

# Scientific Literature Database Food for Animals

## *User Guide*

Version 1.2

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### **Disclaimer**

While this tool summarizes data from an extensive list of scientific literature and recalls related to hazards in ingredients and animal food, The University of Minnesota does not guarantee the completeness of this information.

Therefore, this tool should not be used as the only resource for identifying hazards or determining the probability and severity of those hazards in the absence of a preventive control. Animal food facilities should also consider up-to-date illness data, facility specific experience, and other relevant information when developing a Food Safety Plan for their operations.



This tool was developed by the University of Minnesota through funding provided by the National Grain and Feed Foundation and the Institute for Feed Education and Research. Please direct all questions and comments to one of the following contacts:

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**Note:** The Microsoft® Excel® workbook tool is compatible with Microsoft® Office® 2007 and higher.

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**I. Background:**

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA). Out of this act came the FDA’s final rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, which, when implemented, will require animal food facilities to conduct a hazard analysis in order to identify potential hazards entering their processes. The language from this regulation reads as follows:

21 CFR § 507.33 Hazard analysis.

(a)(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control...”

(c)(1) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

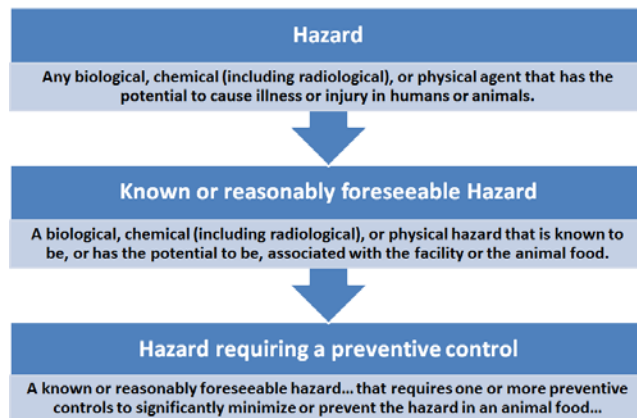
Animal food is defined in the regulation as “food for animals other than man and includes pet food, animal feed and raw materials and ingredients.”

**II. Intended use:**

This tool provides data obtained from a review of scientific literature and recall data that may be used to document the occurrence of hazards in animal food, as well as data describing the severity of hazards to sixteen animal species groups. Summary scores for the documented occurrence of hazards in animal food and severity in animal species groups and in humans are also provided. Note that the human severity scores are based on any direct exposure to the hazard (excluding via injection), not solely through ingestion of the edible food animal product.

The data and scores provided in this tool may serve as a starting point for a facility specific hazard analysis, which must also include other facility specific information, such as experience, illness data, and other information.

It is important to understand that this tool contains potential hazards as reported in literature and recalls, in the broad sense of the term. It is the responsibility of the animal food facility to identify known or reasonably foreseeable hazards and hazards requiring a preventive control that apply to their specific operation.



### **III. Methodology:**

#### **a. Scope/Inclusion criteria**

The following criteria were used to determine which scientific articles were included in the database for the Scientific Literature Database Tool:

- Articles written in English
- Articles published within the past 10 years
- Articles published in Canada or the United States
- Articles discussed both an animal food/ingredient AND a hazard/contaminant
- The types of articles that were included were: Case reports, recalls, sampling/screening studies, and systematic reviews
- The time of contamination occurred while under control of the manufacturer: at pre-manufacturing and during manufacturing (including packaging and transport from the plant)

#### **b. Resources:**

For documented occurrence, scientific literature databases (PubMed and CABI) were used to search for relevant scientific papers using the above criteria. In addition, the FDA recall website provided information on Class I recalls from 2009-2016, and FDA Enforcement Reports provided information on Class II and Class III recalls from 2012-2016. For the evaluation of severity, a combination of textbooks and websites outside of the original literature search were used. For animals and humans, health effects were determined for exposure to the hazard by inhalation, ingestion, or direct skin contact; exposure via injection was excluded. Limited information was available on human exposure via ingestion of the edible food animal product.

#### **c. Data management:**

Data retrieved from the above sources were entered into two master databases, one for information collected from the scientific literature, and the other for information collected from the FDA recalls. Both databases are included in this tool. See Sheet 7 for Literature data and Sheet 9 for Recall data. These variables are defined in Sheet 8 (Literature) and Sheet 10 (Recalls).

### **IV. Scoring System:**

A scoring system was developed to provide a numeric score for the documented evidence of the presence of the hazard in animal food and for the severity of the hazard to animals and humans. Both documented evidence and severity were evaluated separately using a different scoring matrix. Factors to assess the documented evidence and severity were identified and for each one different scores were assigned. In general terms, the higher the score the higher the evidence or severity of the hazard.

#### **a. Documented occurrence**

Table 1 provides a framework to rank the hazards based on the scientific evidence that those hazards will be present in animal food. The scenarios evaluated are solely based on the reported (in scientific literature or FDA recalls) natural occurrence of the hazards. The

intentional (artificial) inoculation of animal food with a specific hazard is out of the scope of the present document. The document assumes good manufacturing practices are followed by the feed industry.

A literature review was done to identify the evidence that a specific hazard has been found in an ingredient, feed or pet food product. The type of information accessed included scientific articles and FDA animal food recalls.

The documented occurrence score was calculated by summing up the scores that were obtained after answering the different factors outlined in Table 1. After all the scores were added, a normalized score (over 100%) was calculated.

Table 1: Documented occurrence

Evidence of occurrence	Numerical score	Definition
Documented evidence of hazard presence	NO=0 YES=10	No reports or scientific evidence could be found on the presence of the hazard in animal food.
Number of articles reporting the presence of the contaminant	One article=1 Two articles=2 Three articles=3 Four articles=4 Five articles=5 More than five articles=10	Articles reporting the presence of the hazard in animal food.
Documented evidence of multi-year occurrence	NO=0 YES=10	The article reports the presence of the hazard occurring more than one year.
FDA recalls involving the hazard	NO=0 YES=10	The hazard has been implicated in FDA animal food recalls.
Number of FDA recalls	1 - 5 recall=1 6-10 recalls=2 11-15 recalls=3 16-20 recalls=4 21 - 40 recalls=5 More than 40 recalls=10	The number of FDA recalls associated with either the potential presence OR the actual presence of a hazard in the animal food.
Documented evidence of multi-year occurrence for recalls	NO=0 YES=10	Hazard has been implicated in the animal food in FDA recalls in multiple years.

The normalized score was then converted to a qualitative term (see Table 2).

Table 2: Qualitative terms based on the normalized score

Qualitative term	Normalized score
Very low	<25%
Low	25-50%
Moderate	51-75%
High	>75%

In addition to the documented occurrence score, each hazard was evaluated based on the number of studies showing levels in an animal food outside the recommended level, as stated by the FDA, the Mineral Tolerance of Animals, or NRC's Nutrient Requirements. This factor was calculated as a percentage of articles showing unacceptable levels by dividing the number of occurrences of that hazard being outside the established levels by the total number of occurrences of the presence of that hazard (see Table 3).

Table 3: Documented occurrence outside of recommended level

Evidence of occurrence	Numerical Score	Definition
% occurrence of hazard outside recommended levels	(# of hazard occurrences that failed to meet the recommended levels / Total # of hazard occurrences) X 100	A hazard was found in an animal food matrix and did not meet the established levels set by the FDA, Mineral Tolerance of Animals, or NRC's Nutrient Requirements.

**b. Severity**

Tables 4 and 5 provide a framework to rank the hazards based on the severity of the health effects the hazard could pose to animals or humans. The severity scores for animals are calculated separately from those for humans, as per 21 CFR § 507.33 ("The hazard analysis must include an evaluation of the hazards... to assess the severity of the illness or injury to humans **or** animals if the hazard were to occur.").

The severity score for animals was calculated by summing up the scores that were obtained after answering the different severity factors outlined in Table 4. The severity score for humans was calculated by summing up the scores that were obtained after answering the different severity factors outlined in Table 5.

Table 4: Severity of hazard in animals\*

Severity level	Numerical score	Definition
Is there a health effect in this species? (YES/NO)	YES=5 NO=0	There is evidence that the hazard is able to affect animal health.
Is the hazard able to cause (subacute or acute) death in this species? (YES/NO)	YES=15 NO=0	There is evidence that the hazard is able to cause subacute or acute death in animals.

\*Exposure via ingestion, inhalation, and/or skin contact

Table 5: Severity of hazard in humans\*

Severity level	Numerical score	Definition
Is there an effect on human health? (YES/NO)	YES=5 NO=0	There is evidence that the hazard is able to affect human.
Is the hazard able to cause (subacute or acute) death in humans? (YES/NO)	YES=15 NO=0	There is evidence that the hazard is able to cause subacute or acute death in humans.

\*Exposure via ingestion, inhalation, and/or skin contact

The numerical scores for severity are then converted to a qualitative term (see Table 6).

Table 6: Qualitative terms based on the severity score

Qualitative term	Score	Meaning
Low	0	The hazard doesn't affect either animal or human health
Moderate	5	The hazard affects either animal health or human health but does not cause subacute or acute death
High	20	The hazard causes subacute or acute death in animals or humans



## V. Excel Workbook Sheet Descriptions

**Note:** The Microsoft® Excel® workbook tool is compatible with Microsoft® Office® 2007 and higher.

### a. Sheet 1. Introduction

This sheet provides a summary of the background, purpose, and scope of the Scientific Literature Database Tool. It also includes this important **CAUTION: The data and scores provided in this tool may serve as a starting point for a facility specific hazard analysis, which must also include other facility specific information, such as facility experience and other factors specified in the Preventive Controls rule.**

**Note:** This tool is based solely on documented reports of hazard presence in the scientific literature and FDA recalls. As a result, only ingredients, feeds or pet foods implicated in a *documented occurrence* of a hazard are listed in this tool.

### b. Sheet 2. How to Use

This sheet outlines the steps for using the Scientific Literature Database Tool in Sheet 3. Detailed steps, including pictures, are provided in the Sheet 3 description below.

### c. Sheet 3. Scientific Literature Database Tool

Based on the user's selection of an ingredient, feed or pet food and a species category, this spreadsheet is populated with a list of the hazards that have documented occurrences in our scientific literature database and/or FDA recalls for the selected animal food. In addition, a Qualitative Documented Occurrence score for each hazard, and a Qualitative Severity Score for each hazard in the selected species category and in humans is displayed. Based on the FSMA regulations in 21 CFR§ 507.33, the **user must also** input *facility-specific* experience, illness data, and other information in order to obtain a Cumulative Probability of Occurrence Score and a Cumulative Severity Score for the selected ingredient, feed or pet food and the selected species category.

The user steps are detailed in the tool on Sheet 2 and are as follows:

1. On the Scientific Literature Database Tool (Sheet 3) the user may select an ingredient, feed or pet food (Cell A7) and an animal species group (Cell E7) from drop down lists. First click in one of the yellow cells to produce the drop down menu, then select the animal food and the species category in each of the respective drop down menus. In the image below, *Corn, whole* has been selected as the animal food, and *Pig* is highlighted as the choice in the drop down menu for species category. **These two yellow cells are the only inputs to be manipulated by the user.**

	A	B	C	D	E	F	G
4	<b>Animal Food</b> Selection of the animal food will populate the table below with a list of hazards reported in that animal food as reported in scientific literature. This is <b>independent of species</b> , except for finished feeds. For additional information on how the qualitative score is calculated, see Sheet 4 (Documented Occurrence Scores).				<b>Species Category</b> Selection of the species category will populate the table below with a score that reflects the severity of a hazard were the selected species to come into contact with that hazard, <b>independent of the animal food selected</b> . For additional information on how the qualitative score is calculated, see Sheet 6 (Severity Scores).		
5							
6							
7	<b>Corn, whole</b>						
8	Documented Occurrence of Hazards in Scientific Lit / Recall Data				Carnivore - captive nondomestic Equid/hindgut ferment Ferret Horse Pet <b>Pig</b> Poultry Reptile		
9	<u>Hazard</u>	<u>Type of Hazard</u>	<u>Qualitative Score</u>		<u>Qualitative Score (Humans)</u>	<u>Qualitative Score (Animals)</u>	
10					(Severity scores marked as N/A indicate hazards for which the documented occurrence was insufficiently specific to determine severity)		

2. \* Upon selecting an ingredient, feed or pet food and species group, a list of hazards that have been documented for the selected ingredient, feed or pet food will populate Column A (starting in Row 11), type of hazard will populate Column B, qualitative scores for documented occurrence will populate Column C, and qualitative scores for severity will populate Columns E and F. The score in Column F is for the selected species category, and is independent of the animal food selected in Cell A7.

<b>Scientific Literature Database Tool</b>						
Click on yellow boxes to select an animal food and/or species category from the drop down menus						
<b>Animal Food</b> Selection of the animal food will populate the table below with a list of hazards reported in that animal food as reported in scientific literature. This is <b>independent of species</b> , except for finished feeds. For additional information on how the qualitative score is calculated, see Sheet 4 (Documented Occurrence Scores).				<b>Species Category</b> Selection of the species category will populate the table below with a score that reflects the severity of a hazard were the selected species to come into contact with that hazard, <b>independent of the animal food selected</b> . For additional information on how the qualitative score is calculated, see Sheet 6 (Severity Scores).		
<b>Corn, whole</b>				<b>Pig</b>		
Documented Occurrence of Hazards in Scientific Lit / Recall Data				Calculated Severity Score for Selected Species Category		
<u>Hazard</u>	<u>Type of Hazard</u>	<u>Qualitative Score</u>		<u>Qualitative Score (Humans)</u>	<u>Qualitative Score (Animals)</u>	
				(Severity scores marked as N/A indicate hazards for which the documented occurrence was insufficiently specific to determine severity)		
Aflatoxin (NS)	Chemical	VERY LOW		HIGH	HIGH	
Deoxynivalenol	Chemical	LOW		MODERATE	HIGH	
E. coli (generic)	Biological	VERY LOW		#N/A	#N/A	
Enterococcus spp.	Biological	VERY LOW		HIGH	HIGH	
Fumonisin	Chemical	LOW		MODERATE	HIGH	
Zearalenone	Chemical	LOW		MODERATE	MODERATE	

\*The formulas for calculating the scores may be found on Sheets 4 and 6, and the data that were used to calculate the scores can be found on Sheets 7, 9, and 11.

3. \*\* Some species are affected more severely than other species in their assigned category. Please refer to Sheet 6 (Severity Scores), illustrated below, for these exceptions. The species is documented in Column H, and the hazard in Column A is highlighted in red. In this example, *Pet* was selected on Sheet 3 as the species category.

Narasin	YES	YES	YES	NO	20	HIGH		5 MODERATE
Nickel	YES	YES	YES	NO	20	HIGH		5 MODERATE
Nitrate/nitrite	YES	NO	YES	YES	5	MODERATE		20 HIGH
Novel mammalian orthoreovirus 3 (MRV3)	UNK	UNK	YES	NO	0	LOW		5 MODERATE
Ochratoxin	YES	NO	YES	NO	5	MODERATE	Dog	5 MODERATE
Perchlorate	YES	NO	YES	NO	5	MODERATE		5 MODERATE
Phosphorus (Deficiency)	YES	NO	YES	NO	5	MODERATE		5 MODERATE
Phosphorus (Excess)	YES	YES	YES	NO	20	HIGH		5 MODERATE
Plastic (physical)	YES	YES	YES	YES	20	HIGH		20 HIGH
Polychlorinated biphenyls (PCBs)	YES	UNK	YES	NO	5	MODERATE		5 MODERATE
Porcine epidemic diarrhea virus	NO	NO	NO	NO	0	LOW		0 LOW
Propylene glycol	YES	NO	YES	NO	5	MODERATE	Cat	5 MODERATE
Rubidium	YES	UNK	YES	NO	5	MODERATE		5 MODERATE
Salinomycin	YES	YES	YES	NO	20	HIGH		5 MODERATE
Salmonella abortus equi	UNK	UNK	YES	YES	0	LOW		20 HIGH

\*\*Please refer to Sheet 6 (Severity Scores) for important information on interpretation. In the severity score formula, "Unknown" was assigned if no information was found on health effect for a species category. **"Unknown" was given the same score (Zero) as "No"** for these categories. It is, therefore, recommended that facilities making animal food for these species consider additional information when determining severity.

4. The results from each Scientific Literature Database Tool search in Sheet 3 will print on one page. It is recommended that the facility print a Scientific Literature Database Tool sheet for each animal food/species group at this time, or transfer the information to a separate worksheet.
5. The user may refer to their own worksheet for adding in facility-specific experience, illness data, and other information required by the FDA to complete the hazard analysis.

d. Sheet 4. Documented Occurrence Scores

Based on the animal food selection in Sheet 3, this spreadsheet displays information on hazards for which there was documented occurrence(s) *in that ingredient, feed or pet food* in the scientific literature and/or FDA recalls. Please see Sheet 5, Documented Occurrences Scores - Definitions, for how the scores were calculated.

e. Sheet 5. Documented Occurrence Scores - Definitions

This sheet describes how the answer was determined for each question or variable column in Sheet 3, Documented Occurrence Scores. The Sheet and Column in which each term is used is in parentheses following the term.

f. Sheet 6. Severity Scores

Based on the species class selection in Sheet 3, this spreadsheet displays *for that species category* the severity information for all of the hazards identified in our scientific literature database and recalls. The Raw Severity Score for the selected species category displayed in Column F is determined by the answers in Columns B and C. The Qualitative Severity Score in Column G is determined by the Raw Severity Score, as described previously in this document

under Scoring System. Any species that is more severely affected by the hazard than the other species in the same category is listed in Column H, and the hazard of concern is highlighted in red in Column A, as illustrated in the above screenshot (Pet species category was selected for this example). It is recommended that the user conduct further research to determine the level of severity in that listed species.

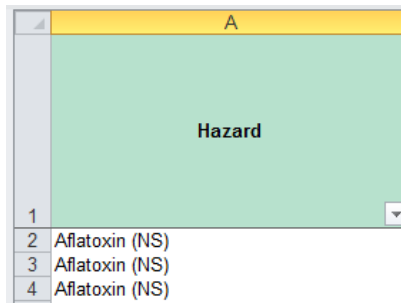
The Raw Severity Score for humans displayed in Column I is determined by the answers in Columns D and E. The Qualitative Severity Score in Column J is determined by the Raw Severity Score, as described previously in this document under Scoring System.

g. Sheet 7. Documented Occurrence (Literature)

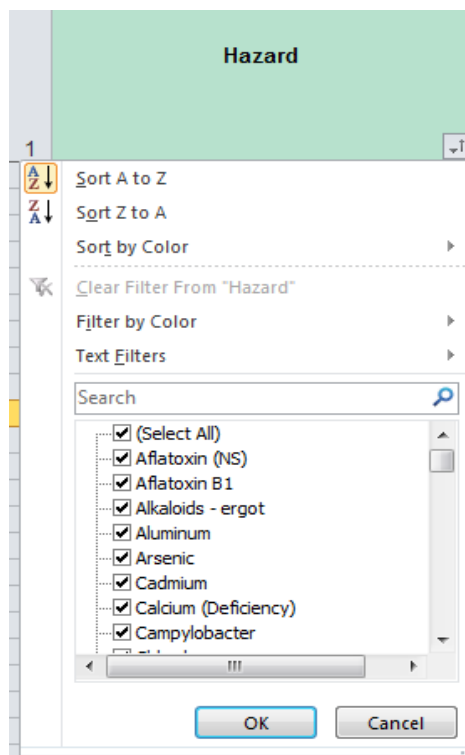
This spreadsheet contains the raw data collected from the scientific literature for the past 10 years. This spreadsheet may be filtered by hazard, species, and/or animal food matrix. Filtering is accessed via the small down arrow in the lower right corner of each column heading:

	A	B	C	D	E	F	G
	Hazard	Type of Hazard	Species Affected	Food animal production system	Type of product (Literature Term)	Type of product (Standardized Term)	Document evidence hazard present (YES/NI)
1							
2	Aflatoxin (NS)	Chemical	NS	NA	Corn ears (non-Bt)	Corn ears	YES
3	Aflatoxin (NS)	Chemical	NS	NA	Corn ears (Bt)	Corn ears	YES
4	Aflatoxin (NS)	Chemical	NS	NA	Corn	Corn	YES
5	Aflatoxin (NS)	Chemical	Cattle	Dairy	Whole corn	Corn	YES

Click on the small down arrow in the chosen column heading to display the filtering (Select) options:



Uncheck the box next to (Select All) to clear the selections, then click on the appropriate box(es) for the choice(s) you wish to select:



#### Sheet 8. Documented Occurrence (Literature) - Definitions

This sheet provides detailed definitions for the column headings used in the Documented Occurrence (Literature) database contained in Sheet 7. The Sheet and Column in which each term is used is in parentheses following the term.

#### h. Sheet 9. Documented Occurrence (Recall)

This spreadsheet contains the raw data collected on Class I, II, and III recalls from the FDA recall website (2009 to 2016), as well as from the FDA Enforcement Reports (2012 to 2016). This spreadsheet may be sorted by hazard, species, and/or animal food matrix in the same manner outlined for Sheet 7.

#### i. Sheet 10. Documented Occurrence (Recall) - Definitions

This sheet provides detailed definitions for the column headings used in the Documented Occurrence (Recall) database contained in Sheet 9. The Sheet and Column in which each term is used is in parentheses following the term.

#### j. Sheet 11. Severity

This spreadsheet contains the data collected on the severity of all hazards *that were documented* in our scientific literature database and the FDA recalls, for all 16 species

categories, when available, as well as for humans. Since most of the scientific papers did not discuss severity, these data were obtained from a combination of textbooks and websites outside of the scientific literature search, as listed in each row in Column G for animals and Column J for humans.

Filtering is accessed via the small down arrow in the lower right corner of each column heading and performed in the same manner as outlined for Sheet 7.

	A	B	C	D	E	F	G	H	I	J	K
1	Hazard	Species categ	Species	Are all species in the category affected the same or are there differences? 0 / 1	Species category health effect (YES/NO/UNK)	Acute or subacute death in species category (YES/NO/UN)	Reference for E&F	Human health effect (YES/N)	Acute or subacute death in humans (YES/NO)	Reference for H&I	Comr
2	Aflatoxin (NS)	Amphibian		0	YES	YES	The Toxicology	YES	YES	<a href="http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm">http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm</a>	
3	Aflatoxin (NS)	Aquatic - non-		0	YES	YES	<a href="http://fisheries">http://fisheries</a>	YES	YES	<a href="http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm">http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm</a>	
4	Aflatoxin (NS)	Avian		0	YES	YES	Mitchell & Tully	YES	YES	<a href="http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm">http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm</a>	
5	Aflatoxin (NS)	Camelid		0	YES	YES	Medicine & Su	YES	YES	<a href="http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm">http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/ucm071020.htm</a>	

k. Sheet 12. Severity Definitions

This sheet provides detailed definitions for the column headings used in the Severity Scores worksheet in Sheet 6 and the Severity database contained in Sheet 11. The Sheet and Column in which each term is used is in parentheses following the term.

l. Sheet 13. Update log

Any updates to the Scientific Literature Database workbook may be recorded on this sheet.

m. Sheet 14. Species Categories

This sheet lists the categories into which animal species were divided in order to provide a manageable number of categories for the purpose of determining hazard severity. As feasible, species were grouped based on physiology and digestive anatomy. Please note that some of the species listed reflect species referenced in the scientific literature and recalls.

n. Sheet 15. Animal food and ingredients

AAFCO standardized terms were assigned to standardize language for this tool. If AAFCO did not provide a term then the term from the literature/recall was used. Pet food was described by the consistency of the product (dry, canned, semi-moist, raw) and is identified by the species for which it was intended. For example: Pet food, dry (dog). Animal feed was described by the species for which it was intended and, if provided, the food animal production system. For example: Feed, cattle (dairy). Pet treats were described by the type of protein they are made of and identified by the species for which they were intended, if provided. For example: Pet treat, beef protein (dog). Supplements were described by the type of supplement, if provided, and the species for which they were intended. For example: Supplement, taurine (cat).

p. Sheet 16. Combined Lit & Recall Lists

This sheet displays the lists that were created from the scientific literature and recall databases to feed into the scoring formulas. It is shown strictly for the user's interest.

q. Sheet 17. Animal Food & Species Lists

The lists on this sheet were created strictly for the drop-down lists on Sheet 3, and are provided solely for the user's interest.

## **VI. Cautions**

- The use of this tool does not ensure compliance with FSMA.
  - o This tool is a starting point for the hazard analysis and is dependent on further facility-specific input, as described above, to meet FDA's requirements.
- Imported ingredients were outside the scope of this study.
  - o However, some of the ingredients addressed in the scientific literature database may have been imported, but not explicitly stated as such; thus, this study does not differentiate the occurrence of hazards in domestic versus imported ingredients.
- For the evaluation of the severity of a hazard, we considered exposure to the hazard via ingestion, skin contact, and inhalation, but not via experimental injection.
  - o Consistent data were lacking for severity of human exposure via ingestion of a contaminated food animal product, so other forms of exposure were included for severity for all hazards, for the sake of consistency.