M. J. Swanson, 2<sup>nd</sup> edition, New York, Chapter 8, pp. 392-439, Kluwer Academic / Plenum Publishers, 2005a. See Reference 26 to the 2013 Draft Risk Assessment.

International Commission on Microbiological Specifications for Foods, "Clostridium Botulinum," In: Microorganisms in Foods 5. Characteristics of Microbial Pathogens, edited by T. A. Roberts, A. C. Baird-Parker, and R. B. Tompkin, London, Chapter 5, pp. 73-333, Blackie Academic & Professional, 1996c. See Reference 60 to the 2013 Draft Risk Assessment.

International Commission on Microbiological Specifications for Foods, "Nuts, Oilseeds, and Dried Legumes," In: Microorganisms in Foods 6. Microbial Ecology of Food Commodities, edited by T. A. Roberts, J.-L. Cordier, L. Gram, R. B. Tompkin, J. I. Pitt, L. G. M. Gorris, and K. M. J. Swanson, 2<sup>nd</sup> edition, New York, Chapter 9, pp. 440-466, Kluwer Academic / Plenum Publishers, 2005b See Reference 27 to the 2013 Draft Risk Assessment..

International Commission on Microbiological Specifications for Foods, "Salmonellae," In: Microorganisms in Foods 5. Characteristics of Microbial Pathogens, edited by T. A. Roberts, A. C. Baird-Parker, and R. B. Tompkin, London, Chapter 14, pp. 224-225, Blackie Academic & Professional, 1996a. See Reference 58 to the 2013 Draft Risk Assessment.

International Commission on Microbiological Specifications for Foods, "Staphylococcus Aureus," In: Microorganisms in Foods 5. Characteristics of Microbial Pathogens, edited by T. A. Roberts, A. C. Baird-Parker, and R. B. Tompkin, London, Chapter 17, pp. 299-333, Blackie Academic & Professional, 1996b. See Reference 59 to the 2013 Draft Risk Assessment.

International Commission on Microbiological Specifications for Foods, "Sugar, Syrups and Honey," In: Microorganisms in Foods 6. Microbial Ecology of Food Commodities, edited by T. A. Roberts, J.-L. Cordier, L. Gram, R. B. Tompkin, J. I. Pitt, L. G. M. Gorris, and K. M. J. Swanson, 2<sup>nd</sup> edition, New York, Chapter 12, pp. 522-543, Kluwer Academic / Plenum Publishers, 2005e. See Reference 60 to CFSAN's 2012 Draft RA, Docket FDA-2012-N-1258

Ito, K. A. and J. K. Chen, "Effect of PH on Growth of *Clostridium Botulinum* in Foods," Food Technology, 32:71-76, 1978. See Reference 70 to the 2013 Draft Risk Assessment.

Jantschke, M. and P. H. Elliott, "Physical Hazards and Controls," In: HACCP: A Systematic Approach to Food Safety, edited by V. N. Scott and K. E. Stevenson, 4<sup>th</sup> edition, Washington, D.C., Chapter 6, pp. 47-51, The Food Products Association, 2006. See Reference 73 to the 2013 Draft Risk Assessment.

Jay, J. M., "Intrinsic and Extrinsic Parameters of Foods That Affect Microbial Growth," In: Modern Food Microbiology, edited by D. R. Heldman, 6<sup>th</sup> edition, Gaithersburg, MD, Chapter 3, pp. 35-56, Aspen Publishers, Inc., 2000. See Reference 56 to the 2013 Draft Risk Assessment.

Johnson, W. D. and R. W. Storts, "Peripheral Neuropathy Associated With Dietary Riboflavin Deficiency in the Chicken I. Light Microscopic Study," Veterinary Pathology, 25:9-16, 1988. See Reference 18 to the 2013 Draft Risk Assessment.

Jones, F. T., "A Review of Practical Salmonella Control Measures in Animal Feed," The Journal of Applied Poultry Research:102-113, 2011. See Reference 33 to the 2013 Draft Risk Assessment.

Koutsoumanis, K. P., P. A. Kendall, and J. N. Sofos, "Modeling the Boundaries of Growth of *Salmonella* Typhimurium in Broth As a Function of Temperature, Water Activity and PH," Journal of Food Protection, 67:53-59, 2004. See Reference 68 to the 2013 Draft Risk Assessment.

Lang, S. "Dogs keep dying: Too many owners remain unaware of toxic dog food." Cornell Chronicle. Jan 6. 2006. <http://www.news.cornell.edu/stories/2006/01/dogs-keep-dying-many-owners-remain-unaware-toxic-dog-food>. Accessed 6/18/2015.

Leibensperger, R. Y. and R. E. Pitt, "A Model of Clostridial Dominance in Ensilage," Grass and Forage Science, 42:297-317, 1987. See Reference 66 to the 2013 Draft Risk Assessment.

Leyer, G. J. and E. A. Johnson, "Acid Adaptation Promotes Survival of *Salmonella* Spp. in Cheese," Applied and Environmental Microbiology, 58:2075-2080, 1992. See Reference 65 to the 2013 Draft Risk Assessment.

Liu, K., "Chemical Composition of Distillers Grains, a Review," Journal of Agricultural and Food Chemistry, 59:1508-1526, 2011. See Reference 3 to the 2013 Draft Risk Assessment.

Lundeen, T., "Feed Marketing & Distribution," *Feedstuffs Reference Issue & Buyers Guide 2015*, 2014,

McGraw-Hill, "McGraw-Hill Dictionary of Science and Technical Terms," <http://www.answers.com/topic/ensiling>, 2003. Accessed on August 26, 2013 and printed on November 15, 2012. See Reference 69 to the 2013 Draft Risk Assessment.

Merck Sharp & Dohme Corp, "Aflatoxicosis," <http://www.merckmanuals.com/vet/toxicology/mycotoxicoses/aflatoxicosis.html>, March, 2012a. Accessed and printed on August 23, 2013. See Reference 1 to the 2013 Draft Risk Assessment.

Merck Sharp & Dohme Corp, "Botulism," [http://www.merckmanuals.com/vet/generalized\\_conditions/clostridial\\_diseases/botulism.html?qt=Botulism](http://www.merckmanuals.com/vet/generalized_conditions/clostridial_diseases/botulism.html?qt=Botulism), March, 2012c. Accessed on August 24, 2013. See Reference 38 to the 2013 Draft Risk Assessment.

Merck Sharp & Dohme Corp, "Fumonisin Toxicosis," [http://www.merckmanuals.com/vet/toxicology/mycotoxicoses/fumonisin\\_toxicosis.html](http://www.merckmanuals.com/vet/toxicology/mycotoxicoses/fumonisin_toxicosis.html), March, 2012d. Accessed on August 24, 2013. See Reference 46 to the 2013 Draft Risk Assessment.

Merck Sharp & Dohme Corp, "Overview of Salmonellosis," [http://www.merckmanuals.com/vet/digestive\\_system/salmonellosis/overview\\_of\\_salmonellosis.html?qt=Salmonellosis&alt=sh](http://www.merckmanuals.com/vet/digestive_system/salmonellosis/overview_of_salmonellosis.html?qt=Salmonellosis&alt=sh), March, 2012b. Accessed on August 24, 2013. See Reference 35 to the 2013 Draft Risk Assessment.

Merck Sharp & Dohme, "Vitamin Deficiencies in Poultry," In: The Merck Veterinary Manual 10th, Merck Publishing, 2015.

Montville, T. J. and K. R. Matthews, "Growth, Survival, and Death of Microbes in Foods," In: Food Microbiology: Fundamentals and Frontiers, edited by M. P. Doyle and L. R. Beuchat, 3<sup>rd</sup> edition 1, pp. 3-22, ASM Press, 2007. See Reference 57 to the 2013 Draft Risk Assessment.

Morita, T., H. Kitazawa, T. Iida, and S. Kamata, "Prevention of Salmonella Cross-Contamination in an Oilmeal Manufacturing Plant," Journal of Applied Microbiology, 101:464-473, 2006. See Reference 28 to the 2013 Draft Risk Assessment.

Muth, M. K., C. Zhen, M. Coglaiti, and S. Karns, "Food Processing Sector Study, Contract HHSF 2232010745G, Task Order 13, Final Report," 2011. See Reference 12 to the 2013 Draft Risk Assessment.

Myllykoski, J., M. Lindstrom, and R. Keto-Timonen, "Type C Bovine Botulism Outbreak Due to Carcass Contaminated Non-Acidified Silage," Epidemiological Infections, 137:284-293, 2009. See Reference 31 to the 2013 Draft Risk Assessment.

National Research Council, S. O. P. N., Nutrient Requirements of Poultry, 1994. See Reference 24 to the 2013 Draft Risk Assessment.

National Research Council, Nutrient Requirements of Beef Cattle: Seventh Revised Edition, Washington, D.C., National Academy Press, 2000. See Reference 19 to the 2013 Draft Risk Assessment.

National Research Council, "Phosphorus," In: Mineral Tolerance of Animals, Second Revised Edition, pp. 290-299 2005. See Reference 20 to the 2013 Draft Risk Assessment.

Orriss, G. D., "Animal Diseases of Public Health Importance," Emerging Infectious Diseases, 3:497-502, 1997. See Reference 22 to the 2013 Draft Risk Assessment.

Pestka, J. J. and A. T. Smolinski, "Deoxynivalenol: Toxicology and Potential Effects on Humans," Journal of Toxicology and Environmental Health. Part B, Critical Reviews, 8:39-69, 2005. See Reference 40 to the 2013 Draft Risk Assessment.

Ruoho, O., "An Epidemic of Salmonellosis Caused by Silage Containing Salmonella at a Dairy Farm," In: XIII International Congress in Animal Hygiene "Animal Health, Animal Welfare and Biosecurity" Proceedings Volume 1, edited by A. Aland, pp. 882-884 2007. See Reference 67 to the 2013 Draft Risk Assessment.

Rutqvist, L.; N.E. Bjorklund, et.al. "Ochratoxin A as the Cause of Spontaneous Nephropathy in Fattening Pigs" Applied and Environment Microbiology 1978 Vol 36:920-925. NEW

Scott, V. N., R. S. Clavero, and J. A. Troller, "Measurement of Water Activity ( $A_w$ ), Acidity, and Brix," In: Compendium of Methods for the Microbiological Examination of Foods, edited by F. P. Downes and K. Ito, 4<sup>th</sup> edition, Washington, DC, Chapter 64, pp. 649-657, American Public Health Association, 2001. See Reference 61 to the 2013 Draft Risk Assessment.

Scott, V. N., C. Yuhuan, T. A. Freier, J. Kuehm, M. Moorman, J. Meyer, T. Morille-Hinds, L. Post, L. Smoot, S. Hood, J. Shebuski, and J. Banks, "Control of *Salmonella* in Low-Moisture Foods I: Minimizing Entry of *Salmonella* into a Processing Facility," Food Protection Trends, 29:342-353, 2009. See Reference 63 to the 2013 Draft Risk Assessment.

Shephard, G. S., "Risk Assessment of Aflatoxins in Food in Africa," Food Additives and Contaminants: Part A - Chemistry, Analysis, Control, Exposure and Risk Assessment, 25:1246-1256, 2008. See Reference 41 to the 2013 Draft Risk Assessment.

Shotwell, O. L., "Aflatoxin in Corn," Journal of the American Oil Chemists' Society, 54:216A-224A, 1977. See Reference 77 to the 2013 Draft Risk Assessment.

Townsend, C. T., L. Yee, and W. A. Mercer, "Inhibition of the Growth of *Clostridium Botulinum* by Acidification," Journal of Food Science, 19:536-542, 1954. See Reference 71 to the 2013 Draft Risk Assessment.

Tsunoda, M., R. P. Sharma, and R. T. Riley, "Early Fumonisin B1 Toxicity in Relation to Disrupted Sphingolipid Metabolism in Male BALB/c Mice," Journal of Biochemical and Molecular Toxicology, 12:281-289, 1998. See Reference 44 to the 2013 Draft Risk Assessment.

USDA National Agricultural Statistics Service, "2012 Census of Agriculture United States Summary and State Data," ([http://www.agcensus.usda.gov/Publications/2012/Full\\_Report/Volume\\_1\\_Chapter\\_1\\_US/usv1.pdf](http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1_Chapter_1_US/usv1.pdf)), May, 2014. Accessed on August 28, 2015

USDA APHIS, "Info Sheet: Fumonisin B1 Mycotoxin in Horse Grain/Concentrate on U.S. Horse Operations," ([http://www.aphis.usda.gov/animal\\_health/nahms/equine/downloads/equine98/Equine98\\_is\\_Fumoni sin.pdf](http://www.aphis.usda.gov/animal_health/nahms/equine/downloads/equine98/Equine98_is_Fumoni sin.pdf)), 2000. Accessed on August 24, 2013. See Reference 45 to the 2013 Draft Risk Assessment.

USDA APHIS, "National Animal Health Monitoring System: National Studies of U.S. Livestock and Poultry, 2010," ([http://www.aphis.usda.gov/animal\\_health/nahms/downloads/NAHMS\\_brochure.pdf](http://www.aphis.usda.gov/animal_health/nahms/downloads/NAHMS_brochure.pdf)), 2012. Accessed on August 24, 2013. See Reference 13 to the 2013 Draft Risk Assessment.

USDA AMS, "Recordkeeping Manual for Private Pesticide Applicators," (<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRD3342981>), August, 2010. Accessed on August 24, 2013. See Reference 72 to the 2013 Draft Risk Assessment.

USDA NASS., "Agricultural Statistics 2010,"

[http://www.nass.usda.gov/Publications/Ag\\_Statistics/2010/2010.pdf](http://www.nass.usda.gov/Publications/Ag_Statistics/2010/2010.pdf), 2010. Accessed on August 24, 2013. See Reference 76 to the 2013 Draft Risk Assessment.

Uzzau, S., D. J. Brown, T. Wallis, S. Rubino, G. Leori, S. Bernard, J. Casadesus, D. J. Platt, and J. E. Olson, "Host Adapted Serotypes of *Salmonella Enterica*," Epidemiol.Infect., 125:229-255, 2000. See Reference 36 to the 2013 Draft Risk Assessment.

Ward, J. L. and N. G. Ducharme, "Traumatic Reticuloperitonitis in Dairy Cows," JAVMA, 204:874-877, 1994. See Reference 53 to the 2013 Draft Risk Assessment.

Williams, J. H., T. D. Phillips, P. E. Jolly, J. K. Stiles, C. M. Jolly, and D. Aggarwal, "Human Aflatoxicosis in Developing Countries: a Review of Toxicology, Exposure, Potential Health Consequences, and Interventions," American Journal of Clinical Nutrition, 80:1106-1122, 2004. See Reference 39 to the 2013 Draft Risk Assessment.

Whitlow, L. W. and W. M. Hagler, "Molds and Mycotoxins in Feedstuffs - Prevention and Treatment," <http://dairy.ifas.ufl.edu/rns/2005/Whitlow.pdf>, 2005. Accessed on August 24, 2013. See Reference 32 to the 2013 Draft Risk Assessment.

World Health Organization, "Dioxin Fact Sheet,"

<http://www.who.int/mediacentre/factsheets/fs225/en/>, 2014. Accessed 6 17 2015

World Health Organization, "FAQs: Japan Nuclear Concerns,"

<http://www.who.int/hac/crises/jpn/faqs/en/index.html>, September, 2011. Accessed August 26, 2013. See Reference 54 to the 2013 Draft Risk Assessment.

Wu, F., S.L. Stacy, T.W. Kensler, "Global risk assessment of aflatoxins in maize and peanuts: are regulatory standards adequately protective?" Toxicological Sciences. 135(1): 251-259, 2013.

## APPENDIX 1. DEFINITIONS RELEVANT TO ACTIVITIES OF FARMS AND FARM MIXED-TYPE FACILITIES

### **Farm** means:

(1) Primary Production Farm. A Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same management; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary Activities Farm. A Secondary Activities Farm is an operation, not conducted on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm as described in paragraph (1)(ii) and (iii) of this definition.

**Harvesting** applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as animal food. Harvesting is limited to activities performed on raw agricultural commodities or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural

commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

**Holding** means storage of animal food and also includes activities performed incidental to storage of an animal food (e.g., activities performed for the safe or effective storage of that animal food, such as fumigating animal food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa). Holding also includes activities performed as a practical necessity for the distribution of that animal food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

**Manufacturing/processing** means making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

**Packing** means placing food into a container other than packaging the animal food and also includes re-packing and activities performed incidental to packing or re-packing an animal food (e.g., activities performed for the safe or effective packing or re-packing of that animal food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

## **APPENDIX 2. A SUMMARY OF KEY CHANGES IN THE FINAL RISK ASSESSMENT COMPARED TO THE DRAFT RISK ASSESSMENT**

We made the following revisions between the draft RA and this RA:

- Made changes to reflect the new farm definition, which increased the number of activities within the farm definition thereby narrowing the scope of the activity/animal food combinations that needed to be considered in the final risk assessment. (For example, harvesting activities conducted by a secondary farm on RACs without additional manufacturing/processing, such as hulling and shelling tree nuts, now falls within the farm definition.)
- Updated several references and added additional ones.
- Deleted discussion of radiological hazards in the RA, because the preventive controls for animal foods rule now considers them as a type of chemical hazard. (We have considered them as part of our consideration of chemical hazards, and we focused in the final RA on the chemical hazards most likely to require a preventive control.)
- Asked questions with respect to “known or reasonably foreseeable hazards” rather than “hazards reasonably likely to occur” because of changes in terminology and because the hazards that require a preventive control are specific to an animal food and a facility.
- Included activities that encompass multiple steps (e.g., making animal food ready for consumption) and grouped these steps to better identify the end product. As such, activities that are encompassed within the making of a particular product are no longer listed as separate activities within the table. (For example, because making silage includes fermenting, fermenting roughage is not listed as a separate activity.)
- Revised the way animal foods were grouped, e.g., categories of animal food were separated into groups according to whether they were RACs, processed animal food that might have been processed at the farm-mixed facility or purchased, processed animal food that would be acquired from off-farm, and finished animal food that includes animal food ready for consumption. To some extent, these groups were developed to coincide with the revised definition of farm in the sense that packing/holding of any of the animal food in the RAC group was included in the risk assessment because that activity is within the farm definition. The group of animal foods that would be acquired from off-farm was developed to contain animal food that is the result of processing activity that is outside the scope of the risk assessment because of the time/temperature controls required to produce them. Once produced, products such as rendered fat or casein may be safely used on farm. This category also includes animal food that most likely could not be produced on farm such as vitamins and minerals.
- Updated the RFR information in Table 2 and the recall information in Table 3, including adding some new references about recent recalls.

- Revised and merged the two draft RA tables addressing whether an activity/animal food combination is low risk (Table 10 in the final RA) to reflect the revised list of animal foods and activities in Table 1.
- Revised the table describing why certain activity/animal food combinations are not low risk (Table 11 in the final RA) to reflect the decisions made in Table 10.
- Revised the answers to the questions posed in the RA and the list of low-risk activity/animal food combinations to reflect the outcome of the final RA.
- Deleted the appendices from the draft RA that focused on the regulatory framework and categorized the low-risk activity/animal food combinations according to that framework.
- Added new appendices on
  - definitions relevant to activities on farms and farm mixed-type facilities,
  - the changes in the final RA compared to the draft RA,
  - the chronology of technical and scientific reviews of the RA,
  - the public comments and FDA/CVM's responses,
  - the food categories for packing and holding activities that were included in the low-risk activity/animal food combinations and those that were not,
  - the animal food categories for manufacturing/processing activities that were included in the low-risk activity/animal food combinations and those that were not.

### APPENDIX 3: CHRONOLOGY OF TECHNICAL AND SCIENTIFIC REVIEWS OF THE QUALITATIVE RISK ASSESSMENT

FDA solicited the advice and opinions of scientific experts and the public throughout the conduct of this risk assessment. A summary of the dates, type of review activity, and participants is provided below.

**Table 12. Chronology of Technical and Scientific Reviews of the Qualitative Risk Assessment**

Date	Activity	Participants
2011-2012	Risk Assessment Team assembled	FDA
June 2012	Submit draft risk assessment for peer review	Independent, external peer review conducted by Versar, Inc.
November 2012	Peer review comments received from Versar, Inc. on draft risk assessment	Independent, external peer review conducted by Versar, Inc.
February 2013	Submit draft risk assessment and draft peer review comments to OMB as part of rulemaking for FSMA	OMB
March – August 2013	Draft risk assessment revised	FDA
September 2013	<i>External Peer Review of the FDA/CVM Draft Qualitative Risk Assessment. Peer Review Report</i>	FDA
October 2013	Draft risk assessment formatted for posting	FDA
October 2013	Notice of Availability of draft risk assessment for public comment (78 FR 64428, October 29, 2013)	Public
February 2014	Extension of public comment period (79 FR 6116, February 3, 2014)	Public
October 2013-June 2015	Revisions made to draft risk assessment to reflect changes to definitions as a result of public comments	FDA
June 2015	Submit draft risk assessment to OMB as part of rulemaking for FSMA	OMB
August 2015	Revisions to draft risk assessment	FDA
September 2015	Notice of Availability of revised risk assessment	N/A

## APPENDIX 4: PUBLIC COMMENTS AND FDA/CVM'S RESPONSES

**Table 13. Summary of Public Comments Received to the Draft Preventive Control Rule for Animal Food or the Draft RA and FDA/CVM Responses**

Topic Areas	Public Comment: 2013 Draft Risk Assessment	FDA/CVM's Response
Process	Some comments assert that we should revise the section 103(c)(1)(C) draft RA and then make it available for additional public comment before finalizing the rule.	We subjected the section 103(c)(1)(C) draft RA to peer review in accordance with the requirements of the Final Information Quality Bulletin for Peer Review (issued by the Office of Management and Budget to implement the Information Quality Act (Pub. L. 106–554)) before we made it available for broader public comment during a time period that exceeded 10 months. The additional iterative process recommended by these comments is not necessary and would go beyond the processes we routinely apply for public input on a risk assessment.
Hazards	A comment states that GMO food should be added to those that are seen as potential risks for animals.	We have not seen evidence that foods derived from genetically engineered plants differ from other foods in any meaningful or uniform way, or that, as a class, such foods present different or greater safety concerns than their non-genetically engineered counterparts. We have a voluntary consultation process for foods derived from genetically engineered plants through which we engage with the developers of genetically engineered plants to help ensure the safety of the derived foods. Foods that have undergone this consultation process are as safe as foods from conventionally-bred plants. Foods derived from genetically engineered plants, irrespective of the method of development, are subject to the same food safety and other regulatory requirements as foods derived from conventionally-bred plants. Therefore genetically engineered foods do not need to be singled out as a hazard

Topic Areas	Public Comment: 2013 Draft Risk Assessment	FDA/CVM's Response
Activities	Some comments state that the exemptions for farming activities are confusing.	<p>The activity/animal food combinations listed in the draft RA and the proposed § 507.5(e) (packing and holding) and § 507.5(f) (manufacturing/processing) had three related parts. As originally proposed, some activities conducted that would have been considered packing/ holding when conducted on the farm's own RACS were considered manufacturing/processing when conducted on others' RACs. This added a layer of complexity. Although these exemptions are more complex than other exemptions (e.g., because they are directed to specific activities conducted on specific animal foods), the final "farm" definition has simplified them to the extent practicable. For example, under the "farm" definition established in the final rule for preventive controls for human food published elsewhere in this Federal Register, packing RACs is a "packing" activity, regardless of ownership of the RACs being packed</p> <p>Furthermore, we have refined the list of animal food categories to facilitate aligning them with the revised definition of farm and to provide more specificity to the examples used to describe the exemptions.</p>
Activities	Some comments ask us to include manufacturing of animal food from low risk ingredients as additional activity/animal food combinations in the exemption. Other comments support our conclusion that manufacturing animal food ready for consumption is not a low risk activity.	We evaluated manufacturing of animal food as one of the activity/animal food combinations within the qualitative risk assessment and found that because nutrient imbalance is a hazard that occurs frequently with severe health consequences for animals, manufacturing animal food could not be considered low risk. This holds for manufacturing animal food from any ingredients.

Topic Areas	Public Comment: 2013 Draft Risk Assessment	FDA/CVM's Response
Activities	Some comments asked us to consider off-farm hulling and shelling of nuts to be low-risk.	The risk assessment evaluates the risk associated with on-farm activity/animal food combinations that are outside the farm definition only. When conducted by a primary or a secondary farm, shelling and hulling, without further processing such as drying, are within the revised definition of “farm”.
Data sources	The risk assessment was qualitative in nature, based on professional judgment rather than data.	FDA acknowledged the data limitations in the draft risk assessment (78 FR 64428; see section I.F in that document). Rather than limit public input to subject matter experts, we requested comment on the draft risk assessment from all interested persons. We received a number of comments about activity/animal food combinations conducted on farms and farm mixed-type facilities to the proposed rule and supplemental rulemaking (Docket No. FDA-2011-N-0922) which were considered in the revision of the definition of “farm” that led to subsequent associated changes in the risk assessment.
Data sources	Some comments assert that we should collect data from large-scale surveys of actual farm mixed-type facilities and their activities. Other comments ask us to collect, analyze, and interpret data about the levels of hazards from animal food samples taken from small and very small mixed-type facilities and use consumption to estimate the likelihood of exposure to hazards in animal food from such facilities. Some comments ask us to consult with subject matter experts to ensure that the final risk assessment reflects sufficient geographic diversity.	We received comments to the proposed rule and supplemental rulemaking (Docket No. FDA-2011-N-0922) from diverse geographic areas comprising both areas where farms and farm mixed-type facilities tend to be small and where they tend to be large. We disagree that we need to conduct large scale surveys, or enter into agreements with agencies/organizations, to collect additional information in light of the previous opportunity for broad public input regarding the activity/animal food combinations conducted on farms and farm mixed-type facilities.

## APPENDIX 5: PACKING/HOLDING ACTIVITIES

Table 14 lists the packing and holding activity/animal food combinations that are considered to be low risk by the risk assessment. This list is different from the list of low-risk packing and holding activity/animal food combinations in the draft RA mainly as a result of changes in the categorization of animal food developed to reflect the changes in the definition of “farm” that occurred subsequent to the completion of the draft RA.

**Table 14. Animal Food Categories That Are Included in the Exemption for On-Farm Low-Risk Packing and Holding Activities, Revised for Clarification as a Result in the Change of “Farm” Definition**

Section	Animal Food for Which On-Farm Packing and Holding Activity is Included in the Exemption
507.5(e)(1)	Roughage products (e.g., alfalfa meal, entire plant meal, stem meal, pomace, and pulp)
507.5(e)(2)	Plant protein meals (e.g., algae, coconut (copra), guar, and peanut l)
507.5(e)(3)	Grain by-products and processed grain products (e.g., bran, flour, germ meal, grits, groats, hominy feed, malt sprouts, middlings, pearled grain, polished grain, brewers grain, distillers grain, and gluten meal)
507.5(e)(4)	Oilseed products (e.g., oil and meal of safflower, soybean, or sunflower)
507.5(e)(5)	Molasses (e.g., processed sugar cane, sugar beets, and citrus)
507.5(e)(6)	Animal protein meals (e.g., blood, feather, meat, meat and bone, and marine (e.g., crab, fish, shrimp)
507.5(e)(7)	Milk products (e.g., casein, cheese rind, and lactalbumin)
507.5(e)(8)	Animal tissue-derived products (e.g., fat)
507.5(e)(9)	Vitamins, minerals, and concentrates
507.5(e)(10)	Processing aids (e.g., enzymes, preservatives, and stabilizers)
507.5(e)(11)	Any other processed animal food that does not require time/temperature control for safety

Table 15 lists the animal food category excluded from the list of low-risk packing and holding activities because the activity/animal food combinations associated with animal food in that category fall within the revised definition of “farm”.

**Table 15. Animal Food Categories That Are Not Included in the Exemption for On-Farm Low-Risk Packing and Holding Activities in the Final RA That Were Included in the Draft RA**

<b>Animal Food for Which Packing and Holding was included as Low-risk in the Draft Rule</b>	<b>Why the Animal Food is Not Listed in the Exemption in the Final Rule</b>
RACs, (e.g., grain and oilseed)	Packing/holding of RACS is within the “farm” definition regardless of whether the RACs were grown on the farm where they are held or a farm under different ownership

## APPENDIX 6: MANUFACTURING/PROCESSING ACTIVITIES

Table 16 lists the manufacturing/processing activity and animal food combinations that are considered low-risk in this risk assessment that were not listed as low-risk in the draft RA. These changes were motivated by the change in the definition of “farm” that occurred subsequent to the completion of the draft RA.

**Table 16. Activity/Animal Food Combinations Included in the Exemption for On-Farm Low-Risk Manufacturing/Processing Activities That Are New in the Final RA**

<b>Section</b>	<b>On-Farm Manufacturing/Processing Activity Included in the Exemption</b>	<b>Reason for the Change to the Final RA</b>
507.5(f)(6)	Labeling roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety	Labeling of RACs was deleted because it is within the revised “farm” definition. When labeling of RACs was deleted, we evaluated other labeling scenarios and concluded that if a farm-mixed-type facility re-packages and labels animal food which they have purchased, the labeling activity would not be within the revised “farm” definition and would need to be evaluated in the RA.

<b>Section</b>	<b>On-Farm Manufacturing/Processing Activity Included in the Exemption</b>	<b>Reason for the Change to the Final RA</b>
507.5(f)(7)	Packaging roughage products, plant protein meals, grain by-products and processed grain products, oilseed products, molasses, animal protein meals, milk products, animal tissue-derived products, vitamins, minerals, concentrates, processing aids, finished animal food, including animal food ready for consumption, or any other processed animal food that does not require time/temperature control for safety	Packing, rather than packaging, of RACs was included in the draft RA. When the “farm” definition was revised to include “packaging and labeling or RACs without further manufacturing/processing”, we evaluated scenarios for packaging of non-RACS and concluded that if a farm-mixed-type facility re-packages and labels animal food which they have purchased, the packaging activity would not be within the revised “farm” definition and would need to be evaluated in the RA.

Table 17 lists the manufacturing/processing activity and animal food combinations that are not included in the list of low-risk on-farm manufacturing/processing activity and animal food combinations in this risk assessment and the reason that they are not included

**Table 17. Activity/Animal Food Combinations That Are Not Included in the Exemption for On-Farm Low-Risk Manufacturing/Processing Activities**

<b>Activity/Animal Food Combination</b>	<b>Why the Activity/Animal Food Combination is Not Listed in the Exemption</b>
Labeling grain and oilseed	This activity was included in the draft RA but has been removed because it is within the revised “farm” definition
Packing grain and oilseed	This activity was included in the draft RA but has been removed because it is within the revised “farm” definition
Activities such as rendering and calcining used to manufacture animal protein meals and animal tissue-derived products such as fat, hydrolyzed feathers, meat, fish, blood or bone meal	These activities were considered out of the scope of the draft RA and remain so in the final RA because the production of animal protein meals and animal tissue-derived products requires time/temperature controls making them not low risk.

<b>Activity/Animal Food Combination</b>	<b>Why the Activity/Animal Food Combination is Not Listed in the Exemption</b>
Activities such as churning used to make milk products	These activities were considered out of the scope of the draft RA and remain so in the final RA because the production of milk products requires time/temperature controls making them not low risk.
Activities used in the production of pet food, including pet treats	These activities were considered out of the scope of the draft RA and remain so in the final RA because the production of pet food requires time/temperature controls making them not low risk.
Making complete animal food (including processing activities such as mixing/extruding/pelleting and other activities such as sifting/separating/weighing/labeling/packaging	The RA determined that this is activity is not a low-risk activity.
Making mineral and vitamin mixes and concentrates for feeding to animals without further processing (including weighing/mixing/packaging/labeling)	The RA determined that this is activity is not a low-risk activity.