

**Title: CVM Annual Report on Mycotoxins in Animal Food
Report for Fiscal Year 2016 (FY16)**

Analyses Completed from October 1, 2015 through September 30, 2016

Food and Drug Administration

Center for Veterinary Medicine

Division of Animal Feeds

I. Introduction

This report summarizes the mycotoxin analyses performed by the FDA laboratories for domestic surveillance and import samples of animal food and animal food ingredients in fiscal year 2016 (FY16). The samples were collected under the Feed Contaminants Compliance Program (71003C). These results are for samples analyzed in FY16, which started October 1, 2015, and ended September 30, 2016. The information was obtained from FDA's Field Accomplishment and Compliance Tracking System (FACTS) database. The mycotoxins included in this report are aflatoxins, fumonisins, deoxynivalenol (DON, vomitoxin), zearalenone, and ochratoxin A. The analyses are either a multi-mycotoxin residue screen or a more specific quantitative method. If a sample was analyzed using unofficial and official methods, only the results of the official method will be considered in this report. A sample can be analyzed for up to five mycotoxins.

For this report, when the specific types and classes of animals to be fed are unknown, the lowest recommended guidance level for a particular mycotoxin is used in determining if a sample "exceeded guidance." A positive result is one that is above the limit of detection (LOD) of the official method at the FDA laboratory. A negative result indicates that the mycotoxin was not present or present at a level below the LOD for the method. For the purpose of determining the median mycotoxin levels, the negative results were not used.

II. Guidance levels for mycotoxins

A. Aflatoxins:

FDA's recommended Action levels for aflatoxins in animal feeds and feed ingredients can be found in Compliance Policy Guide 683.100 (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed>). These levels apply to total aflatoxins; thus, combined values for individual aflatoxins (B₁, B₂, G₁, G₂) are used in this report. The action levels for aflatoxins in feed ingredients are listed in [Table A](#).

Table A. Action levels for total aflatoxins in livestock feed.

Class of Animal	Feed	Aflatoxins Action Level
Finishing beef cattle	Corn and peanut products	300 ppb
Beef cattle, swine or poultry	Cottonseed meal	300 ppb
Finishing swine over 100 lb.	Corn and peanut products	200 ppb
Breeding cattle, breeding swine and mature poultry	Corn and peanut products	100 ppb
Immature animals	Animal feeds and ingredients, excluding cottonseed meal	20 ppb
Dairy animals, animals not listed above or unknown use	Animal feeds and ingredients	20 ppb

B. Fumonisin:

Fumonisin B₁ causes equine leukoencephalomalacia in horses and pulmonary edema in pigs. Corn screenings can contain especially high levels of fumonisins. The FDA's final guidance document regarding fumonisin levels for corn and corn by-products in animal food is available at the agency's website (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fumonisin-levels-human-foods-and-animal-feeds>). The guidance levels for fumonisins in corn and corn by-products are listed in [Table B](#).

Table B. Guidance levels for **fumonisins (B₁+B₂+B₃)** in corn and corn by-products.

Class of Animal	Portion of Diet	Fumonisin Guidance Levels
Equids and Rabbits	Corn and corn by-products not to exceed 20% of the diet	5 ppm
Swine and Catfish	Corn and corn by-products not to exceed 50% of the diet	20 ppm
Breeding Ruminants, Breeding Poultry and Breeding Mink*	Corn and corn by-products not to exceed 50% of the diet	30 ppm
Ruminants ≥3 Months Old being Raised for Slaughter and Mink being Raised for Pelt Production	Corn and corn by-products not to exceed 50% of the diet	60 ppm
Poultry being Raised for Slaughter	Corn and corn by-products not to exceed 50% of the diet	100 ppm
All Other Species or Classes of Livestock and Pet Animals	Corn and corn by-products not to exceed 50% of the diet	10 ppm

Notes

- i. Breeding Ruminants, Breeding Poultry and Breeding Mink includes lactating dairy cattle and hens laying eggs for human consumption.
- ii. These guidance levels are on dry weight basis.

C. Vomitoxin:

The FDA's guidance document regarding advisory levels for Deoxynivalenol (DON) levels for grains and grain by-products used for animal food is available at the agency's website (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-advisory-levels-deoxynivalenol-don-finished-wheat-products-human>). The guidance levels for DON in feed ingredients & portion of ration are listed in [Table C](#).

Table C. Advisory levels for **vomitoxin** (DON) in animal feeds.

Class of Animal	Feed Ingredients & Portion of Ration	DON Levels in Feed Ingredients	DON Levels in Total Ration
Ruminating beef and feedlot cattle older than 4 months	Grain and grain by-products	10 ppm	10 ppm
Ruminating beef and feedlot cattle older than 4 months	Distillers grains, brewers grains, gluten meals, and gluten feeds derived from grains not to exceed 33% of total ration	30 ppm	10 ppm
Ruminating dairy cattle older than 4 months	Grain and grain by-products not to exceed 50% of the total ration	10 ppm	5 ppm
Ruminating dairy cattle older than 4 months	Distillers grains, brewers grains, gluten meals, and gluten feeds derived from grains not to exceed 17% of total ration	30 ppm	5 ppm
Chickens	Grain and grain by-products not to exceed 50% of the total ration	10 ppm	5 ppm
Swine	Grain and grain by-products not to exceed 20% of the total ration	5 ppm	1 ppm
All other animals	Grain and grain by-products not to exceed 40% of the total ration	5 ppm	2 ppm

These guidance levels are established on an 88% dry matter basis

D. Ochratoxin A and Zearalenone:

FDA has not established guidance levels for ochratoxin A or zearalenone. Therefore, any sample positive for either of these mycotoxins will be marked "No Official Guidance" (NOG) in the column titled "Above Guidance" in the tables. Feed and feed ingredient samples that are found positive for ochratoxin A and/or zearalenone are referred to the Center for Veterinary Medicine to determine if regulatory actions are required.

III. Summary of Results

In FY16, 89 of 302 samples were positive for one or more mycotoxins. Of the 89 samples that were positive for mycotoxins, 10 samples contained two classes of mycotoxins ([Table D](#)). These analytical results show that 30% (80 of 265) of samples from the [domestic animal food commodities](#) and 24% (9 of 37) of samples from [imported animal foods](#) contain detectable levels of aflatoxins, fumonisins, deoxynivalenol, and zearalenone ([Table E](#)).

- [Aflatoxins](#) were analyzed for in 241 samples and 16.18% contain detectable levels.
- [Fumonisins](#) were analyzed for in 53 samples (46 corn and 7 complete feed) and 64.2% (34) of the samples contain detectable levels. 70% of all corn samples contain detectable levels.
- [Vomitoxin](#) was analyzed for in 45 samples (18 wheat products, 12 complete feeds, 9 oats, 3 barleys, 2 soybeans, and 1 rye), and 51.1% (23) of the samples contain detectable levels.
- [Zearalenone](#) were analyzed for in 29 samples (8 poultry layer feeds, 7 soybean meals, 3 poultry broiler feeds, 3 soybeans and 1 of each corn, beef cattle, cattle feed, cattle supplement, oats, rice bran, wheat, and wheat middling)) and 10.3% (3) samples contain detectable levels.
- No detectable levels of [ochratoxin A](#) were found in the 6 samples analyzed.

Of the 80 positive samples collected from animal foods of domestic origin, nine (9) contained mycotoxin residues that exceeded established guidance levels or contained mycotoxin residues for which there are no official guidance levels ([Table E](#)). No sample collected for imported animal foods contained mycotoxin residues that exceeded established guidance levels or mycotoxin residues for which there are no official guidance levels. The 6 samples of animal foods that contained mycotoxins at levels above the FDA established guidance levels are:

- 3 samples of swine feed manufactured in Michigan, Oklahoma, and Utah contained 1.33, 1.45, and 1.74 ppm of vomitoxin, respectively. These samples exceed the guidance level of 1 ppm [vomitoxin](#) in complete swine feed.
- 2 samples of corn produced in Kansas and Texas contained 23.3 and 33.5 ppb of [aflatoxins](#), respectively ([Table F](#)). These corn lots were not classified as food for a particular species and class of animal. These samples exceed the most sensitive species guidance level of 20 ppb aflatoxins in animal food ingredients intended for dairy animals, for animal species or uses not specified, or when the intended use is not known.
- One sample of corn produced in Arkansas contained 9.0 ppm of [fumonisins](#). The corn was not classified as food for a particular species and class of animal. This sample exceeds the most sensitive species guidance level of 5 ppm for equids and rabbits (or if the target species is unknown) in corn and corn by-products not to exceed 20% of the diet.

Three samples of animal foods contained mycotoxins for which there are no official guidance levels are:

- Two samples identified as poultry feed for layers produced in South Carolina and Missouri contained 54.3 and 179.6 ppb of [zearalenone](#), respectively.
- One sample identified as wheat from Missouri contained 512 ppb of [zearalenone](#).

IV. Summary Tables:

Tables [D](#), [E](#), and [F](#) summarize the mycotoxin results for feed samples analyzed in FY16 and entered in the FACTS database. Because some samples contain more than one mycotoxin, the number of positive results may exceed the number of samples collected.

Table D. Total of number samples analyzed, the number of positive samples, and the number of samples exceeding guidance and the states or country origin of all commodities analyzed during FY16

Class of Samples	Number samples	Origin of Samples (States or Countries of origin)
Total Domestic samples	265	AL, AR, AZ, CA, CO, GA, IL, IA, KY, KS, LA, MA, MD, MI, MN, MO, MS, NC, ND, NE, OH, OK, OR, PA, PR, SC, SD, TN, TX, UT, VT, WA, and WI
Total Import samples	37	Brazil, Canada, China, Columbia, Finland, India, Romania, and Turkey
Total Samples	302	N/A
Domestic positive samples	80	AL, AZ, CA, CO, GA, KS, KY, LA, MD, MI, MO, MS, NC, ND, NE, OH, OK, PA, PR, SC, SD, TN, TX, UT, WA, and WI
Imports positive samples	9	Turkey Canada, Columbia, Finland, India, and Turkey
Total positive samples	89	N/A
Domestic Samples exceeding recommended guidance	9	KS, MI, MO, OK, SC, TX, and UT
Imports Samples exceeding recommended guidance	0	N/A

N/A = not applicable

Table E. For each mycotoxin, the number of samples analyzed, the number positive, range, median, and the number exceeding recommended guidance levels during FY16.

Mycotoxins	Number of Samples Analyzed	Number of Positive Samples	Mycotoxin Ranges In Samples	Mycotoxin Medians of positive samples	Number of Samples Above Guidance	Origin of Samples Above Guidance
Aflatoxins (ppb)	242	39	0.4 – 33.5	1.64	2	KS, TX, 1 each
Fumonisin s (ppm)	53	34	0.1 – 9.0	0.8	1	KS
Vomitoxin (ppm)	45	23	0.1 – 3.7	0.9	3	MI, OK, UT, 1 each
Zearalenone (ppb)	29	3	54 - 512	179	3 (NOG)	MO = 2, SC = 1
Ochratoxin A (ppb)	6	0	N/A	N/A	0	N/A
Total	375	99	N/A	N/A	9	N/A

Notes:

74 samples were analyzed for 2 mycotoxins

10 samples were positive for 2 mycotoxins

NOG = “No official guidance” levels established.

N/A = not applicable

Table F. Commodities and number of samples analyzed during FY16, number of positive samples for each mycotoxin analyzed, number of mycotoxin analyses exceeding guidance levels, and the range and median values for each mycotoxin.

Feed Commodities and Feeds	Number of Samples	Mycotoxins	Number of Analyses	Number. of Positive Analyses	Number of Samples Above Guidance	Mycotoxin Ranges in positive samples	Mycotoxin Medians of positive samples
alfalfa	3	aflatoxins	3	0	0	0	0
almond hulls	1	aflatoxins	1	0	0	0	0
animal feed, multispecies	8	aflatoxins	4	1	0	1.70 ppb	0
animal feed, multispecies	N/A	fumonisins	2	1	0	0.9 ppm	0
animal feed, multispecies	N/A	vomitoxin	1	1	0	0.29 ppm	0
animal feed, multispecies	N/A	ochratoxin A	1	0	0	0	0
animal feed, deer and elk	1	fumonisin	1	0	0	0	0
animal feed, sheep	1	aflatoxins	1	0	0	0	0
barley	4	aflatoxins	1	0	0	0	0
barley	N/A	vomitoxin	2	0	0	0	0
barley	N/A	ochratoxin A	1	0	0	0	0
barley hull	1	aflatoxins	1	1	0	1.70 ppb	0
barley malt pellets	1	vomitoxin	1	0	0	0	0
beet pulp pellets	1	aflatoxins	1	0	0	0	0
canola meal	3	aflatoxins	3	0		0	0
cattle feed	2	aflatoxins	2	0	0	0	0
cattle feed		zearalenone	1	0	0	0	0
cattle feed, beef	6	aflatoxins	6	2	0	1.23 - 1.86 ppb	0
cattle feed, beef	N/A	zearalenone	1	0	0	0	0

Feed Commodities and Feeds	Number of Samples	Mycotoxins	Number of Analyses	Number of Positive Analyses	Number of Samples Above Guidance	Mycotoxin Ranges in positive samples	Mycotoxin Medians of positive samples
cattle feed, calves	3	aflatoxins	3	1	0	1.86 ppb	0
cattle feed, dairy	13	aflatoxins	12	2	0	1.23 - 2.09 ppb	0
cattle feed, dairy	N/A	fumonisin	2	0	0	0	0
cattle feed, dairy	N/A	vomitoxin	1	0	0	0	0
cattle supplements	6	aflatoxins	6	3	0	1.20 - 2.30 ppb	1.90 ppb
cattle supplements	N/A	zearalenone	1	0	0	0	0
corn	113	aflatoxins	106	15	2	1.0 - 33.5 ppb	2.23 ppb
corn	N/A	fumonisin	46	32	1	0.1 - 9.0 ppm	0.7 ppm
corn	N/A	zearalenone	1	0	0	0	0
corn gluten	3	aflatoxins	3	0	0	0	0
cottonseed	3	aflatoxins	3	0	0	0	0
cottonseed hull	1	aflatoxins	1	0	0	0	0
cottonseed meal	1	aflatoxins	1	1	0	1.64 ppb	0
DDG	5	aflatoxins	5	1	0	2.74 ppb	0
flaxseed	1	aflatoxins	1	0	0	0	0
horse feed	3	aflatoxins	2	0	0	0	0
horse feed	N/A	fumonisins:	1	0	0	0	0
oats	11	aflatoxins	1	0	0	0	0
oats	N/A	vomitoxin	9	5	0	0.11 - 2.13 ppm	0.99 ppm
oats	N/A	zearalenone	1	0	0	0	0
oats		ochratoxin A	1	0	0	0	0
pet treats, dogs	1	ochratoxin A	1	0	0	0	0
pet food, dogs	4	aflatoxins	3	0	0	0	0

Feed Commodities and Feeds	Number of Samples	Mycotoxins	Number of Analyses	Number of Positive Analyses	Number of Samples Above Guidance	Mycotoxin Ranges in positive samples	Mycotoxin Medians of positive samples
pet food, dogs	N/A	vomitoxin	3	3	0	0.15 - 0.44 ppm	0.19 ppm
poultry feed (nonspecific)	1	aflatoxins	1	0	0	0	0
poultry ration, broilers	5	aflatoxins	5	2	0	1.1 - 1.26 ppb	0
poultry ration, broilers	N/A	zearalenone	3	0	0	0	0
poultry ration, layers	19	aflatoxins	19	3	0	0.7 - 6.94 ppb	3.4 ppb
poultry ration, layers	N/A	fumonisin	1	1	0	1.0 ppm	0
poultry ration, layers	N/A	vomitoxin	1	1	0	1.98 ppm	0
poultry ration, layers	N/A	zearalenone	8	2	2 (NOG)	54.2 - 179.6 ppb	0
rice	1	aflatoxins	1	0	0	0	0
rice bran	2	aflatoxins	2	0	0	0	0
rice bran	N/A	zearalenone	1	0	0	0	0
rye	1	vomitoxin	1	1	0	0.18 ppm	0
sorghums	4	aflatoxins	3	1	0	1.0 ppb	0
sorghums	N/A	ochratoxin A	1	0	0	0	0
soybean hulls	2	aflatoxins	2	0	0	0	0
soybean meal	16	aflatoxins	16	4	0	1.38 - 1.63 ppb	1.6 ppb
soybean meal	N/A	zearalenone	7	0	0	0	0
soybean	23	aflatoxins	19	1	0	1.20 ppb	0
soybean	N/A	vomitoxin	2	0	0	0	0
soybean	N/A	zearalenone	3	0	0	0	0
soybean	N/A	ochratoxin A	1	0	0	0	0

Feed Commodities and Feeds	Number of Samples	Mycotoxins	Number of Analyses	Number. of Positive Analyses	Number of Samples Above Guidance	Mycotoxin Ranges in positive samples	Mycotoxin Medians of positive samples
sunflower seed meal	1	aflatoxins	1	0	0	0	0
swine ration	7	aflatoxins	1	0	0	0	0
swine ration	N/A	vomitoxin	6	3	3	1.3 - 1.7 ppm	1.4 ppm
wet distiller grains	2	aflatoxins	2	1	0	1.0 ppb	0
wheat	12	vomitoxin	12	3	0	0.2 - 1.6 ppm	0.4 ppm
wheat	N/A	zearalenone	1	1	1 (NOG)	512 ppb	0
wheat bran	1	vomitoxin	1	1	0	3.69 ppm	0
wheat middling	4	vomitoxin	4	4	0	0.6 - 3.9 ppm	0.88 ppm
wheat middling	N/A	zearalenone	1	0	0	0	0
wheat shorts	1	vomitoxin	1	1	0	2.3 ppm	0
Total	302		375	99	9	0	0

Notes:

There are 375 mycotoxin analyses on 302 total samples identified in this report.

The numbers in the "Positive" column indicate the number of positive analyses for that commodity.

There were 89 samples positive and eight of the samples were positive for 2 mycotoxins.

No. of Samples = The number of samples of the commodity analyzed for mycotoxins

Median values were calculated using only positive results for specified mycotoxins (Median is the value lying at the midpoint of a frequency distribution of observed values).

ppb = parts per billion; ppm = parts per million.

DDG = dried distillers' grains

NOG = "No official guidance" levels established

N/A = not applicable

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