FOOD AND DRUG ADMINISTRATION

COMPLIANCE PROGRAM GUIDANCE MANUAL PROGRAM 7371.003

SUBJECT:	IMPLEMENTATION DATE:
FEED CONTAMINANTS PROGRAM	December 13, 2005
	COMPLETION DATE: 9/30/2010

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES (PACs)
Industry Codes: **54, 69, 70, 71, 72**	**71003A - Pesticides/Industrial Chemicals** **71003B - Elements** **71003C - Mycotoxins** **71003E - Microbes** **71003G - Dioxins**

This compliance program is intended to provide guidance and instructions to Food and Drug Administration (FDA) staff for obtaining information and taking action to help fulfill the Agency's plans for controlling the presence of deleterious chemicals and microorganisms in feeds. The program does not create or confer any rights for any person and does not operate to bind the FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations. It is intended for use by FDA personnel, but is available electronically to the public.

A. MAJOR DELETIONS FROM THE PREVIOUS FEED CONTAMINANTS PROGRAM

1. A separate compliance program for all bovine spongiform encephalopathy (BSE)-related matters was finalized on October 21, 2003. This new BSE-related compliance program is Compliance Program 7371.009 - BSE/Ruminant Feed Ban Inspections and it can be viewed from the following website: http://www.fda.gov/cvm/Documents/7371-009.doc. Thus, PAC 71003F (BSE Activities) was removed from the Feed Contaminants Program (7371.003).

   On September 30, 2005, PACs for the new BSE-related compliance program (7371.009) will be:

71009	BSE/Ruminant Feed Ban Inspections Program
71R844	BSE Import Activities CVM Products
71S011	BSE State Contract Inspections

Send all reports involving BSE activities to Dr. Neal Bataller, BSE Activities Monitor, Division of Compliance, Compliance Information Management Team, HFV-235; (240-276-9202; e-mail: Neal.Bataller@fda.gov.

2. PAC 71003D – Treated Seed Diversions has been archived. Therefore, this PAC was removed from the Feed Contaminants Program (FCP) and all mention of treated seed diversions was deleted.

3. FDA/Center for Veterinary Medicine (CVM)/Division of Animal Feed (DAF) recently learned that the Contamination Response System (CRS) is no longer an active program of the USDA/Food Safety Inspection Service (FSIS). Thus, all mention of CRS in the FCP was removed.

   [Note: USDA/FSIS continues to analyze animal-derived products for contaminants and to report elevated findings to CVM. CVM may request that ORA investigate these elevated findings as part of the FCP, but these investigations will not be associated with the CRS.]

B. MAJOR ADDITION TO THE PREVIOUS FEED CONTAMINANTS PROGRAM

Guidance on the analytical priority for mycotoxins in various feed ingredients and complete feeds (see Attachment A).

C. FIELD REPORTING

1. Report all collections/analyses of domestic and imported feed samples for pesticides, industrial chemicals, elements, mycotoxins, microbes and dioxins against this program even though the samples may have been collected during inspections conducted under other compliance programs.

2. Submit the following information and all reports involving pesticides, industrial chemicals, elements, mycotoxins, microbes, and dioxins to Division of Animal Feed, Medicated Feeds Team, HFV-226; Attn: Zoe Gill, Feed Contaminants Program Monitor, 7519 Standish Place, MPN4, Rockville, Maryland 20855 (240-453-6867; e-mail: Zoe.Gill@fda.gov):

   a. Each district/region should submit an annual feed contaminants report by November 30 after the conclusion of each fiscal year. This annual report is to be used as a mechanism to provide CVM with information that is not readily apparent or retrievable through the Field Accomplishments and Compliance Tracking System (FACTS) and Operational and Administrative System for Import Support (OASIS) databases. Examples include descriptions of federal/state cooperation under this compliance program; any local district initiatives and the impact of those initiatives; training given and other outreach programs; problems encountered; and other noteworthy events.

   b. A copy of the collection report **ONLY** when directed by the special assignment/survey.

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PART I - BACKGROUND

The FDA has the responsibility to enforce the Federal Food, Drug, and Cosmetic Act (FFDCA) and to ensure that foods for man and animal are safe. Within FDA, CVM is responsible for protecting the animal feed supply and ensuring that it is safe and wholesome, and that the incidence of harmful residues in human food derived from animals is minimized. This program is designed to address this responsibility as it relates to all contaminants, except drug residues and BSE matters.

Animal feeds can be adulterated with pesticides, industrial chemicals, dioxins, elements, mycotoxins, and microbes. They may present a hazard to livestock health and production, and to the public health by residues in animal-derived human food or by their ability to cause disease. Many of the more frequently identified contaminants in animal feeds are toxic, carcinogenic, mutagenic, teratogenic, or otherwise deleterious to animal and human health.

The Feed Contaminants Program (FCP) provides guidance for:

A. Collection of animal feed samples and analysis for pesticides, industrial chemicals, dioxins, elements, mycotoxins and microbes.

B. Surveillance of the feed industry to identify potential problem areas and additional sampling of these problem areas to ensure compliance.

C. Investigation of violative findings.

The scope of the program includes, but is not limited to:

A. Guidance on submitting an annual feed contaminants report (see Field Hardcopy Reporting section above).

B. Guidance on developing FDA/State cooperative sampling plans.

C. Guidance on the analytical priority for mycotoxins in feeds and feed ingredients.

D. Coverage of feed and feed ingredients to determine microbial contaminants, such as *Salmonella* and *E. coli* O157:H7, and their antimicrobial susceptibility patterns.

Based on review of contaminant data and other information, CVM may issue assignments to survey segments of industry or to direct sampling of specific target products. The Center anticipates that directed assignments will utilize some of the program's resources, especially for dioxins and microbes. These directed assignments coupled with the districts' surveillance and compliance activities are expected to provide contaminants-related data which will supplement that available from such sources as the United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), states and industry.

Under this program, the commodities collected and analyses performed may vary both during the year and from year-to-year. Districts are encouraged to use some of their resources to maintain adequate coverage of imported products and to address local or regional contamination problems.

CVM issued directed assignments in 2000, 2001, 2002, 2003, 2004, and 2005 to help determine background levels of dioxins and dioxin-like compounds in commonly used animal feeds and feed ingredients. In 1997, 2002 and 2003, CVM was involved in recalls of feeds and feed ingredients because of elevated dioxin levels. CVM anticipates issuing more directed surveillance assignments for dioxins in 2006. CVM will continue working with the FDA Center for Food Safety and Applied Nutrition (CFSAN) to determine background dioxin levels in food.

PART II – IMPLEMENTATION

A. OBJECTIVES

1. To collect animal feed samples and analyze them for pesticides, industrial chemicals, dioxins, elements, mycotoxins, and microbes.

2. To generate information on contaminant levels in domestic and imported feeds.

3. To assure the public that the health of animals is not impaired and that human health is not compromised by contaminants in animal feed.

4. To investigate violative feed samples and try to determine the source(s) of contamination.

B. PROGRAM MANAGEMENT INSTRUCTION

The field's approach to this program is regulatory in nature with emphasis on intelligence gathering, selective sampling, and aggressive compliance follow-up. Surveillance sampling should be done to cover gaps in information. Emphasis should be placed on identifying violations of regulatory significance and taking action to control the immediate problem and deter future violations. Food and feed sample collections and investigations should be planned and conducted to prevent unnecessary duplication of efforts.

State officials are valuable sources of information on current and potential problems in feed products. Districts should encourage state participation in data exchange programs and should coordinate equivalent program activities with state officials to prevent duplication of efforts in both food and feed sampling and to facilitate greater state cooperation. Report time expended on intelligence gathering activities, such as meeting with state/local officials or gathering data on pesticide usage patterns, as investigations. Contact Kevin Smith, Division of Federal-State Relations, HFC-150 (301-827-2915; e-mail: Kevin.Smith1@fda.gov) for further guidance on developing FDA/State cooperative sampling plans.

Several districts have a Pesticide Coordination Team (PCT) whose purpose is to coordinate efforts to ensure implementation of all pesticide programs within the district (Field Management Directive - 134). CVM encourages each district to form a PCT and also encourages each district to form teams to coordinate other aspects of this program (mycotoxins, elements, dioxins, microbes, etc.).

1. District Contact for the Feed Contaminants Program

Each district will annually submit the name, telephone number and e-mail address of a District Contact for this program to Zoe Gill, the FCP Monitor. In addition, each district will promptly provide any change in the District Contact during the year to the FCP Monitor. The District Contact will coordinate and communicate with the FDA investigator(s), the FDA lab(s), and CVM to try and resolve any concerns or questions that may arise from FCP-related activities.

2. Inter-Agency Agreements

a. Per current Memorandum of Understanding (MOU) between FDA, USDA and EPA, (described in the Federal Cooperative Agreements manual, August 1996, Chapter 3 - Residues of Drugs, Pesticides and Environmental Contaminants in Foods), FDA has agreed to notify immediately the appropriate USDA/FSIS regional offices whenever:

(1) FDA sample analysis detects pesticide or industrial chemical residues in feeds which exceed established tolerances or action levels.

b. In this MOU, FDA has agreed to notify immediately the appropriate EPA regional office whenever:

(1) An FDA investigation reveals the possible misuse of pesticides, or

(2) FDA sample analysis detects pesticide or industrial chemical residues in feeds which exceed established tolerances or action levels.

Note: Field Management Directive (FMD) No. 129 contains specific notification criteria.

The field should inform the Feed Contaminants Program Manager, Randall Lovell, at (240) 453-6857 (e-mail: **Randall.Lovell@.fda.gov)** of all violative contamination incidents in feed. The Program Manager or designee will provide notification to FSIS and EPA headquarters as appropriate. District offices should notify local and state officials and regional FSIS and EPA offices of these incidents as appropriate.

3. Program Interactions

The Feed Contaminants Program (7371.003) is one of several food safety related compliance programs directed by the FDA. CVM wants to list some of these other food safety related compliance programs so that investigators can consider performing activities from more than one program while at a firm (e.g. collect dairy feed samples for mycotoxin analysis, collect milk samples for drug and/or aflatoxin M_1 analysis, and perform a BSE-related inspection).

7303.803A*	Domestic Low Acid Canned Foods
7304.004	Pesticides and Industrial Chemicals in Domestic Foods
7318.003	Milk Safety Program
7371.004	Feed Manufacturing Compliance Program
7371.006	Illegal Drug Residues in Meat & Poultry Program
7371.009	BSE/Ruminant Feed Ban Inspections
7303.842	Domestic Fish and Fishery Products Inspection Program
7303.844	Import Seafood Products

*Note: The FDA's low acid canned food (LACF) program is administered by CFSAN. Thus, the inspections of all LACF manufacturers, even those that exclusively produce pet food products, should be reported under a CFSAN PAC, 03803A.

4. EPA Regional Office Contacts

Regional, state, tribal and/or local contact information for EPA's pesticide programs can be found at the following website: http://www.epa.gov/pesticides/contacts/index.htm#office. Go to the By Region column on the right hand side of the screen and find the appropriate EPA Region (for example, EPA Region 7 serves Iowa, Kansas, Missouri and Nebraska). Click on Pesticide Program (do not click on Contact Page). The contact information should be readily apparent on the next screen, although you may have to click on the contact you want in the upper left corner of this screen. After you click on Pesticide Program in Regions 8 and 10, look to the bottom of the screen that comes up (but you shouldn't have to scroll down) and click on Region 8 Pesticide team or on EPA Region 10 Pesticides Staff. After you click on Pesticide Program in Region 6, you should scroll down to the bottom of the screen that appears and then click on the appropriate contact in the section entitled EPA, State, and Tribal Contacts in Region 6.

PART III - INSPECTIONAL

This program does not direct routine inspections. Time is allocated for follow-up investigations and industry surveillance.

A. INVESTIGATIONS

Investigations Operations Manual (IOM) Subchapter 570 provides guidance concerning pesticide intelligence gathering operations.

Conduct mycotoxin investigations only as follow-ups to previously identified problems. For example, when a milk sample is found to contain elevated levels of aflatoxin M_1, dairy feed should be sampled to determine the source of the contamination.

The district will conduct investigations into other feed contamination incidents, such as dioxins, after an assignment is issued by CVM or by CFSAN.

B. SURVEILLANCE

FDA Districts will conduct surveillance of local industries to provide a clearer picture about the safety of feed ingredients/finished feed and to identify potential problem areas. Surveillance may be conducted by districts during routine inspectional activities carried out under other compliance programs (e.g., 71004 – Feed Manufacturing and 71006 – Illegal Tissue Residues) or by visits from various local, state and federal officials. The establishment of a working relationship with various local, state and federal authorities is encouraged to alert them of FDA's interest in feed safety and to facilitate information exchange about feed contaminants.

C. SAMPLE COLLECTIONS

1. Collect a wide variety of complete feeds and feed ingredients for pesticide/industrial chemical analysis. Emphasis should be placed on the most commonly used feeds in the district/region. The commodities collected may change annually.

2. Grains, oilseeds, and complete feeds are the commodities that should be emphasized when collecting samples for mycotoxin analysis. In **Attachment A**, the most common grains, oilseeds, and complete feeds are placed into nine (9) categories and guidance on the mycotoxin analytical priority for each category is provided. CVM would like to see more feed samples analyzed for vomitoxin, zearalenone and ochratoxin A.

3. Collect a wide variety of complete feeds and feed ingredients, including animal and vegetable proteins, for microbe analysis (*Salmonella* and *E. coli* O157:H7).

4. Due to the limited resources for PAC Code 71003B, carefully choose samples for element analyses. Pet foods containing fish or fish by-products should be considered for mercury analysis. Mineral premixes for food-producing animals should be considered for selenium analysis.

5. Collect animal feed and feed ingredients produced, imported, or distributed within the district. District discretion and inspectional findings should guide sampling. Animal feed for food-producing animals, especially lactating dairy cows and laying hens, should have priority over feeds for non-food producing animals.

6. When collecting feed/feed ingredients, attempt to determine the following:

   a. the percentage of the ingredients in the finished feed,
   b. the intended use of the finished feed, i.e., starter feed, finishing feed, etc,
   c. the animal species or type for which the feed/feed ingredient is intended, especially in samples collected for mycotoxin analyses,
   d. whether the feed/feed ingredient will undergo further heat processing, especially in samples collected for microbe analyses.

7. Proper sampling techniques should be used. Whenever possible, collect a representative sample of the feed or feed ingredient in the original packaging material. If the product is in large units or bulk, collect subsamples per Investigations Operations Manual (IOM) Subchapter 420 sampling instructions. For bulk material, supply labeling or a list of components. Your servicing laboratory can provide guidance regarding contamination control procedures.

8. Collect official samples when possible. It is not necessary to document interstate commerce at the time of collection unless violative findings are expected or when following up a violative sample. Investigational (INV) samples may be collected to provide surveillance information or to investigate violative findings.

9. Although CVM may issue them at any time, directed assignments are likely only for dioxins and microbes. Collect these samples as directed in the assignment. PAC codes 71003H and 71003I, currently inactive, have recently been used in directed assignments for microbes.

D. DISTRICT SURVEILLANCE AND COMPLIANCE SAMPLES

District surveillance samples should give priority to coverage of locally grown or produced animal feed and feed ingredients. Base coverage on past violative samples, current analytical findings, and on information obtained through intelligence gathering activities. The district should emphasize feeds which comprise a significant portion of the local industry.

As warranted, coordinate with local, state and federal EPA officials to cover pesticides applied under experimental or emergency use permits. Guidance may be found in CFSAN's Pesticide and Industrial Chemical Compliance Program (7304.004). Districts should not ordinarily extend sampling coverage to commodities subject to an experimental use permit.

Compliance samples may be collected whenever an inspection or investigation reveals that a feed or feed ingredient is contaminated or is suspected of being contaminated. Finished feed, intermediate products and raw materials should be sampled as appropriate to document the probable cause and source of the contaminant.

E. IMPORT SAMPLES

District discretion will be used to sample imported animal feeds and feed ingredients. Sampling priority should be given to imported feeds and feed ingredients from countries and/or companies which export significant quantities to the U.S. or which have previously shipped violative commodities. The guidelines for sample collections in Part III (C) apply to import samples, except for documenting interstate commerce. Imported feeds are subject to registration and prior notice.

F. SAMPLE SIZE/HANDLING/SHIPMENT

1. When collecting samples for analysis of pesticides, industrial chemicals, and elements, refer to IOM Chapter 4, Sample Schedule 3 for minimum sample sizes. This sample schedule includes subsection 4.1 on legume animal feeds, and other forages and fodders and subsection 4.2 on straw, hay and other dried products.

2. For collection of samples for mycotoxin analysis, refer to IOM Chapter 4, Sample Schedule 6 for sample sizes.

3. IOM Chapter 4 contains several other sample schedules that may be helpful in some situations. These include Sample Schedule 2 (Sample Schedule for Canned and Acidified Food), Sample Schedule 4 (Wheat Carload Sampling), Sample Schedule 15 (Veterinary Products, Feeds, & By-products for Animal Feeds) and Sample Schedule 16 (Medicated Animal Feeds Sampling).

4. For microbes in feed and feed ingredients, aseptically collect two samples. One is an official sample and the other an investigational sample. The official sample, which consists of ten subsamples (~200 g per subsample), will be for regulatory purposes and should be sent to the FDA servicing laboratories. Report time for the collection and submission of these 10 subsamples under PAC 71003E.

   The investigational sample (~300 g) will be for research purposes. The investigational sample (~300 g) should be sent to Dr. David Wagner [MOD II, Room 1503, HFV-530, 8401 Muirkirk Road, Laurel, MD 20708; Phone: (301) 210-4255; E-mail address: David.Wagner@fda.gov] or his designee and should be labeled "Investigational Sample for Research Purposes Only." The investigational sample should be identified with the FACTS sample number, the collector's name, the date of collection, the State (Oklahoma, New Jersey, etc.) in which the sample was collected, and a description of the sample (for complete feeds, concentrates or supplements please include the production class or species for which the feed is intended). Report time for the collection and preparation of the investigational sample under PAC 71R800.

5. Refer to IOM Subchapter 450 for handling and shipment details.

G. SAMPLE SUBMISSION

Send samples to servicing laboratories as outlined in Part IV, Subpart A.

H. SPECIAL REPORTING

Report collection information into the FACTS electronic collection report (c/r).

1. PESTICIDE SAMPLES

When collecting surveillance samples, districts may use an abbreviated c/r format. As per IOM Subchapter 439, select “pesticide sample” from list of options in the Flag field of the c/r. Select either "Pesticide Surveillance" or "Pesticide Compliance" in the Flag Remarks field of the c/r. Compliance samples are collected on a selective basis as the result of an inspection, complaint or other evidence there may be a problem with the product.

Report pesticide usage information, when available, into the Remarks field of the c/r to assist laboratory and compliance personnel. For corn and other raw agricultural products, list the name and address of the grower or processor if different from the shipper.

In accordance with Field Management Directive (FMD) No. 129, FDA districts are to notify EPA regional offices when FDA investigations or sample analyses reveal possible pesticide misuse. For this reason, consider the need to collect additional samples or other evidence documenting possible pesticide misuse when violative residues are suspected. Include information concerning potential pesticide misuse and/or drift in the Remarks field of the c/r. When this information cannot be obtained, so indicate.

2. INDUSTRIAL CHEMICAL SAMPLES

For compliance samples collected because of suspected contamination by industrial chemicals, report where the commodity was produced along with the source of the suspected contaminant(s).

3. MICROBE SAMPLES

The field should immediately notify Jack Geltman or the FCP Manager, Randall Lovell, about any feed sample collected for regulatory purposes that is found positive for *Salmonella* or *E. coli* O157:H7. Jack Geltman is a Consumer Safety Officer in the Division of Compliance, Enforcement and Regulatory Policy Team, HFV-232, at CVM (240-276-9203; Jack.Geltman@fda.gov).

PART IV - ANALYTICAL

A. SERVICING LABS

At the time this document was written, the following information was current. If this information differs from that published in the current ORA Field Workplan, Part 1, Appendix III, then the Field Workplan is the lead document.

1. Pesticide, Industrial Chemical and Element Samples

Servicing labs:

Northeast Region	all to NRL
Southeast Region	all to SRL
Central Region	BLT & CIN to SRL; NWJ & PHI to NRL; CHI & MIN to KAN; DET to ARL
Southwest Region	DAL, DEN & KAN to KAN; SWID to ARL
Pacific Region	LOS to PRS; SAN to SAN; SEA to PRN

2. Dioxin Samples

Servicing labs:
All districts will send samples for dioxin analysis to ARL

3. Mycotoxin Samples

Servicing labs:
Send all import samples to PRN

Send domestic samples from:
Pacific, Northeast & Central Regions to PRN
Southeast Region to SRL
Southwest Region to KAN

[Note: All mycotoxin servicing labs perform fumonisin analysis so shipment of feed samples (primarily corn and corn based feeds) to KAN for this analysis is no longer necessary.]

4. Microbe Samples

Servicing labs:

Central Region	CHI & MIN to DEN; DET to ARL; BLT, CIN, NWJ & PHI to SRL
Southwest Region	DAL, DEN & KAN to DEN; SWID to ARL
Northeast Region	all to NRL
Pacific Region	all to SAN
Southeast Region	all to SRL

If a positive subsample is identified, pulsed-field gel electrophoresis (PFGE) is performed on all isolates (*Salmonella* and *E. coli* O157:H7) by the servicing labs.

Salmonella serotyping is performed by both ARL and DEN. NRL and SRL will send the *Salmonella* isolates to ARL for serotyping. SAN will send the *Salmonella* isolates to DEN for serotyping.

Antimicrobial susceptibility testing is performed on all isolates (*Salmonella* and *E. coli* O157:H7) by DEN. After serotyping, ARL will send the *Salmonella* isolates to DEN for antimicrobial susceptibility testing.

If Center assignments are issued, they will designate the analyzing laboratories.

B. PROCEDURAL CONSIDERATIONS

1. Pesticides, Industrial Chemicals and Elements

a. In the initial stages of commodity coverage, examine pesticide surveillance samples for as many classes of chemicals as feasible. Try to examine for the contaminant(s) specified in the Reason for Collection field of the c/r and for organohalogen and organophosphorus residues. Consider using three or more multi-residue methods to provide broader coverage for pesticide residues.

b. A sample considered for regulatory action should be check analyzed by a second analyst. A method reagent blank and appropriate recovery determinations should be run by the check analyst concurrently with his/her analysis.

Residue identity (and quantity, when possible) should be confirmed by at least two independent tests such as: thin layer chromatography (TLC), derivatization, element selective gas chromatography (GC) detector, mass spectrometry (MS), etc, as deemed necessary by the Laboratory Director. Identity of residues which are unusual or of particular significance should also be confirmed.

c. All pesticide analytical packages for actionable samples should meet the "Criteria for Analytical Packages to Support Regulatory Action on Pesticide Residues". This document is located at http://www.cfsan.fda.gov/~comm/cp04016.html (see Attachment C) and copies also may also be obtained by contacting an ORA Scientific Coordinator [George Salem (301-827-1031; e-mail: George.Salem@fda.gov) or Steven Robbs (301-827-9555; e-mail: Steven.Robbs@fda.gov).

d. For all element analyses, follow the specifications provided in the document "Criteria for Analytical Packages to Support Regulatory Action on Toxic Elements in Food and Food-Related Products" (July 1998). This document has been distributed to the field and copies can also be obtained by contacting an ORA Scientific Coordinator (George Salem or Steven Robbs). The results of the quality control analyses prescribed should meet the established acceptance criteria to validate analytical findings on the samples.

2. Mycotoxins

All mycotoxin servicing labs perform fumonisin analysis so shipment of feed samples (primarily corn and corn based feeds) to KAN for this analysis is no longer necessary.

For all feeds and feed ingredients, CVM would like to see more samples analyzed for vomitoxin, zearalenone, and ochratoxin A (see Attachment A for guidance).

3. Microbe Samples

Ten subsamples (200 g per subsample) of the feed or feed ingredient are collected by the FDA investigators for regulatory purposes under PAC Code 71003E and sent to the appropriate FDA servicing laboratory. Approximately seventy-five (75) grams from each of the 10 subsamples should be reserved for the 702(b) portion.

The servicing laboratory should prepare one 375 g composite sample for *Salmonella* analysis. Thirty-seven and a half (37.5) grams should be collected from each of the 10 subsamples and combined to form a 375 g composite sample.

Once a sample is found positive for *Salmonella*, the servicing lab will send each isolate to ARL or DEN for serotyping (as indicated in Part IV (A)(4)). ARL will send *Salmonella* serotyped isolates to DEN. DEN will conduct antimicrobial susceptibility testing on every *Salmonella* isolate found in animal feed.

For *E. coli* O157:H7, a 25 g portion from each sub-sample will be analyzed individually. Once a sample is found positive for *E. coli* O157:H7, the servicing lab will send each isolate to DEN for antimicrobial susceptibility testing.

In addition, the servicing lab will determine the pulsed-field gel electrophoresis (PFGE) patterns of each *Salmonella* and *E. coli* O157:H7 isolate found in animal feed. If feasible, conduct the PFGE analysis on animal feed isolates separate from human food isolates. The servicing lab will electronically send the image(s) of the PFGE patterns from the animal feed isolates to Mr. Jason Abbott, CVM OR [MOD II, Room 1501, HFV-530, 8401 Muirkirk Road, Laurel, MD 20708; Phone: (301) 210-4185; E-mail Address: Jason.Abbott@fda.gov] or his designee. Include the FACTS sample number when sending each PFGE image to CVM OR. CVM OR will be responsible for sending the PFGE image(s) from the animal feed isolates to PulseNet.

Requests to send the *Salmonella* and *E. coli* O157:H7 isolates to CVM OR for research purposes will be processed after sample disposition according to ORA Laboratory Manual, Volume III, Section 2.9.2 (http://intranet.ora.fda.gov/dfs/policies/manuals/lm/vol3/section/02.pdf). The *Salmonella* and *E. coli* O157:H7 isolates should be sent to the attention of Dr. David Wagner [CVM Office of Research, MOD II, Room 1503, HFV-530, 8401 Muirkirk Road, Laurel, MD 20708].

CVM OR will not analyze the ~300 g investigational samples collected under PAC 71R800 for *Salmonella* or *E. coli* O157:H7 as this could hinder regulatory action by FDA.

C. METHODOLOGY

1. Chemical Contaminants

a. Pesticides and Industrial Chemicals

Use the multi-residue methods described in the most recent edition (currently 3rd) of the Pesticide Analytical Manual, Vol. 1 (PAM I) and the most recent edition (currently 17th) of the Official Methods of Analysis (OMA) of the Association of Official Analytical Chemists International (AOAC) when applicable. When the multi-residue methods are inappropriate, use any of the methods cited in (1) the current edition of PAM I or of the OMA of AOAC, (2) the FDA Laboratory Information Bulletins (LIB), or (3) the peer-reviewed literature.

Refer to PAM 1, 3rd edition, Chapter 1, Section 105, guidelines for determining the analytical limits of quantitation. Findings below the limits of quantitation are to be reported as "Trace" (T) with an estimated level entered into the "Amount Found" field.

Violative pesticide and industrial chemical residues should be confirmed by tests such as element selective gas chromatography (GC) detector, gas chromatography-mass spectrometry (GC-MS), etc.

b. Elements

For element analyses use the appropriate Elemental Analysis Manual reference or contact an ORA Scientific Coordinator (George Salem or Steven Robbs) for guidance and information. The limits of quantitation for elements are based on sample weights prescribed in the analysis.

(1) Lead (Pb) 0.05 mg/kg
(2) Cadmium (Cd) 0.005 mg/kg

Analyze the sample for Pb and Cd using graphite furnace atomic absorption spectrometry as described in JAOAC Int. (1993, vol. 76, pages 798-813) or FDA Laboratory Information Bulletin (LIB) # 3640 using peak area absorbance mode or using anodic stripping voltammetry as described in the most recent edition of the OMA of AOAC (currently 17th ed., 2000). In addition, KAN-DO Total Diet Study SOP Kan-Lab-Met.93 can be used for the graphite furnace determination of Pb and Cd.

(3) Arsenic (As) 0.05 mg/kg
(4) Selenium (Se) 0.05 mg/kg

A method to support regulatory action for As, Se, Pb and Cd is AOAC method 986.15 (OMA of AOAC, 17th ed., 2000). The KAN-DO Total Diet Study SOP Kan-Lab-Met.96 will support regulatory action for As and Se.

(5) Mercury (Hg) 0.02 mg/kg

Total mercury is determined using AOAC method 971.21 (OMA of AOAC, 17th ed., 2000) with the option of using a commercially available mercury vapor generator for the flasks, tubes and recirculation pump described in the AOAC procedure. A method to support regulatory action for Hg includes KAN-DO Total Diet Study SOP Kan-Lab-Met.91.

Inductively coupled plasma (ICP) may be used in lieu of the above methods to simultaneously determine all five of these elements, i.e. Pb, Cd, As, Se and Hg. A method to support regulatory action would include KAN-DO Total Diet Study SOP Kan-Lab-Met. 92.

c. Mycotoxins

Follow the procedures and methods in (1) the most recent edition of the OMA of the AOAC (currently 17th ed., 2000), (2) the FDA Laboratory Information Bulletins (LIB), or (3) peer reviewed literature.

SAFETY: Be aware of the potential hazards in the preparation of aflatoxin samples. See Section 49.2.01 (AOAC Method 977.16).

General Procedures

Chapter 49, OMA of AOAC, 17th edition, 2000.

Section 49.2.01 (AOAC Method 977.16) - Sampling and preparation of sample and safety precaution.

Section 49.2.02 (AOAC Method 971.22) - Preparation of standards.

Aflatoxins (B_1, B_2, G_1, and G_2)

Section 49.2.03 (AOAC Method 971.22) - Standards for Aflatoxins.

Initial screening: LIB 3555, Aflatest Method (manual or robotic).

Official Methods

Section 49.2.04 (AOAC Method 975.35) identification of aflatoxins by TLC.

Section 49.2.26 (AOAC Method 975.37) identification of aflatoxins by TFA derivative formation on TLC plate.

Section 49.2.08 (AOAC Method 968.22) for peanut products.

Section 49.2.15 (AOAC Method 993.17) for corn and peanuts by TLC.

Section 49.2.17 (AOAC Method 990.33) for corn and peanut butter by LC.

Section 49.2.18 (AOAC Method 991.31) for corn, raw peanuts and peanut butter.

Section 49.2.19 (AOAC Method 980.20) for cotton seeds.

Section 49.2.27 (AOAC Method 985.17) identification of aflatoxin B_1 by mass spec.

Results of 15 ppb or higher total aflatoxins should be run by the official method.

Zearalenone

Rapid Test Kits in Grains, Cereals and/or Feed: http://www.aoac.org/testkits/kits-toxins.htm

Veratox® for Zearalenone:
http://www.neogen.com/pdf/FS_CatalogPages/VeratoxZearalenone.pdf

Official Methods

Journal of the Association of Official Analytical Chemists (JAOAC), 1986, 69 (5): 894-898, Zearalenone in Feeds.

Section 49.9.02 (AOAC Method 985.18),
α-Zearalenol and Zearalenone in Corn.

Ochratoxin A

Rapid Test Kits in Grains, Cereals and/or Feed: http://www.aoac.org/testkits/kits-toxins.htm

Veratox® for Ochratoxin:
http://www.neogen.com/pdf/FS_CatalogPages/VeratoxOchratoxin.pdf

Official Methods

Section 49.6.03 (AOAC Method 991.44) for corn and barley.
Modifications – JAOAC, 1996, 79 (5): 1102-1105.

Section 49.6.04 (AOAC 2000.03) Immunoaffinity column for ochratoxin A .

Fumonisins (B_1, B_2 and B_3)

LIB 3621 (LC/fluorescence detector) (Fumonisin B_1 in corn).

Analytical Letters, 1994, 27 (4): 693-715 (NDA Fumonisin B_1 & B_2 in Corn (LC).

JAOAC, 1995, 78 (3): 705-710 (Immunoaffinity Column Coupled with Liquid Chromatography for Determination of Fumonisins).

Official Methods

Section 49.5.01 (AOAC Method 995.15) OPA Fumonisins B_1, B_2, and B_3 in Corn.

Section 49.5.02 (AOAC 2001.04) Immunoaffinity column for fumonisins.

Vomitoxin (DON)

Rapid Test Kits in Grains that are performance verified by USDA/GIPSA: http://151.121.3.117/tech-servsup/metheqp/testkit.htm

LIB 3844.

JAOAC, 1996, 79 (4): 833-887.

Official Method

Section 49.4.02 (AOAC Method 986.18) Deoxynivalenol in Wheat.

2. Microbes

Analyze feed/feed ingredient samples for *Salmonella* and *E. coli* O157:H7. Use the methods described in the Bacteriological Analytical Manual (BAM) Online (see Chapter 5 for *Salmonella* and Chapter 4A for *E. coli* O157:H7).

For *Salmonella*, use the 10 subsample composite totaling 375 grams.

For *E. coli* O157:H7, test individual subsamples using 25 grams from each subsample.

Note: Instructions will be contained in directed assignments, when issued.

D. REPORTING

1. Analytical Results and Method Performance Data

Report the pesticide, industrial chemical, element, mycotoxin, dioxin, and microbe findings into FACTS.

Report all method performance data (recoveries, control blanks, duplicate analyses, etc.) according to instructions in FACTS.

For follow-up regulatory samples, report the sample number and analytical findings for the screening samples into FACTS.

2. Sample Classification

When classifying samples, please review Part V – Regulatory/Administrative Strategy, A. Regulatory Action and be guided by the following examples:

a. **Sample Class "l":** The sample contains no residue or contains residues that are within the limits of an established tolerance or guideline.

b. **Sample Class "2":** The sample contains a confirmed residue for which no tolerance or guideline in the sampled feed has been established, but the residue level is of no regulatory significance.

c. **Sample Class "3":** The sample contains a residue which exceeds a tolerance or guideline or contains a residue at a significant level for which no tolerance or action level in the sample feed has been established.

When applying the guidance in FDA/ORA Compliance Policy Guide, Sec. 683.100, "Action Levels For Aflatoxins in Animal Feeds" to sample classification, be guided by the following:

i. If the intended use of the corn, cotton seed or peanut product is known and documented, use the guidance in Sec. 683.100 to determine the sample class.

ii. If the intended use of the corn, cotton or peanut product is unknown or the animal species is not listed in Sec. 683.100, then a sample with an aflatoxin level exceeding 20 ppb is considered in **Sample Class 3.**

NOTE: For samples coded as Class 3, each violative residue found should have the appropriate code entered into the violative residue field (i.e., "X" for exceeds tolerance, "N" for no tolerance, or "A" for at or above action level). The code should be entered into the data records for both the original and check analyses.

When classifying samples analyzed for microbes, those positive for *Salmonella* or *E. coli* O157:H7 should be **Sample Class 3.**

3. Special Reporting

Immediately notify the home district and Randall Lovell, Program Manager, at (240) 453-6857 (e-mail: Randall.Lovell@.fda.gov) of all violative sample results.

Notify the Director, Division of Field Investigations, HFC-130, at (301) 827-5653, when lots of corn or other grain that are destined for export are reported by USDA/GIPSA (Grain Inspection, Packers and Stockyards Administration) to contain actionable levels of mycotoxins.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

Each sample classified as **"3"** should be evaluated for possible compliance action and may include a meeting with responsible parties, a warning letter, recall, seizure, and/or other corrective action.

Contact the Division of Compliance, HFV-230, as needed and as directed by the referenced Compliance Policy Guides. When the firm's initial corrective actions are not effective, consider recall, seizure or injunction (e.g., a number of illegal residues from the same firm). These actions should be initiated only after consultation with the Division of Compliance. A copy of the findings which may warrant regulatory action should contain documentation of the sampling scheme, method of collection, preservation (including storage conditions), analytical methods, and data generation signature along with the date(s) of these procedures. **Ensure that sample continuity is fully documented**. The package should be submitted to HFV-230 (Attn. Jack Geltman) for review along with a recommendation from the district office.

A. REGULATORY ACTION

1. Domestic Samples

a. Pesticides and Industrial Chemicals

Tolerances for pesticide residues in raw agricultural commodities are established by the EPA. These tolerances can be found in 40 CFR 180 (Title 40 of the Code of Federal Regulations Part 180) or at the following website:

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=33c46d4599df4fe5e76ad50625d92fe8&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl

FDA/ORA Compliance Policy Guide (CPG) Sec. 575.100 "Pesticide Residues in Food and Feed - Enforcement Criteria" also provides guidance for regulatory action. This CPG lists FDA action levels for unavoidable residues of pesticides whose tolerances have been revoked by the EPA. This document can be found at http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg575-100.html

Immediately notify the regional EPA office when investigation reveals possible misuse of pesticides (see FMD 129).

The temporary tolerances for polychlorinated biphenyls in animal feed can be found in 21 CFR 509.30.

Regulatory action for pesticides and industrial chemicals in feed and feed ingredients will be decided on a case-by-case basis.

b. Elements

"Mineral Tolerance of Animals" was published in 2005 by the National Academy of

Sciences/National Research Council and this book provides estimates of the maximum tolerated level for several elements in complete feed. Regulatory action for elements in feed and feed ingredients will be decided on a case-by-case basis.

c. Aflatoxins

Consult FDA/ORA Compliance Policy Guide Sec. 683.100 for regulatory guidance. It can be found at http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg683-100.html. Mass spectrometry confirmation of aflatoxin B_1 identity should be completed prior to taking regulatory action. The home district should promptly report analytical results on regulatory samples found to be "out of compliance" (i.e., judged to be of regulatory significance) to the responsible firm and to cooperating state officials. Regulatory action for aflatoxins in feed and feed ingredients will be decided on a case-by-case basis.

d. Vomitoxin

The advisory levels for vomitoxin in animal feeds were provided in a letter dated September 16, 1993, from Ronald G. Chesemore, FDA Associate Commissioner for Regulatory Affairs (**see Attachment B for details**). Regulatory action for vomitoxin in feed and feed ingredients will be decided on a case-by-case basis.

e. Fumonisins

The agency recently published Guidance for Industry on the Fumonisin Levels in Human Foods and Animal Feeds (www.cfsan.fda.gov/%7Edms/fumongu2.html; Guidance for Industry 112). Corn and corn by-products intended for animals and complete animal feeds should not exceed the total fumonisin (FB_1+FB_2+FB_3) levels listed in **Attachment C**. Regulatory action for fumonisins in feed and feed ingredients will be decided on a case-by-case basis.

f. Ochratoxin A and Zearalenone

No tolerances or guidance have been established for these two mycotoxins. Regulatory action on positive analytical findings should be submitted to the Division of Compliance, HFV-230 (Attn. Jack Geltman), for review. Regulatory action for ochratoxin A and zearalenone in feed and feed ingredients will be decided on a case-by-case basis.

g. *Salmonella* and *E. coli* O157:H7

Feed and feed ingredients in which *Salmonella* or *E. coli* O157:H7 are detected are considered adulterated under Section 402 (a)(1) of the FFDCA and 21 CFR 500.35. When *Salmonella* or *E. coli* O157:H7 are found in a feed sample, the documentation package described in Part V above should be submitted to HFV-230 (Attn. Jack Geltman) for review by HFV-222.

CVM will evaluate the information provided in a district's recommendation for

regulatory action and will make a decision, on a case-by-case basis, whether such recommendation has met the criteria for regulatory action. CVM's decision will be based on inspectional findings, technical review findings, type of sample, etc. The decision will be provided to the district office for implementation. Enforcement action will not be initiated by CVM. Even if no regulatory action is recommended, the district will still be responsible for contacting the firm about the analytical findings.

2. Import Samples

Imported animal feeds are subject to prior notice under 801(m) of the Federal Food, Drug & Cosmetic Act (FFDCA) and to registration requirements under 801(l). Failure to provide prior notice or to register is prohibited under section 301 of the FFDCA and would make the food/feed shipment subject to refusal, and the importer or consignee liable to potential enforcement actions such as injunction and prosecution. More specific information on FDA's response to registration or prior notice violations is included in the Compliance Policy Guide, "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

In addition, the importer could be subject to permissive debarment as described in Section 306(b)(1)(C) of the FFDCA if they are found to be importing adulterated food that presents a threat of serious adverse health consequences or death to humans or animals or have been convicted of a felony for conduct relating to the importation into the United States of any food [Section 306(b)(3) of the FFDCA]. Detention without physical examination (DWPE) may be considered for imported feeds and feed ingredients which may represent a hazard to animal or human health. All recommendations for DWPE should be forwarded to the Division of Import Operations and Policy, HFC-170.

The guidance for taking regulatory action on import samples of feed can be found in the same locations as that for domestic samples -- 40 CFR 180 and Compliance Policy Guide Sec. 575.100 for pesticides; 21 CFR 509.30 for polychlorinated biphenyls; Mineral Tolerance of Animals (National Academy of Sciences/National Research Council, 2005) for elements; Compliance Policy Guide (CPG) Sec. 683.100 for aflatoxins; Letter dated September 16, 1993, from Ronald G. Chesemore (FDA Associate Commissioner for Regulatory Affairs) for vomitoxin; FDA Guidance for Industry 112 for fumonisins; and Section 402 (a)(1) of the FFDCA and 21 CFR 500.35 for *E. coli* O157:H7 and *Salmonella*.

Refer to Import Alert #72-03 for how to handle *Salmonella*-contaminated pig ears (pet treats). Refer to Import Alert #71-04 for how to handle *Salmonella*-contaminated feeds other than pet treats. These 2 import alerts are found at the following websites:

http://www.fda.gov/ora/fiars/ora_import_ia7203.html
http://www.fda.gov/ora/fiars/ora_import_ia7104.html

Contact Jack Geltman, Consumer Safety Officer, Enforcement and Regulatory Policy Team, HFV-232, at 240-276-9203 or by e-mail at Jack.Geltman@fda.gov if additional guidance is necessary.

3. Additional Regulatory Guidance

a. Contact Gloria Dunnavan, Director, Division of Compliance, HFV-230, for unusual findings which suggest the need for a health hazard evaluation. Gloria can be reached by phone at (240) 276-9201 or by e-mail at Gloria.Dunnavan@fda.gov

b. The final disposition of each violative shipment and the action taken should be reported into FACTS for all Class **"3"** samples.

PART VI - REFERENCES, ATTACHMENTS & CONTACTS

A. REFERENCES*

1. Compliance Program (CP) 7304.004, "Pesticides and Industrial Chemicals in Domestic Foods" – website: http://www.cfsan.fda.gov/~comm/cp04004.html

2. Memorandum of Understanding (MOU), Federal Cooperative Agreements Manual (August, 1996), "MOU with USDA (FSIS and AMS) and EPA Regarding Regulatory Activities Concerning Residues of Drugs, Pesticides and Environmental Contaminants in Foods." (FDA 225-85-8400)

3. Field Management Directive (FMD) No. 129, "Interagency Pesticide Referrals Between EPA and FDA" (February 19, 1982; Revised 12/16/92) - website: http://www.fda.gov/ora/inspect_ref/fmd/fmd129.htm

4. Investigations Operations Manual (IOM), (2005) - website: http://www.fda.gov/ora/inspect_ref/iom/default.htm

   Chapter 4, Sampling
   - Sub Chapter 420 – Collection Technique
   - Sub Chapter 430 – Documentation & CR
     - Part 439 – Reporting Sample Collections
   - Sub Chapter 450 – Sampling: Preparation, Handling, Shipping
     - Part 452 – Sample Handling
     - Part 454 – Sample Shipment
   - Sample Schedule 2, Sample Schedule for Canned and Acidified Foods
   - Sample Schedule 3, Pesticide Samples
   - Sample Schedule 4, Wheat Carload Sampling
   - Sample Schedule 6, Mycotoxin Sample Sizes
   - Sample Schedule 15, Veterinary Products, Feeds and By-products for Animal Feeds
   - Sample Schedule 16, Medicated Animal Feeds Sampling

   Chapter 5, Establishment Inspection
   - Sub Chapter 570 – Pesticides

5. Official Methods of Analysis of the AOAC, 17th edition, 2000, Chapter 49, Vol. II.

6. Pesticide Analytical Manual, Vol. 1 (PAM I), 3rd Edition, Chapter 1, Section 105, "Analytical Limits of Quantitation", - website: http://www.cfsan.fda.gov/~frf/pami3.html

7. Elemental Analysis Manual for Food and Related Products, January 2000 – website: http://www.cfsan.fda.gov/~dms/eam-toc.html

8. Bacteriological Analytical Manual (BAM) Online, Chapters 4a and 5 - website: http://www.cfsan.fda.gov/~ebam/bam-toc.html

9. FDA Office of Regulatory Affairs, Compliance Policy Guides, Sec. 683.100, "Action Levels for Aflatoxins in Animal Feeds (CPG 7126.33)", March 1995, -website: http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg683-100.html.

10. FDA Office of Regulatory Affairs, Compliance Policy Guides, Sec. 575.100, "Pesticide Residues in Food and Feed – Enforcement Criteria (CPG 7141.01)", March 1995, http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg575-100.html

***References listed with dates were current at time of publication**.

B. ATTACHMENTS

ATTACHMENT A – Guidance on the Analytical Priority for Mycotoxins in Various Feed Ingredients and Complete Feeds

ATTACHMENT B – Advisory Levels for Vomitoxin (DON or Deoxynivalenol) in Animal Feeds

ATTACHMENT C – Guidance for Fumonisins in Animal Feeds

C. CONTACTS

1. CVM Contacts

a. Program Inquiries

Zoe Gill, Industry Compliance Analyst
Program Monitor
Medicated Feeds Team, HFV-226
Division of Animal Feeds, CVM
Telephone: (240) 453-6867
E-mail: Zoe.Gill@fda.gov

b. Regulatory Inquiries

Jack Geltman, Consumer Safety Officer
Enforcement and Regulatory Policy Team, HFV-232
Division of Compliance, CVM
Telephone: (240) 276-9203
E-mail: Jack.Geltman@fda.gov

Gloria Dunnavan, Director
Division of Compliance, HFV-230, CVM
Telephone: (240) 276-9201
E-mail: Gloria.Dunnavan@fda.gov

c. Feed Contaminants Program Manager and Scientific Contact for Dioxins, Pesticides and Industrial Chemicals

Dr. Randall Lovell, Veterinary Medical Officer
Feed Safety Team, HFV-222
Division of Animal Feeds, CVM
Telephone: (240) 453-6857
E-mail: Randall.Lovell@fda.gov

d. Scientific Contact for Mycotoxins

Dr. Michael Henry, Biologist
Feed Safety Team, HFV-222
Division of Animal Feeds, CVM
Telephone: (240) 453-6861
E-mail: Mike.Henry@fda.gov

e. Scientific Contact for Microbes

Dr. Henry Ekperigin, Biologist
Feed Safety Team, HFV-222
Division of Animal Feeds, CVM
Telephone: (240) 453-6868
E-mail: Henry.Ekperigin@fda.gov

2. ORA Contacts

a. Inspectional Inquiries

James Dunnie Jr.
ORA/ORO/DFI, HFC-132
Telephone: (301) 827-5652
E-mail: James.Dunnie@fda.gov

b. FDA/State Cooperative Sampling Plans

Kevin Smith, Supv. Consumer Safety Officer
ORA/ORO/DFSR, HFC-150
Telephone: (301) 827-2915
E-mail: Kevin.Smith1@fda.gov

c. Methodology Inquiries on Pesticide/Industrial Chemicals/Dioxins/Mycotoxins/Elements

George Salem, Chemist
ORA/ORO/DFS, HFC-141
Telephone: 301-827-1031
E-mail: George.Salem@fda.gov

Steven Robbs, Chemist
ORA/ORO/DFS, HFC-140
Telephone: 301-827-9555
E-mail: Steven.Robbs@fda.gov

d. Methodology Inquiries on Microbes

Marsha Hayden, Microbiologist
ORA/ORO/DFS, HFC-141
Telephone: (301) 827-1039
E-mail: Marsha.Hayden@fda.gov

Lydia Rosas-Marty, Microbiologist
ORA/ORO/DFS, HFC-141
Telephone: (301) 827-6624
E-mail: Lydia.Rosas-Marty@fda.gov

e. Import Inquiries

Ted Poplawski, Consumer Safety Officer
ORA/ORO/DIOP, HFC-172
Telephone: (301) 594-3849
E-mail: Ted.Poplawski@fda.gov

f. FACTS – Data Input Inquiries

Cheryl Stoddard, IT Specialist
OC/OM/OCIO/OIT-ORA, HFR-SW200 (Denver)
Telephone: (303) 236-3032
E-mail Address: Cheryl.Stoddard@fda.gov

g. FACTS – National Tables of Field Data

John Lechus, Director, DEPM
ORA/ORM/DPEM, HFC-40
Telephone: (301) 827-1637
E-mail: John.Lechus@fda.gov

3. CFSAN Contact

Dr. Paul South, Consumer Safety Officer
OO/OPDF/DPPS/RPBPP, HFS-306
Telephone: (301) 436-1640
E-mail: Paul.South@fda.gov

PART VII - CENTER RESPONSIBILITIES

The Division of Animal Feeds, HFV-220, will evaluate the implementation and effectiveness of this program when requested by the Director, CVM. The Feed Contaminants Program Manager or designee will prepare an annual report of the pesticide/industrial chemical, mycotoxin, dioxin, and microbe findings from this program.

Inter-center coordination is necessary between CVM and CFSAN because residue findings in feeds and in food derived from animals are often correlated.

Attachment A:

Guidance on the Analytical Priority for Mycotoxins in Various Feed Ingredients and Complete Feeds.

COMMODITIES	MYCOTOXIN ANALYTICAL PRIORITY GUIDANCE*			
	Priority 1	**Priority 2**	**Priority 3**	**Priority 4**
Barley, Oats, Wheat and Rye and their Products	Vomitoxin	Zearalenone	Ochratoxin A	Ergot Alkaloids
Corn and Corn Products	Aflatoxins Fumonisins	Zearalenone	Vomitoxin	Ochratoxin A
Cottonseed, Peanuts, and Sorghum (milo) and their Products	Aflatoxins	Zearalenone	Ochratoxin A	
Rice and Rice Products	Zearalenone	Fumonisins Aflatoxins	Ochratoxin A	
Soybean and Soybean Products	Aflatoxins Zearalenone	Vomitoxin	Ochratoxin A	
Horse and Rabbit Feed	Fumonisins	Aflatoxins	Zearalenone	Vomitoxin Ochratoxin A
Swine Feed	Vomitoxin Zearalenone	Ochratoxin A	Aflatoxins Fumonisins	
Cattle and Poultry Feed	Aflatoxins	Zearalenone	Ochratoxin A	Vomitoxin Fumonisins
Dog and Cat Food	Vomitoxin Aflatoxins	Zearalenone	Ochratoxin A Fumonisins	

*The mycotoxin(s) mentioned in the Priority 1 column for a particular commodity should be analyzed for in almost every sample. The mycotoxin(s) mentioned in the Priority 2 column for a particular commodity should be analyzed for in most samples. The mycotoxin(s) mentioned in the Priority 3 column for a particular commodity should be analyzed for occasionally. The mycotoxin(s) mentioned in the Priority 4 column for a particular commodity should only be analyzed for on rare occasions.

Attachment B:

Advisory Levels for Vomitoxin (DON or Deoxynivalenol) in Animal Feeds.

1. 10 ppm vomitoxin on grains and grain by-products destined for ruminating beef and feedlot cattle older than 4 months and for chickens with the added recommendation that these ingredients not exceed 50% of the diet of cattle or chickens.

2. 5 ppm vomitoxin on grains and grain by-products destined for swine with the added recommendation that these ingredients not exceed 20% of their diet.

3. 5 ppm vomitoxin on grains and grain by-products destined for all other animals with the added recommendation that these ingredients not exceed 40% of their diet.

Attachment C:

Guidance for Fumonisins in Animal Feeds.

Animal or Class	Recommended Maximum Level of Total Fumonisins in Corn and Corn By-Products (ppm[1])	Feed Factor[2]	Recommended Maximum Level of Total Fumonisins in the Total Ration (ppm[1])
Horse[3]	5	0.2	1
Rabbit	5	0.2	1
Catfish	20	0.5	10
Swine	20	0.5	10
Ruminants[4]	60	0.5	30
Mink[5]	60	0.5	30
Poultry[6]	100	0.5	50
Ruminant, Poultry & Mink Breeding Stock[7]	30	0.5	15
All Others[8]	10	0.5	5

[1] Total fumonisins = $FB_1 + FB_2 + FB_3$.
[2] Fraction of corn or corn by-product mixed into the total ration.
[3] Includes asses, zebras and onagers.
[4] Cattle, sheep, goats and other ruminants that are $\geq$ 3 months old and fed for slaughter.
[5] Fed for pelt production.
[6] Turkeys, chickens, ducklings and other poultry fed for slaughter.
[7] Includes laying hens, roosters, lactating dairy cows and bulls.
[8] Includes dogs and cats.