U.S. DEPARTMENT OF AGRICULTURE
GRAIN INSPECTION, PACKERS AND STOCKYARDS ADMINISTRATION
FEDERAL GRAIN INSPECTION SERVICE
STOP 3630
WASHINGTON, D.C. 20250-3630

CHAPTER 1

GENERAL INFORMATION

1.1 PURPOSE

This handbook establishes official procedures for determining aflatoxin in grain and processed grain products, and certifying the official results.

1.2 BACKGROUND

Aflatoxin is a naturally occurring mycotoxin produced by two types of mold: *Aspergillus flavus* and *Aspergillus parasiticus*. *Aspergillus flavus* is common and widespread in nature and is most often found when certain grains are grown under stressful conditions such as drought. The mold occurs in soil, decaying vegetation, hay, and grains undergoing microbiological deterioration and invades all types of organic substrates whenever and wherever the conditions are favorable for its growth. Favorable conditions include high moisture content and high temperature. At least 13 different types of aflatoxin are produced in nature with aflatoxin B1 considered as the most toxic. While the presence of *Aspergillus flavus* does not always indicate harmful levels of aflatoxin, it does mean that the potential for aflatoxin production is present.

The Grain Inspection, Packers and Stockyards Administration (GIPSA) provides aflatoxin testing service as official criteria for corn, sorghum, wheat, and soybeans, as official criteria under the United States Grain Standards Act (USGSA). Testing is also provided for rice, popcorn, corn meal, corn gluten meal, corn/soy blend, and other processed products governed by the Agricultural Marketing Act of 1946 (AMA).

Aflatoxin testing services are available nationwide, upon request and for a fee, as either a qualitative (screening above or below a threshold determined by the customer) or as a quantitative (actual results in parts per billion) service using several different types of test kits approved by GIPSA.

To further assist the grain industry, GIPSA also provides, on a limited basis, a complex chemical testing method, High Performance Liquid Chromatography (HPLC), for aflatoxin. The HPLC testing procedure is performed, upon request, for Board Appeal inspections only. All official aflatoxin testing is performed as prescribed in the GIPSA Aflatoxin Handbook by authorized employees of GIPSA, or by licensed agency personnel.

Individuals wanting official aflatoxin testing should contact the nearest GIPSA, Federal Grain Inspection Service (FGIS)/field office or official agency service provider.

1.3 MANDATORY TESTING

The 1990 Farm Bill (Food, Agriculture, Conservation, and Trade Act of 1990, P.L. 101-624) amended section 5 of the USGSA to "... require that all corn exported from the United States be tested to ascertain whether it exceeds acceptable level of aflatoxin contamination, unless the contract for export between the buyer and seller stipulates that aflatoxin testing shall not be conducted."

1.4 CONTAMINATION LIMITS

The Food and Drug Administration (FDA) has established action levels for aflatoxin present in food or feed. These limits are established by the FDA to provide an adequate margin of safety to protect human and animal health.

FGIS and FDA, having certain related objectives in carrying out their respective regulatory and service functions, have an agreement Memorandum of Understanding (MOU) to assure the most effective possible system for identifying lots of grain, rice, pulses, and food products which exceed the FDA action levels of aflatoxin contamination. Under the provisions of the MOU, FGIS and officially delegated/designated agencies report to FDA, on a lot-by-lot basis, each lot (grain, rice, and processed products) that, during the course of an official sample-lot inspection, exceed the 20 ppb FDA action limit.

Listed below are the FDA action levels for aflatoxins in animal feeds.

20 ppb	For corn and other grains intended for immature animals (including immature poultry) and for dairy animals, or when its destination is not known;
20 ppb	For animal feeds, other than corn or cottonseed meal;
100 ppb	For corn and other grains intended for breeding beef cattle, breeding swine, or mature poultry;
200 ppb	For corn and other grains intended for finishing swine of 100 pounds or greater;
300 ppb	For corn and other grains intended for finishing (i.e., feedlot) beef cattle and for cottonseed meal intended for beef cattle, swine or poultry.

Aflatoxin-contaminated corn lots may be reconditioned under the certain conditions established by FDA. (See Attachment)

1.5 APPROVED TEST METHODS

FGIS has approved test kits for use at field testing locations. The Aflacard T20, AgraStrip, Agri-Screen, QuickTox, Re√eal, ROSA® P/N, Diachemix FPA, and SDI Myco✓ Aflatoxin test kits are approved for qualitative analysis of corn. The Aflatest, Fluoroquant, , Myco✓, RIDASCREEN Fast Aflatoxin SC, ROSA® Quantitative, Veratox, Veratox-AST Neogen NeoColumn, Re√eal SQ, and Flouroquant Afla IAC test kits provide quantitative analysis but can be used for qualitative results. High Performance Liquid Chromatography (HPLC) testing is reserved for quantitative testing at the Technical Services Division (TSD) only.

FGIS APPROVED TEST METHODS			
Method and Test Kit	Approved for		Test Kit Range
	Qualitative	Quantitative	
Aflacard T20 – (R-Biopharm Rhone)	X		20 ppb
AgraStrip – (Romer)	X		10 or 20 ppb
AgriScreen - (Neogen)	X		20 ppb
Diachemix® FPA – (Diachemix)	X		20 ppb
QuickTox - (Envirologix)	X		20 ppb
QuickTox-(2006) (Envirologix)	X		20 ppb
Re√eal for Aflatoxin – (Neogen)	X		20 ppb
SDI Myco✓ Aflatoxin Test Strips	X		20 ppb
ROSA® Aflatoxin P/N – (Charm Sciences, Inc.)	X		10 or 20 ppb
Re√eal for Aflatoxin SQ- (Neogen)	X		10 ppb
Aflatest – (Vicam)	X	X	5 - 100 ppb
Fluoroquant - (Romer)	X	X	5 - 100 ppb
Myco✓ - (Strategic Diagnostics Inc.)	X	X	5 - 80 ppb
RIDASCREEN Fast Aflatoxin SC - (R-Biopharm)	X	X	5 - 100 ppb
ROSA® Aflatoxin Quantitative (Charm Sciences, Inc.)	X	X	5 – 100 ppb
Veratox – (Neogen)	X	X	5 – 50 ppb
Veratox AST - (Neogen)	X	X	5 - 100 ppb
Neogen NeoColumn	X	X	5 – 100 ppb
Flouroquant Afla IAC (Romer)	X	X	5 – 100 ppb

NOTE: The test ranges are for performing an individual analysis with an undiluted sample extract. To obtain accurate results above the test kit range a supplemental analysis must be performed, permitted per test kit instructions only.

Kits Approved for Qualitative Analysis

Listed in the table below are the test kits that are commonly used for official qualitative aflatoxin analysis. Use the table to determine the appropriate test kit(s) to use for testing the listed grain.

GRAIN	TEST METHOD								
	Aflacard T20	AgraStrip	Agri-Screen	QuickTox	Re√eal	ROSA® P/N	Diachemix FPA	Myco✓ Aflatox	Re√eal SQ
Corn	X	X	X	X	X	X	X	X	X
Cracked Corn			(*)						
**** Two separate qualitative QuickTox test kits are approved for corn. One kit (Chapter 13) requires Methanol/Water as an extraction solvent and the other kit (Chapter 20) allows either Methanol/Water or Ethanol/Water as an extraction solvent.**									

NOTE: An X entered into a block denotes that the test kit has been evaluated and approved for the grain/commodity.

The symbol (*) entered into a block denotes that the test kit is under evaluation by TSD for the grain/commodity and is temporarily approved for official use.

Kits Approved for Quantitative Analysis

Listed in the table below are the test kits that are commonly used for official quantitative aflatoxin analysis. Use the table to determine the appropriate test kit(s) to use for testing the listed grain/commodity. For information concerning the testing of mixed grain, contact the GIPSA, Field Management Division, Policies and Procedures Branch.

GRAIN/ COMMODITY	TEST METHOD								
	Aflatest	Fluoroquant	Myco✓	Ridascreen Fast Aflatoxin SC	ROSA® Quantitative	Veratox	Veratox AST	Neo Column	Flouroquant Afla IAC
Corn	X	X	X	X	X	X	X	X	X
Sorghum	X	X	X	X	X		X		
Wheat	X	X		X	X		X		
Soybeans	X	X		X	X		X		
Corn Screenings	(*)				X		(*)		X
Corn Meal	X	X	X	X	X	X	X		
Corn Germ Meal	X			X	X		X		
Corn Gluten Meal	X			X	X	X	X		
Corn/Soy Blend	X	X	X	X	X	X	X	X	
Corn Gluten Feed	X								
Flaking Corn Grits	X	(*)			X		(*)		
Corn Flour	X			X	X		(*)		
Corn Bran	X						(*)		
Popcorn	X	X	X	X	X		X		
Milled Rice	X	X			X	X	X	X	
Rough Rice	X				X		(*)	X	
Brown Rice	X								
Rice Bran	X			X		X	X	X	
Cracked Corn	(*)	(*)	(*)	X	X		(*)		
Condensed Distillers Solubles	X								

GRAIN/ COMMODITY	TEST METHOD								
	Aflatest	Fluoroquant	Myco✓	Ridascreen Fast Aflatoxin SC	ROSA® Quantitative	Veratox	Veratox AST	Neo Column	Flouroquant Afla IAC
Distiller Dried Grains	X				X				
Distiller Dried Grains w/Solubles	X			X	X				X
Oats					X				
Rye					X				

NOTE: An X entered into a block denotes that the test kit has been evaluated and approved for the grain/commodity. The symbol (*) entered into a block denotes that the test kit is under evaluation by TSD for the grain/commodity and is temporarily approved for official use.

1.6 DISCLAIMER CLAUSE

The mention of firm names or trade products does not imply that they are endorsed or recommended by the U.S. Department of Agriculture over other firms or similar products not mentioned.

1.7 TESTING SERVICES

Applicants requesting aflatoxin testing must specify whether qualitative or quantitative testing service is desired. If qualitative analysis is requested, the applicant must specify the threshold (level) desired (e.g., 20 ppb). Three types of aflatoxin testing services are available as follows:

a. Submitted Sample Service.

Analysis based on a sample submitted by the applicant for service.

b. Official Sample-Lot Service.

Analysis based on an official sample obtained and analyzed by official personnel.

(1) Single lot inspection.

Samples may be obtained and tested on either an individual carrier basis or a composite sample basis (maximum of 5 railcars or 15 trucks per composite sample).

(2) Unit train inspection under the CuSum Loading Plan.

Unit trains are analyzed on a sublot basis for corn and sorghum and on a composite basis for other grains. Acceptable sublots must conform to contract specifications when "maximum" limits are specified.

When aflatoxin testing is required, samples may be obtained and tested on either an individual carrier basis or a sublot basis. The maximum size sublot for aflatoxin testing is 5 railcars for unit trains consisting of less than 200,000 bushels, or less than 50 railcars.

For unit trains consisting of 200,000 bushels or more, or 50 railcars or more, the maximum sublot size is 10 railcars.

(3) Export shiplots.

Export shiplots are analyzed on a sublot basis for corn and sorghum and on a composite basis for other grains. Acceptable sublots must conform to contract specifications when "maximum" limits are specified.

(4) Supplemental Testing.

Upon request, supplemental testing may be performed as follows:

Composite samples may be analyzed in addition to the sublot test for corn and sorghum shiplots or unit trains.

(5) Alternate Testing.

Upon request, alternate testing methods may be used, provided that the minimum testing requirements are met. Examples of alternate testing are as follows:

(a) Sublot testing may be used instead of composite sample analysis for grains routinely tested on a composite basis.

(b) Grain shipments may be tested on a component sample basis in lieu of the sublot basis under the provisions of Book III, Inspection Procedures. Components are combined and averaged to determine the sublot result. Acceptable quality will be based on the sublot result as compared to the contracted "maximum" specification.

c. Warehouse Sample-Lot Inspection Service.

Analysis based on an official sample obtained by a licensed warehouse sampler and analyzed by official personnel.

1.8 REVIEW INSPECTIONS

USGSA Title 7, Code of Federal Regulations (CFR) Part 800.125 and 800.135 permit a review inspection on either official grade/factors or official criteria. When requested, a review inspection for official grade or official factor and official criteria may be handled separately even though both sets of results are reported on the same certificate.

Review inspection services for aflatoxin are provided on either a new sample or the file sample in accordance with the regulations. Board appeal inspection services are limited to the analysis of file samples.

NOTE: Do not consider any excess grain sample as a "new sample" for the basis of testing.

For submitted samples, lots that are certified on an individual carrier basis, and composite samples representing multiple carriers, a maximum of three review inspections (reinspection, appeal, board appeal) may be performed on the original inspection service.

Only one field review (reinspection or appeal inspection) is permitted for shiplot, unit train, or lash barge material portions when testing is performed on a sublot basis. However, if the applicant requests a review of the entire lot, up to three review levels of service (reinspection, appeal, board appeal) may be obtained for each sublot included in the lot. Inspection results for each review level shall replace the previous inspection result.

a. Reinspection Service.

The laboratory providing original testing services also provides reinspection services. Applicants may request either qualitative or quantitative analysis unless the original test was quantitative. Then, only a quantitative analysis is available.

b. Appeal Inspection Service.

FGIS field offices provide appeal testing services for aflatoxin. Field offices not equipped to provide testing will make arrangements with another FGIS office to provide the most timely service possible. Applicants may request either qualitative or quantitative analysis unless the original or reinspection tests were quantitative. In that case, only a quantitative analysis is available. If samples are sent to a field office for analysis, write the words **"AFLATOXIN APPEAL"** in the "Remarks" section of the grain sample ticket and on the back of the mailing tag.

c. Board Appeal Inspection Services.

Board appeal inspection services are limited to the file sample and are provided by the Board of Appeals and Review (BAR) in Kansas City. Applicants may request either qualitative or quantitative analysis unless the original or reinspection tests were quantitative. In that case, only a quantitative analysis is available.

The HPLC method is also available for determining aflatoxin in Board appeal samples. The applicant must specify the HPLC method as the desired determination method. Otherwise, the Board appeal inspection will be conducted using the rapid method (test kits).

When sending samples to the BAR, write the words **"AFLATOXIN BOARD APPEAL"** in the "Remarks" section of the grain sample ticket and on the back of the mailing tag.

1.9 QUALITY ASSURANCE PROGRAM

The Technical Services Division (TSD), located at the Kansas City Technical Center, conducts an aflatoxin check sample program for all specified service points and laboratories providing testing services. TSD is responsible for preparing and distributing check samples each quarter to all official aflatoxin testing locations, analyzing check sample results, notifying field locations of any results indicating problems, and releasing a quarterly summary report to all participating laboratories. Field offices are responsible for routine supervision to assure all laboratories in their circuit provide accurate results. The TSD check sample program is designed to test the capability of the official system and to monitor the accuracy of approved testing methods. The check sample program provides limited performance information that can be used to supplement the routine supervision of official personnel performing testing services.

AFLATOXIN SAMPLING AND RECONDITIONING PROCEDURES

1. FDA RECONDITIONING GUIDELINES

The Food and Drug Administration (FDA) will permit reconditioning of aflatoxin-contaminated corn lots at export locations by mechanical cleaning under the following conditions:

a. Only one attempt at reconditioning is allowed. The analytical results from the reconditioned lot will be the final determination for disposition of the entire lot.

b. To assure proper reconditioning, the grain company must mechanically clean the lot at a rate not to exceed 50 percent of the rated cleaner capacity.

c. FGIS must oversee the cleaning process, sample the reconditioned lot (cleaned corn) using a diverter-type mechanical sampler, and analyze the samples for aflatoxin.

d. FGIS must sample the cleanings/screenings using the most practical procedures available and test the cleanings and/or screenings for aflatoxin contamination.

At interior locations, the local FDA office may modify the reconditioning procedures to provide for a cost effective process.

2. FGIS RESPONSIBILITIES

When positive lots are identified at export locations, field office managers (FOM) should work with the grain facility representatives and develop a standard operating procedure (SOP) for reconditioning aflatoxin-contaminated corn.

FOM's should review the SOP with local FDA officials before implementing the reconditioning process, unless instructed otherwise by FDA.

a. Export Locations.

At export locations, FGIS or official delegated state agency personnel, as applicable, are responsible for:

(1) Reporting actionable lots to the local FDA field office.

(2) Preserving the identity of actionable lots prior to reconditioning.

(3) Monitoring the reconditioning process at the grain facility.

(4) Sampling and testing reconditioned lots (cleaned corn and screenings) for aflatoxin. When sampling screenings, use the most practical method available to obtain a representative sample.

(5) Preserving the identity of reconditioned lots and screenings. (Screenings are not considered a reconditioned lot.)

(6) Reporting aflatoxin results of reconditioned lots and screenings to FDA.

(7) Completing a report of the reconditioning process. Include in the report the following information:

(a) Date Reconditioned.

(b) Grain Elevator/Location.

(c) Type of Sample/Carrier.

(d) Original Results.

(e) Reconditioned Whole Grain Results.

(f) Cleanings/Screenings Results.

(g) Size of Cleaner Screens used to Recondition the Lot.

(h) Elevator Set-up Information.

b. Domestic Locations.

FOM's servicing interior locations should contact the local FDA office servicing the area where the contaminated lot is located to discuss and determine responsibilities for managing the reconditioning process. Official agencies and affected grain companies are encouraged to participate in these discussions to facilitate the development of an SOP.

3. SAMPLE SIZE AND PREPARATION

Obtain the minimum sample size as directed in Chapter 3 of this handbook. If requested by the applicant, a larger sample size may be obtained.

Grind the entire corn sample obtained for aflatoxin testing and prepare three 500-gram subportions from the ground sample.

Sample Portion	Use
Test Portion	Original inspection service
File Portion	Review inpection service
FDA Portion	Retain for FDA analysis if results exceed 20 ppb.

When reconditioned lots are re-sampled in accordance with the FDA guidelines, a file portion is not required.

If FGIS original results for a reconditioned lot of corn or screenings exceed 20 ppb, the FDA sample portion will be used for any subsequent verification (by FDA) of results.

4. DISPOSITION POLICY

The grain industry must comply with FDA policy regarding the disposition of corn and screenings resulting from the reconditioning process. In general, disposition will occur as follows:

a. Cleanings/screenings may be used for animal feed if the aflatoxin content meets FDA feed guidelines. The screenings may not re-enter human food channels in any fashion.

b. Reconditioned (cleaned) corn with less than 20 ppb aflatoxin may be handled without restrictions. When the reconditioning process fails and the corn continues to exceed the 20 ppb level, disposition is based on current FDA policy.

Contact the local FDA office regarding other questions concerning specific disposition action.

United States Department of Agriculture
Risk Management Agency

August 2012

Aflatoxin Testing

Illinois Indiana Michigan Ohio

The impact of high levels of aflatoxin varies from a discount in price to the requirement to destroy the grain.

If you think your insured crop has aflatoxin, contact your crop insurance agent **before** you:

- harvest the grain;
- put the grain in storage; or
- deliver it for sale.

Your insurance provider will:

- take samples for testing; and
- submit them to an approved aflatoxin testing facility.

Because aflatoxin can worsen in storage, aflatoxin losses are only insurable if:

- the grain is tested at an approved testing facility **before** being moved into commercial or on-farm storage; or
- your insurance provider asks you to leave representative sample areas of the unharvested crop for taking samples for testing.

Losses not covered under the crop insurance policy include:

- losses due to increases in the aflatoxin level while in farm storage.
- losses that cannot be determined because proper testing was not completed.

Refer to the applicable Special Provisions of Insurance for the most current policy on testing.

Criteria for Approved Testing Facilities

Testing facilities meeting the criteria below can be considered “approved testing facilities” for crop insurance.

1. A certified facility must be able to perform quantitative tests on grain, itemizing results in parts per million (ppm) and parts per billion (ppb). Test kits used must be certified by the Grain Inspection, Packers and Stockyards Administration (GIPSA).

2. The facility must be a recognized commercial, government, or university testing lab that uses industry-recognized sample sizes, equipment, and procedures for testing aflatoxin.

3. The facility must be a disinterested testing facility unless RMA issues a written authorization to waive this requirement.

*Talk to your crop insurance provider for more information.

Approved Testing Facilities

Following is a list of certified testing facilities for aflatoxin in **Illinois, Indiana, Ohio, and Michigan.** This is not a complete list and should only serve as a guide.

Cairo Grain Inspection Agency, Inc.
4007 Sycamore Street
Cairo, IL 62914-1037
(618) 734-0689

Central Illinois Grain Inspection, Inc.
P.O. Box 3631
Bloomington, IL 61702-3631
(309) 827-7121

Champaign-Danville Grain Inspection Departments, Inc.
2002 N. Linview
Urbana, IL 61801
(217) 344-9306

Columbus Grain Inspection, Inc.
P.O. Box 157
Circleville, OH 43113-0157
(740) 474-3519

Decatur Grain Inspection, Inc.
3460 E. William, Suite 1
Decatur, IL 62521-1649
(217) 429-2466

Detroit Grain Inspection Service, Inc.
P.O. Box 176
Emmett, MI 48022-0176
(810) 395-2105

East Indiana Grain Inspection, Inc.
7020 North Walnut Street
Muncie, IN 47303-9796
(765) 744-6425

Eastern Iowa Grain Inspection and Weighing Service
1908 South Stark Street
Davenport, IA 52802-2429
(563) 322-7149

Frankfort Grain Inspection, Inc.
5233 N. County Road, 200E
Frankfort, IN 46041-8061
(765) 258-3624

J. W. Barton Grain Inspection Service, Inc.
2115 Barton Ave.
Owensboro, KY 42303-0180
(270) 683-0616

John R. McCrea Agency, Inc.
PO Box 166
Clinton, IA 52733-0166
(815) 589-9955

Keokuk Grain Inspection Service
2626 Belmont Rd.
Keokuk, IA 52632-9822
(319) 524-6482

Indianapolis Grain Inspection & Weighing Service
9332 E. 10th Street
Indianapolis, IN 46229-2505
(317) 899-2337

Kankakee Grain Inspection, Inc.
P.O. Box 328
Essex, IL 60935-0328
(815) 365-2268

Michigan Grain Inspection Services, Inc.
P.O. Box 465
Marshall, MI 490-0465
(269) 781-2711

Northeast Indiana Grain Inspection, Inc.
2405 W 1100 N
Decatur, IN 46733-8728
(260) 341-7496

Ohio Valley Grain Inspection, Inc.
P.O. Box 6532
Evansville, IN 47719-0532
(812) 423-9010

Springfield Grain Inspection, Inc.
1301 North Fifteenth Street
Springfield, IL 62702-4132
(217) 522-5233

Titus Grain Inspection, Inc.
1111 East County Road 800 North
West Lafayette, IN 47906-9006
(765) 497-2202

Tri-State Grain Inspection Service, Inc.
3906 River Road
Cincinnati, OH 45204-1066
(513) 251-6571

For More Information

See the GIPSA Web site: http://www.gipsa.usda.gov

Regional Contact

USDA/Risk Management Agency
Springfield Regional Office
3500 Wabash Avenue
Springfield, IL 62711-8287
Telephone: (217) 241-6600
Fax: (217) 241-6618
E-mail: rsoil@rma.usda.gov

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Visit our online fact sheets page at: http://www.rma.usda.gov/aboutrma/fields/il_rso/

FDA Mycotoxin Regulatory Guidance

A Guide for Grain Elevators, Feed Manufacturers, Grain Processors and Exporters

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1250 Eye St., N.W., Suite 1003, Washington, D.C., 20005-3922
Phone: (202) 289-0873 Fax: (202) 289-5388
Web Site: www.ngfa.org

August 2011

FDA Regulatory Guidance for Mycotoxins

A Guide for Grain Elevators, Feed Manufacturers, Grain Processors and Exporters

by National Grain and Feed Association

The Food and Drug Administration (FDA) has issued regulatory guidance for three mycotoxins that may be present in raw grains, feed ingredients and finished feed: aflatoxin, deoxynivalenol (vomitoxin), and fumonisin.

Types of Regulatory Guidance Issued by FDA

Under the regulatory framework adopted by FDA, it issues policy guidance or enforcement pronouncements in one of three forms:

- **Advisory Levels:** FDA uses "**advisory levels**" to provide guidance to the industry concerning levels of a substance present in food or feed that are believed by the agency to provide an adequate margin of safety to protect human and animal health.

  While FDA reserves the right to take regulatory enforcement action -- including seizure of the product -- on a case-by-case basis (particularly in egregious situations), enforcement is not the fundamental purpose of an advisory level.

  FDA has used advisory levels to provide guidance to the industry on **deoxynivalenol (vomitoxin)** and **fumonisin.**

- **Action Levels:** FDA uses "**action levels**" when it wishes to specify a precise level of contamination at which the agency is prepared to take regulatory action.

  FDA uses the term "guidelines" when referring to action levels because of a May 1987 ruling by the U.S. Court of Appeals for the District of Columbia Circuit. The court ruled that it was improper to use "action levels" as mandatory regulatory enforcement limits unless they have been developed through public notice-and-comment rulemaking. Thus, action levels are a signal to the industry that FDA believes it has the scientific data to support regulatory and/or court action if a toxin or contaminant is present at levels exceeding the action level if the agency chooses to do so. In this respect, it is important to

note that FDA's regulatory policy provides flexibility to its regional and district offices on whether and when to take enforcement action.

FDA has used action levels to convey its regulatory policy to the industry on **aflatoxin**.

- **Regulatory Limits:** FDA issues "regulatory limits" for the presence of toxins or contaminants that have been established after issuing valid regulations under the public notice-and-comment rulemaking procedures set forth in the Administrative Procedures Act.

  Generally, courts will find a per se violation of the law if the regulatory limits in the regulations are exceeded; in these cases, FDA does not bear the burden of proof in demonstrating that the specific level of contamination in food or feed causes it to be injurious to human or animal health, and therefore adulterated.

  FDA currently has **not** established regulatory limits for mycotoxins found in food or feed, although it has stated its intent to eventually establish such limits for aflatoxin.

Significance of FDA Regulatory Guidelines in Contracts

In addition to their legal consequences, FDA regulatory guidelines are important because they often are referenced in industry contracts to define the term "merchantable quality."

For instance, language similar to the following often is present in commercial contracts between buyers and sellers of raw grains and animal feed:

> *"**Merchantable Quality:** All grain (feed) delivered under this contract shall be of merchantable quality, unadulterated and unrestricted from movement in interstate commerce within the meaning of the **federal Food, Drug and Cosmetic Act**, Environmental Protection Agency tolerances, the U.S. Grain Standards Act and applicable state law." [Emphasis added.]*

In complying with the federal Food, Drug and Cosmetic Act, for most purposes grain and feed containing naturally occurring contaminants are considered to be "adulterated" within the meaning of the law if they are deemed by FDA to be injurious to human or animal health. The following is the relevant section of the federal Food, Drug and Cosmetic Act that applies to such situations:

> *"[A commodity is deemed to be adulterated] if it bears or contains any poisonous or deleterious substance which may render it injurious to health; **but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health**." [Emphasis added.]* [21 U.S.C. Section 342(a)(1).]

Importantly, the term "food" is synonymous with "feed" within the meaning of the federal Food, Drug and Cosmetic Act.

FDA's Action Levels for Aflatoxin

FDA has established the following action levels for aflatoxins present in human food, animal feed and animal feed ingredients as indicated in Chart 1.

Chart 1: FDA Action Levels for Aflatoxin in Human Food, Animal Feed and Animal Feed Ingredients

Intended Use	**Grain, Grain By-Product, Feed or other Products**	**Aflatoxin Level** [parts per billion (p.p.b.)]
Human consumption	Milk	0.5 p.p.b. (aflatoxin M1)
Human consumption	Foods, peanuts and peanut products, brazil and pistachio nuts	20 p.p.b.
Immature animals	Corn, peanut products, and other animal feeds and ingredients, excluding cottonseed meal	20 p.p.b.
Dairy animals, animals not listed above, or unknown use	Corn, peanut products, cottonseed, and other animal feeds and ingredients	20 p.p.b.
Breeding cattle, breeding swine and mature poultry	Corn and peanut products	100 p.p.b.
Finishing swine 100 pounds or greater in weight	Corn and peanut products	200 p.p.b.
Finishing (i.e., feedlot) beef cattle	Corn and peanut products	300 p.p.b.
Beef, cattle, swine or poultry, regardless of age or breeding status	Cottonseed meal	300 p.p.b.

The following additional policies and legal provisions concerning aflatoxin also are important:

- **FDA Blending Policy:** Importantly, with respect to aflatoxin, FDA currently generally does **not** permit corn containing aflatoxin to be blended with uncontaminated corn to reduce the aflatoxin content of the resulting mixture to levels acceptable for use as human food or animal feed. However, on occasion FDA has relaxed its "no-blending" policy in

response to widespread outbreaks of aflatoxin or in response to state-specific requests to address local outbreaks (as occurred with the states of Iowa and Missouri in 2005).

FDA technically does **not** consider mixing of corn containing a level of aflatoxin up to the action level considered to be "acceptable" for a given species to be a violation of its "no-blending" policy. For example, since corn containing aflatoxin of up to 300 parts per billion (p.p.b.) that is intended to be fed to mature beef cattle does not violate FDA's action level, technically any corn containing less than 300 p.p.b. may be mixed and fed to that species without violating the "no-blending" policy. But mixing corn containing up to 200 p.p.b. with uncontaminated corn (less than 20 p.p.b.) so as to reduce the level of aflatoxin in the resulting mixture to 50 p.p.b. so it could be fed to laying hens constitutes a violation of the "no-blending" policy since a 100 p.p.b. action level applies to mature poultry. Likewise, mixing corn containing up to 600 p.p.b. aflatoxin with lower levels in an attempt to reduce the level in the resulting mixture to 300 p.p.b. for feeding to feedlot cattle is not permitted, since a 600 p.p.b. aflatoxin action level does not apply to any species.

- **Export Provisions:** Under Section 801(d) of the federal Food, Drug and Cosmetic Act, corn intended for export that contains aflatoxin at levels greater than those specified in FDA's action levels is permitted to be shipped in interstate commerce so long as the corn meets each of the following conditions:

  1) It is in accordance with the specifications of the foreign buyer;

  2) The aflatoxin levels present in the shipment do not conflict with the laws of the country for which it is intended for export;

  3) The shipment is "labeled on the outside of the shipping package that it is intended for export."FDA considers inclusion of a specific statement that the shipment is "intended for export" on the bill-of-lading or shipping documents to suffice for shipments of bulk commodities; and

  4) The shipment is not diverted for sale in domestic commerce. FDA's policy specifically states that "export is not available as a means of salvaging corn in domestic commerce."

  FDA has said that the first two requirements must be met by the exporter being able to provide FDA, upon demand, with a copy of the importing country's laws and implementing regulations and interpretive statements, as well as appropriate documentation of each shipment's conformance to the importing country's legal requirements. Exporters that anticipate using the "export exemption" should obtain such documentation from the responsible government authorities of the importing country stating that the grain complies with the laws of that country.

- **Detoxification Policy for Aflatoxin:** Currently, there is no FDA- approved nor sanctioned method for "detoxifying" – through ammoniation or other means – corn that contains aflatoxin. FDA has approved ammoniation as a method for detoxifying

cottonseed, as specified within the agency's compliance policy guide – ***Compliance Policy Guide Sec. 670.500 - Ammoniated Cottonseed Meal - Interpretation of 21 CFR 573.140.***

In 1992, the National Grain and Feed Association requested that FDA and the U.S. Department of Agriculture's Federal Grain Inspection Service respond to a series of questions to further amplify on their respective policies pertaining to aflatoxin. On July 30, 1992, the NGFA's publication ***FOCUS*** provided a report on the two agencies' responses. That publication is attached as an appendix to this "***FDA Regulatory Guidance for Mycotoxins."***

Also attached as an appendix to this "***FDA Regulatory Guidance for Mycotoxins"*** is the FDA's compliance policy guide for aflatoxins in animal feeds – ***Compliance Policy Guide Sec. 683.100 – Action Levels for Aflatoxins in Animal Feeds.***

FDA's Advisory Levels for Deoxynivalenol (Vomitoxin)

FDA first established advisory levels for grain and grain products containing deoxynivalenol (vomitoxin) in 1982.

On Sept. 16, 1993, in response to the outbreak of mold in a significant portion of the wheat crop, FDA revised its advisory levels for vomitoxin in several important respects:

- FDA eliminated its previous 2-part-per-million (p.p.m.) advisory level that applied to vomitoxin present in raw wheat and wheat byproducts for all species. Instead, FDA said it would rely upon the purchasing specifications and cleaning practices used by millers and processors to reduce the vomitoxin level so that the level present in finished wheat products, such as flour, germ and bran, does not exceed 1 p.p.m.

- FDA increased its advisory levels for vomitoxin present in grain and grain products intended for animal feed. Previously, the agency had a single advisory level for animal feed – 4 p.p.m., with the additional recommendation that such feed not exceed 10 percent of the ration for swine and pet diets, nor more than 50 percent of the ration for beef cattle, other ruminants and poultry. Further, the advisory level applied only to wheat and wheat products.

  When revising the vomitoxin advisory level in 1993, FDA expanded the scope to apply to all grains and grain products. In addition, the agency increased its advisory levels for commodities intended as feed.

On June 29, 2010, FDA further revised its advisory levels for vomitoxin – increasing the level for grain and grain co-products destined for beef cattle, and establishing for the first time a separate level for dairy cattle.

The agency's action came in response to a joint letter from the National Grain and Feed Association and American Feed Industry Association. The two organizations requested that FDA reexamine and update its vomitoxin advisory levels to reflect more recent scientific studies that

demonstrated that higher levels of DON could be fed to certain species while still fully protecting human and animal health.

Chart 2 lists FDA's current vomitoxin advisory levels for commodities intended for use in human food and animal feed. The second figure within parentheses in the right-hand column (if listed) is the advisory level for the species' complete diet.

Chart 2: FDA Advisory Levels for Vomitoxin

Intended Use	**Grain or Grain By-Products**	**Vomitoxin Levels in Grains or Grain By-Products and Complete Diet **** [parts per million (p.p.m.)]
Human Consumption	Finished wheat products	1 p.p.m.
Swine	Grain and grain by-products not to exceed 20% of diet	5 p.p.m. (1 p.p.m.)**
Chickens	Grain and grain by-products not to exceed 50% of diet	10 p.p.m. (5 p.p.m.)**
Ruminating beef and feedlot cattle older than 4 months	Grain and grain by-products *	10 p.p.m. (10 p.p.m.)**
Ruminating dairy cattle older than 4 months	Grain and grain by-products not to exceed 50% of diet *	10 p.p.m. (5 p.p.m.)**
Ruminating beef and feedlot cattle older than 4 months, and ruminating dairy cattle older than 4 months	Distillers grains, brewers grains, gluten feeds, and gluten meals *	30 p.p.m. (10 p.p.m. beef/feedlot)** (5 p.p.m. dairy)**
All other animals	Grain and grain by-products not to exceed 40% of diet	5 p.p.m. (2 p.p.m.)**

* 88 percent dry matter basis

** Complete diet figures shown within parentheses

FDA Guidance to Industry on Fumonisin

FDA on November 9, 2001 issued a "final guidance for industry" document containing recommended maximum levels of fumonisins "that FDA considers adequate to protect human and animal health, and that are achievable in human foods and animal feeds with the use of good agricultural and good manufacturing practices."

Fumonisins are mycotoxins produced by molds.

Importantly, the FDA "final guidance" does not constitute action levels or enforceable regulatory limits. FDA said it was issuing the guidance as a "prudent public health measure" while it further studies the potential human health risk associated with fumonisins and develops a long-term risk-management policy and program for controlling fumonisins in human foods and animal feeds. FDA said fumonisins "are associated with a variety of adverse health effects in livestock and experimental animals." The agency noted that "currently, there is no direct evidence that fumonisins cause adverse health effects in humans because available studies demonstrate only inconclusive associations between fumonisins and human cancer, (but) based on the wealth of available information on the adverse animal health effects associated with fumonisins, human health risks associated with exposure to fumonisins are possible."

For corn and corn products intended for human food, the FDA-recommended maximum levels for total fumonisins (FB1, FB2 and FB3) are shown in Chart 3.

For animal feeds, FDA-recommended maximum levels for total fumonisins (FB1, FB2 and FB3) are shown in Chart 4. The second figure within parentheses in the right-hand column (if listed) is the advisory level for the species' complete diet.

FDA said it will use risk-exposure information obtained at future national and international conferences and workshops to determine whether to establish tolerances, regulatory limits or action levels for fumonisins in human food and animal feed at some point in the future.

Chart 3: FDA Guidance Levels for Fumonisin for Corn and Corn Products Intended for Human Food

Product	Total Fumonisins (FB1, FB2 and FB3) [parts per million (p.p.m.)]
Degermed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of <2.25 %, dry weight basis)	2 p.p.m.
Cleaned corn intended for popcorn	3 p.p.m.
Whole or partially degermed dry milled corn products (e.g. flaking grits, corn grits, corn meal, corn flour with 4 fat content of ≥ 2.25% dry weight basis)	4 p.p.m.
Dry milled corn bran	4 p.p.m.
Cleaned corn intended for masa production	4 p.p.m.

Chart 4: FDA Guidance Levels for Fumonisin in Animal Feed		
Class of Animal	**Grain or Grain By-Products**	**Total Fumonisins (FB1, FB2 and FB3) Levels in Grain or Grain By-Products and (Complete Diet)** [parts per million (p.p.m.)]
Equids and Rabbits	Corn and corn by-products not to exceed 20% of the diet**	5 p.p.m. (1 p.p.m.)
Swine and Catfish	Corn and corn by-products not to exceed 50% of the diet**	20 p.p.m. (10 p.p.m.)
Breeding Ruminants, Breeding Poultry and Breeding Mink*	Corn and corn by-products not to exceed 50% of the diet**	30 p.p.m. (15 p.p.m.)
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 p.p.m. (30 p.p.m.)
Poultry being Raised for Slaughter	Corn and corn by-products not to exceed 50% of the diet**	100 p.p.m. (50 p.p.m.)
All Other Species or Classes of Livestock and Pet Animals	Corn and corn by-products not to exceed 50% of the diet**	10 p.p.m. (5 p.p.m.)
*Includes lactating dairy cattle and hens laying eggs for human consumption **Dry weight basis		

APPENDIX

FOCUS

Volume 10, Number 10, July 30, 1992

FDA, FGIS Provide Guidance on Handling Corn Containing Aflatoxin

*[Editor's Note: This edition of **FOCUS** contains a condensed version of the responses received from the Food and Drug Administration and Federal Grain Inspection Service to questions submitted by the NGFA seeking clarification and guidance on the two agencies' policies and procedures applying to commodities containing aflatoxin. The questions were submitted by the NGFA in late April after the two federal agencies issued a joint letter on April 22 reminding the industry about the prohibition on blending corn containing aflatoxin exceeding 20 parts per billion with uncontaminated corn for the purpose of reducing the aflatoxin content of the resulting mixture. FGIS responded to the questions on April 29; FDA responded to a more extensive list of questions on July 13.*

This condensed version of the two agencies' responses contains the information most pertinent to country, terminal and export elevator and processing operations. The NGFA is providing this information to further assist the industry in its ongoing aflatoxin-compliance efforts. In recognition that aflatoxin compliance affects all sectors of the industry, this article is divided into three parts. Part I contains information applicable to domestic grain. Part II contains information applicable to export grain. And Part III contains information applicable to all grain. NGFA members wishing to obtain the complete set of responses by the two agencies should contact the Association's office at (202) 289-0873.]

* * *

PART I: DOMESTIC GRAIN

1. *NGFA:* What are FDA's general rules governing aflatoxin present in corn in domestic commerce:

FDA: When aflatoxin is found at violative levels in corn in domestic commerce (see accompanying chart), FDA will take appropriate steps to ensure that the product is either: 1) legally diverted for use as animal feed; 2) is redesignated for non-food/non-feed use; or 3) is disposed of. However, food or feed offered for sale in domestic commerce may not be exported if the food or feed is adulterated due to aflatoxin contamination. (*Emphasis added.*)

FDA Regulatory Policy on Aflatoxin

FDA's "Aflatoxin Regulation Policy for Food and Feed" states that the agency **can support enforcement action** against interstate shipments of corn **exceeding** the following levels of aflatoxin:

If corn is destined for use for...	**Then FDA can support enforcement action if aflatoxin levels...**
Human food Feed for immature livestock and poultry (such as broilers) Feed for dairy animals Destination unknown	Exceed 20 p.p.b.
Breeding cattle Breeding swine Mature poultry (such as laying hens)	Exceed 100 p.p.b.
Finishing swine (weighing 100 pounds or more)	Exceed 200 p.p.b.
Finishing beef cattle	Exceed 300 p.p.b.

2. ***NGFA:*** **If the corn has been introduced in interstate commerce for unrestricted use, and it is later found to contain aflatoxin exceeding 20 p.p.b., can it be diverted to approved feed uses?**

FDA: Corn introduced in interstate commerce for unrestricted use and found to exceed 20 p.p.b. aflatoxin can be diverted to appropriate feed use provided that the occurrence of aflatoxin is due to unavoidable circumstances (e.g., not resulting from the blending of violative product.)

3. ***NGFA:*** **Because of the severe drought that reduced the size of the 1988 corn crop, FDA authorized domestic elevators to blend corn containing aflatoxin under carefully prescribed conditions (i.e., the blending had to be done under FDA supervision and the resulting mixture could only be sold for feed uses.) Was this blending authority limited to the 1988 crop only? Or does it apply to all crop years?**

FDA: Although such blending is illegal under the federal Food, Drug and Cosmetic Act, the memorandum (issued by FDA on Oct. 4, 1988) stated that the agency had decided to exercise its enforcement discretion to refrain from objecting to this practice when carried out under certain prescribed conditions for corn to be used only as animal feed (the agency has never permitted such blending for aflatoxin-contaminated corn to be used as human food.) FDA's action was taken in response to higher-than-normal levels of aflatoxin in the 1988 corn harvest caused by severe climate conditions that occurred in many corn-producing states that summer to provide an acceptable means of using corn that could not otherwise be lawfully shipped in interstate commerce. This policy on blending addressed only corn from the 1988 harvest and does not apply to all crop years.

4. ***NGFA:*** **What are the objectives of FDA's surveillance program concerning aflatoxin for domestic grain?**

FDA: The objectives...are to collect and analyze samples of foods and feeds to determine compliance with FDA regulatory levels; to remove from interstate commerce those foods and feeds that contain aflatoxin at concentrations judged to be of regulatory significance; and to determine the awareness of potential problems and control measures employed by distributors, manufacturers or processors. The monitoring efforts are directed at regions and commodities that historically have a high level of aflatoxin contamination, or in response to new information on contamination problems developing in regions or commodities not normally affected....Each FDA district office is provided a sampling plan and a quota of samples to be collected under the compliance program. The number of each commodity sampled is determined by the district office....FDA conducts inspections of various facilities as a follow-up procedure when violative levels of aflatoxins are detected in samples originating from that facility.

PART II: EXPORT GRAIN

1. ***NGFA:*** **Please review the meaning of the so-called export exemption found in Section 801(e) of the federal Food, Drug and Cosmetic Act applying to corn containing aflatoxin.**

FDA: This section of the Act states that: "A food, drug, device or cosmetic intended for export shall not be deemed to be adulterated or misbranded if it: 1) accords to the specifications of the foreign purchaser; 2) is not in conflict with the laws of the country to which it is intended for export; 3) is labeled on the outside of the shipping package that it is intended for export; and 4) is not sold or offered for sale in domestic commerce.

If corn in domestic commerce (or offered for sale in domestic commerce) is found to contain aflatoxin above acceptable levels, it is not eligible for the exemption provided for export products.

To be eligible for the (export) exemption, the exporter must be able to demonstrate that the product meets the requirements of the foreign buyer. To demonstrate such compliance, the exporter must be able to provide, upon demand by FDA, a copy of the foreign country's laws, regulations and statements of interpretation of them, where applicable, as well as the specific requirements of the contract with the foreign buyer, together with appropriate documentation of each shipment's conformance to these laws, regulations and specifications. FDA then will determine if the exporter is in compliance. As further evidence of compliance, the exporter should obtain documentation from the responsible government

authorities of the importing country stating that the corn complies with the laws of that country.

For bulk commodities, the requirement that food be labeled on the outside of the shipping package can be met by indicating such information in the shipping documents.

Food initially intended for export may be sold in domestic commerce so long as the food complies with the requirements for domestic use. A domestic shipper can market the product for use as feed in a specific animal species when the product exceeds acceptable levels for human use but complies with the aflatoxin level for the specific animal feed use, provided that the shipper notifies the buyer in writing that the product is not for human consumption and details the reasons.

If an exporter decides to divert corn above the 20 p.p.b. aflatoxin level to a legal domestic market, FDA does not require the exporter to document the legality of the action, but the exporter should do so for its own protection.

2. ***NGFA*: What operational procedures do FGIS and FDA advise export elevators take when detecting corn containing aflatoxin that exceeds 20 p.p.b.?**

FDA: Segregate contaminated corn from uncontaminated corn when aflatoxin levels exceeding 20 p.p.b. are detected. Such actions will permit the elevator operator to dispose of the contaminated corn in an acceptable manner without jeopardizing the sale and use of the uncontaminated corn.

FGIS: FGIS provides official results on lots or sublots tested for the presence of aflatoxin. When original test results exceed the 20 p.p.b. actionable limit, the applicant for inspection is notified of their options with regard to review inspection procedures. FGIS does not provide any information or specific guidance concerning the disposition of the actionable lot.

3. ***NGFA*: Under what circumstances can an elevator blend corn containing aflatoxin exceeding 20 p.p.b. with uncontaminated corn under the "export exemption" of Section 801(e) of the federal Food, Drug and Cosmetic Act? What actions can an export elevator take with a sublot that exceeds 20 p.p.b.?**

FDA: Assuming the question pertains to corn for human use, an export elevator may blend corn containing aflatoxin above 20 p.p.b. with uncontaminated corn only if the resulting mixture is intended for export, and such action is consistent with Section 801 of the Act. Once the corn has been blended, the resulting mixture is no longer acceptable for human use domestically.

4. ***NGFA*: Under the "export exemption," is an export elevator allowed to blend corn that exceeds 20 p.p.b. aflatoxin with uncontaminated corn (less than 20 p.p.b.) for the purpose of reducing the aflatoxin content of the resulting mixture if: 1) the contract with the foreign buyer does not expressly prohibit blending and the specific aflatoxin content of the resulting mixture is within contract specifications of that buyer; and 2) blending is not expressly prohibited by the laws of the importing country?**

FDA: If the elevator can document that it meets the conditions of the contract, then such conformance will be acceptable to FDA when determining the elevator's compliance with the provisions of Section 801(e).

5. ***NGFA*: If an elevator chooses to use the "export exemption," does the burden of proof for demonstrating compliance with the law shift from FDA to the elevator? If so, what kinds of documentation and/or records should the elevator maintain?**

FDA: If an elevator operator (exporter) chooses to take advantage of the provisions of Section 801(e) of the Act, it is the elevator operator's (exporter's) responsibility to adequately demonstrate to FDA by appropriate documentation that the product complies with all provisions of Section 801(e) and is therefore eligible for export.

6. ***NGFA*: If FGIS detects a sublot of corn being loaded aboard a vessel that exceeds FDA's 20 p.p.b. action level, what specific procedures does it take?**

FGIS: The office performing the official inspection immediately reports by phone all sublot results exceeding 20 p.p.b. to the FDA district office nearest to the location....The telephone report is promptly confirmed in writing to the FDA district office and FGIS headquarters.

7. ***NGFA*: Does the shipping export elevator have the right to call for a reinspection or appeal inspection of the aflatoxin test result from FGIS?**

FGIS: Yes. The applicant has the option to request a reinspection, appeal, or Board of Appeals inspection.

8. ***NGFA*: If the shipping export elevator calls for a reinspection, and subsequently for an appeal inspection, does FGIS immediately notify FDA of the results of the initial inspection, or wait until the reinspection or appeal inspection results are known?**

FGIS: When a review inspection (reinspection, appeal or Board appeal) is requested, FDA is not notified until the review inspection results are completed. If the result of the review inspection exceeds 20 p.p.b., FGIS notifies FDA.

9. ***NGFA*: Once it is alerted by FGIS about an inspection result that exceeds 20 p.p.b. at a given elevator location, or if improper blending practices are detected, what procedures does FDA implement?**

FDA: FDA will take appropriate action against the grain as a violation of the Food, Drug and Cosmetic Act. Seizure of the grain is the preferred course of action...to remove the goods from their intended market. FDA may rely on FGIS analytical results when recommending this course of action. In addition, FDA may conduct a follow-up inspection and collect additional samples for further regulatory consideration.

Under certain circumstances, FDA may choose to proceed with injunction or prosecution of the responsible persons.

10. ***NGFA*: Does FDA retest the suspect lot for aflatoxin? Does it draw a new sample, or rely upon the samples previously obtained by FGIS?**

FDA: Historically, FDA has taken its own sample for analysis. However, FDA and FGIS are exploring ways of reducing time and resources needed for inspection and enforcement. As a part of this effort, the agencies are studying the feasibility of sharing samples and relying on each other's analyses. FDA's normal practice has been to perform two separate analyses on a shipment of food before deciding to take legal action.

PART III: General Questions Applicable to Domestic and Export Grain

1. ***NGFA*: What, if any research is being done to reduce the variability of aflatoxin test results?**

FDA: There are at least three types of errors associated with obtaining an accurate estimate of the true concentration of aflatoxin in a given lot of foodstuff. They are: 1) sampling; 2) sample preparation; and 3) the analysis. Of these, the largest relative errors encountered are associated with sampling. There is a need to continuously emphasize the importance of obtaining a representative sample for analysis from a given lot.

2. ***NGFA*: What, if any, research is underway to substantiate the carcinogenicity of aflatoxin? Is FDA still considering initiating a rulemaking to propose aflatoxin tolerances, rather than continuing to rely on action levels?**

FDA: A number of human epidemiological studies beginning in the 1970s have shown a positive correlation between aflatoxin contamination levels in foods and incidence of liver cancer. The presence of hepatitis virus also may be critical. These studies do not definitively prove the causative role of aflatoxin in human liver cancer, but taken together they strongly indicate a need for FDA regulatory concern and control of aflatoxin levels in food.

FDA last performed a quantitative risk assessment for aflatoxin in 1979. Since that time, several new scientific studies, particularly in epidemiology, have been published. We are currently updating our risk assessment for aflatoxin to reflect the new information. After we have updated our risk assessment, we will determine what, if any, changes are necessary in our regulatory policy on aflatoxin, including whether we will propose to establish a formal tolerance for this substance.

Food and Drug Administration Compliance Policy Guide

Compliance Policy Guide Sec. 683.100 - Action Levels for Aflatoxins in Animal Feeds

BACKGROUND:

Aflatoxins are toxic by-products of mold growth on certain agricultural commodities. Since their discovery in the early 1960's, aflatoxins have been shown to be carcinogenic to *laboratory test animals.* In 1969, FDA set an action level for aflatoxins at 20 p.p.b. for all foods, including animal feeds, based on FDA's analytical capability and the agency's aim of limiting aflatoxin exposure to the lowest possible level.

*Animal feeding studies conducted in the 1970's and 1980's, however, demonstrated that levels of aflatoxins above 20 p.p.b. could be fed to certain food-producing animals without presenting a danger to the health of these animals or posing a risk to consumers of food derived from the exposed animals. On the basis of these scientific studies, the agency revised its action level in 1982 to 300 p.p.b. for aflatoxins in cottonseed meal intended for use as a feed ingredient for beef cattle, swine, and poultry; in 1989 to varying levels for corn intended for use as a feed ingredient for subgroups of the same animals. In 1990, FDA issued guidance that aflatoxins in peanut products (i.e., peanuts, peanut meal, peanut hulls, peanut skins, and ground peanut hay) intended for use as a feed ingredient are no more toxic to these same subgroups of animals than is aflatoxin in corn.

These changes in the action levels were premised on two underlying principles: (1) that FDA must show that an amount of aflatoxins in the feed of a particular animal will support a charge of adulteration under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, and (2) that FDA can confirm the ultimate use of the animal feed ingredient in question.

Action levels are not binding on the courts, the regulated industry, or the agency (see: 55 FR 20782, May 21, 1990). There may be situations where circumstances warrant enforcement action at levels below an action level or where enforcement action is not warranted even though an action level is exceeded.*

REGULATORY ACTION GUIDANCE:

When samples of import or domestic shipments are analyzed in accordance with applicable methods of the current Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), contact Case Guidance Branch (HFV-236) if:

1) The original and check analysis show the presence of aflatoxins above the applicable action level, as follows:

    - *- 300 p.p.b. for corn and peanut products intended for finishing (i.e., feedlot) beef cattle;

- 300 p.p.b. for cottonseed meal intended for beef cattle, swine, or poultry (regardless of age or breeding status);

- 200 p.p.b. for corn or peanut products intended for finishing swine of 100 pounds or greater;

- 100 p.p.b. for corn and peanut products intended for breeding beef cattle, breeding swine, or mature poultry;

- 20 p.p.b. for corn, peanut products, and other animal feeds and feed ingredients, but excluding cottonseed meal, intended for immature animals;

- 20 p.p.b. for corn, peanut products, cottonseed meal, and other animal feeds and feed ingredients intended for dairy animals, for animal species or uses not specified above, or when the intended use is not known;*

  and

2) The identity of aflatoxin B1 is confirmed by chemical deriviative formation.

Before consulting with HFV-236, determine, if possible, the intended use of the feed or feed ingredient (animal species, age, etc.) as well as the proportion of the ingredient in the mixed feed (number of pounds per ton). If information concerning the intended use is not available, consult with CVM when the presence of aflatoxins has been confirmed at levels above 20 p.p.b.

In considering enforcement action for aflatoxin levels below an action level, consideration must be given to the agency's ability to support the adulteration charge. Discussions of possible enforcement actions at levels below an action level should include consideration of all compelling reasons for pursuing the action. Similar consideration is required if a field office believes that enforcement action at levels above an action is not warranted.

Material between asterisks is new or revised

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Aflatoxins in Corn

Aflatoxins are a group of chemicals produced by certain mold fungi. These fungi, *Aspergillus flavus* and *Aspergillus parasiticus,* can be recognized by yellow-green or gray-green, respectively, on corn kernels, in the field or in storage (Figure 1). Although aflatoxins are not automatically produced whenever grain becomes moldy, the risk of aflatoxin contamination is greater in damaged, moldy corn than in corn with little mold. Aflatoxins are harmful or fatal to livestock and are considered carcinogenic (cancer-causing) to animals and humans. In the Midwest, aflatoxin levels are highest during hot, dry summers. The prime conditions for the fungus to produce toxin are warm August nights in a period of drought.

In high-risk years, aflatoxin screening may be done at the elevator or where the corn is marketed. Rapid, on-site tests can determine the possible presence of aflatoxin, but they do not provide specific quantitative results. The toxins are produced inside the corn kernels and their presence can be determined only by specific analytical tests. Because aflatoxin levels can vary greatly from kernel to kernel, sampling the load, bin, or unit of grain is the most critical step in determining actual levels of aflatoxin.

How to sample corn for aflatoxin testing

Because aflatoxin does not occur uniformly through a lot of grain and is usually localized in a small area, the best approach is to make a composite sample consisting of subsamples from every part of a load, bin, or unit of corn. The recommended procedure is to sample periodically from a moving stream, combining these samples to obtain a composite sample of at least 10 lb of corn. An alternative is to sample with a probe through a storage unit (five perimeter samples and one center sample for each 6 feet of bin height). In the field, sample individual fields or parts of fields separately. Grain in trucks can probed in the same way to collect samples of at least 5 lb per truck.

Fields that vary in cropping history, tillage practices, planting date, soil type, or hybrid can differ greatly in aflatoxin vulnerability. Sample a minimum of 10 to 30 locations within each field. To reach the same sampling frequency as testing grain in trucks, collect one sample (5-10 lb) for about every 5 acres. Immediately dry samples to 12–14 percent moisture to prevent aflatoxin development during transit or storage. High-moisture samples should be frozen and delivered to the laboratory in the frozen state. Dried samples maintain their quality best if shipped in cloth or paper containers.

Figure 1. Aspergillus ear rot symptoms on corn ear (left) and growth of *Aspergillus flavus* in artificial culture (right).

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How to test for aflatoxin

Currently, two types of screening tests are available: blacklight tests and commercial test kits. The blacklight (also called ultraviolet light) test is a visual inspection for the presence of a greenish gold fluorescence under light at a wavelength of 365 nm (nanometers). The greenish gold fluorescence looks like a firefly glow. More than four glowing particles per 5-pound sample (before grinding) indicate a likelihood of a +20 ppb (parts per billion) level of aflatoxins. However, remember that this test is an initial screening for the presence of aflatoxin and the results should be verified by laboratory analysis. If there are less than four glowing particles per 5 lb sample, this does not guarantee that the sample is free of aflatoxins.

Commercial test kits with immunoassay or ELISA techniques are available for on-site tests for aflatoxin. Immunoassay analysis is based on the detection of specific proteins found in aflatoxins using antibodies to identify these proteins. The tests are very specific for aflatoxin, but they require operator training and practice to be accurate. Some tests determine only the presence or absence of aflatoxin; others can quantify, within a range, the amount of aflatoxin present. If a lot of corn is rejected based on the results of an immunoassay test kit, the results also should be confirmed by laboratory analysis. The entire sample should be ground before removing a subsample for the test kit.

Analytical laboratories use one of several procedures such as thin-layer chromatography, mini columns, gas chromatography, or mass spectroscopy to determine aflatoxin levels. These procedures are highly accurate and quantitative. The laboratory should grind the entire sample of corn together before taking subsamples for analysis.

Corn samples to be analyzed can be sent to the Iowa State University (ISU) Plant Disease Clinic, to official USDA–FGIS (United States Department of Agriculture–Federal Grain Inspection Service) laboratories, or to a private laboratory. The ISU Veterinary Diagnostic Laboratory analyzes samples submitted through a veterinarian. Contact your local extension office or go to www.iowagrain.org for a current list of public and private laboratories equipped for aflatoxin analysis.

Regulations regarding aflatoxin in corn

The Food and Drug Administration (FDA) has established an "action level" of 20 ppb for aflatoxins in corn in interstate commerce. This is the level at which federal agencies may take action, including seizure of the corn or prohibition of its sale. Elevators do not accept corn with 20 ppb or more of aflatoxin unless they have a known alternative use. Even one contaminated kernel in a 5-lb sample could result in more than 20 ppb aflatoxin. The FDA has guidelines for using contaminated grain in livestock feed (Table 1). These guidelines are based on maintaining performance and avoiding disease related to aflatoxin, except for dairy cattle where prevention of carcinogenic aflatoxin residues in milk is the concern.

Consequences of high concentrations of aflatoxin in corn

Aflatoxins are very potent compounds that cause a variety of human and animal health problems. On rare occasions, livestock can die from ingesting aflatoxin-contaminated feed. Most commonly, aflatoxin reduces the feed efficiency and reproductivity of livestock. It can suppress the immune system of animals, leading to more frequent occurrence of infectious diseases.

Unfortunately, the most abundant aflatoxin, aflatoxin B1, is a carcinogen. This raises human health concerns because aflatoxin can appear in the milk of dairy cows fed contaminated corn.

Table 1. FDA guidelines for acceptable aflatoxin level in corn based on intended use.

Intended use	Aflatoxin level (ppb)
Milk (Dairy Feed)	None detected
Corn of unknown destination	<20
Corn for young animals	<20
Corn for dairy cattle	<20
Corn for breeding beef cattle, swine, and mature poultry	<100
Corn for finishing swine	<200
Corn for finishing cattle	<300

How to prevent aflatoxin in corn

In Iowa, problems associated with *Aspergillus* and aflatoxins are most common in hot, dry years. The fungi survive in plant residues and produce abundant spores. The spores are carried by the wind and infect silks or kernels, usually through insect wounds. The fungi grow best in weather that is hot and sunny, warm at night, and dry during the silk and fill stage. Injury by insects, hail, drought stress, and early frost expose the kernels to infection. Insects can help spread the fungus within infected ears.

The amount of aflatoxin produced in storage is determined by storage conditions. The most important factors are grain moisture content and temperature. Optimum storage temperatures for *A. flavus* to grow are 80–90°F; optimum grain moisture content is 18 percent. Damaged corn also favors the growth of *A. flavus*. Importantly, aflatoxin concentration never decreases in storage; it only increases or remains the same.

The key to preventing ear rot and storage mold problems is detecting them early, in the field and in the bin. The following practices can reduce aflatoxin production in grain:

1. Control insects in the field. Second-generation European corn borers and corn earworms damage the ears, allowing for infection.

2. Scout. Early detection can prevent serious losses and avoid crises. Obtain good advance information as to the potential in your area. Scout at black-layer (physiological maturity) and again a couple weeks before harvest. Look at the primary ear for insect damage and *Aspergillus* spores (Figure 2).

   If extensive infection is observed, a sample should be collected, as described on page 1, for aflatoxin analysis. Decisions on handling moldy grain should be made before the field is combined. Depending on the toxin results, the field should be harvested as soon as possible and the corn dried immediately to prevent further toxin development. After harvest, spoilage can occur quickly if delays result from indecision.

3. Adjust the combine to minimize kernel damage. Fungi infect damaged kernels more easily than intact ones.

4. Clean bins and grain-handling equipment and remove fines from the corn before storing. Old corn residue is frequently a source of contamination.

5. After the harvest, **clean** corn can be kept at 16 or 17 percent moisture during the winter. Moldy corn should be dried immediately to 15 percent moisture or less. Holding grain for even a short time can allow significant mold and mycotoxin development. For long-term storage, all corn should be dried to 14 percent, depending on the duration of storage. Moldy corn is not suitable for long-term storage.

6. Cool grain after drying, and maintain it at 35–40°F for the duration of the winter. Aeration can be used for temperature control. If the corn will be stored during the summer, use aeration to warm it to 50–60°F in the spring. Use aeration to control moisture and temperatures during cool periods in the summer. Next to moisture content, temperature is the most important factor in preventing the development of molds and toxins.

7. Control storage insects.

8. Check grain every 2 weeks in storage (more often if quality is suspect) for temperature, crusting, hot spots, moisture, and mold. If any of these conditions are detected, steps should be taken immediately to reduce the temperature, aerate the bin, break up hot spots, or remove spoiled grain.

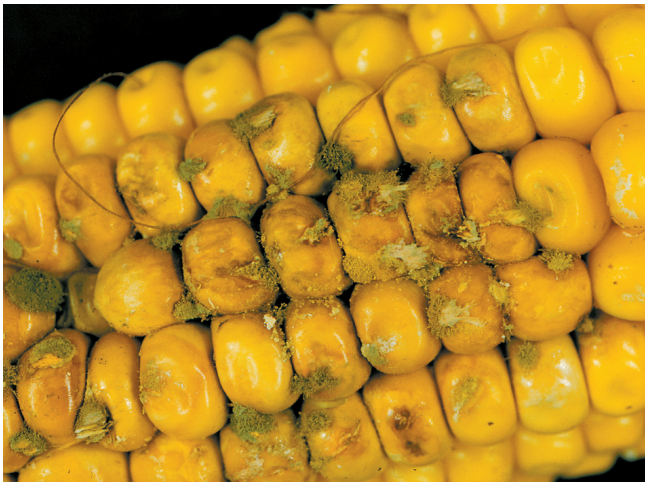

Figure 2. *Aspergillus flavus* spores on damaged corn kernels.

9. Antifungal agents can be applied to grain to reduce mold growth in storage. These products, such as propionic acid, do not kill the mold already present or reduce toxins already formed. They may have disadvantages, such as restricting use of the corn. **If you plan to sell the corn, be certain that antifungal agents are allowable before using them.**

For more details on proper grain handling to prevent mold, mycotoxins, and other problems, see ISU publications AED 20, *Managing Dry Grain in Storage*, and Midwest Plan Service publication MWPS 13, *Grain Drying, Handling, and Storage Handbook*.

What to do with aflatoxin-contaminated corn

Corn that is contaminated at levels greater than 20 ppb may not be sold for interstate commerce. However, most grain can find a safe and legitimate use. Cleaning grain by screening or a gravity table can reduce aflatoxin concentrations by removing the most heavily contaminated particles. However, this can be expensive and it is not possible to predict just how much the aflatoxins will be reduced. The discards from the cleaning process should not be used as feed.

Feeding contaminated grain

Aflatoxin-contaminated grain may be used locally for animal feed, under the guidelines shown in Table 1. Livestock producers may be willing to purchase contaminated corn if it is below 200–300 ppb. There will probably be a discount to the price received, but there may not be other options. It is important that a good estimate of the aflatoxin level is obtained so that informed decisions can be made about feeding.

Binding agents such as sodium bentonite and aluminosilicates reduce the effects of aflatoxins on livestock. These products are approved for use in feed, although the FDA does not recognize their aflatoxin management properties.

Blending aflatoxin-contaminated grain with clean grain is not legal except in advance of direct feeding operations. Blended grain may not be sold in general commerce. Once aflatoxin levels are known or suspected, it is the owner's responsibility to isolate that corn from general commerce.

Ensiling corn usually does not reduce aflatoxin concentrations, although concentrations are unlikely to increase in properly managed silage.

Ethanol/Wet Milling

Corn with aflatoxins can be used for ethanol production. Aflatoxins do not accumulate in the ethanol but will be concentrated in the distiller's grains co-product. In wet-mill processing, aflatoxins concentrate in the gluten co-products. A rough estimate is that aflatoxin levels in feed co-products will be four times those in whole corn. Therefore, processors may not accept corn with aflatoxin if their co-product markets are sensitive to aflatoxin levels, such as dairy feed.

Ammoniation

Anhydrous ammonia reacts with aflatoxins and reduces concentration. However, this practice is not approved for interstate commerce, so ammoniated grain can be used only on-farm. Ammonia can be applied as a gas or liquid, but in either form it is a difficult and dangerous procedure. This should be done only by a trained and experienced operator.

File: Pest management 2-5

Prepared by Gary Munkvold, extension plant pathologist; Charles Hurburgh, professor of agricultural and biosystems engineering; and Julie Meyer, plant pathologist.

Updated by Charles Hurburgh, professor of agricultural and biosystems engineering; Dan Loy, professor, animal science and Alison Robertson, extension plant pathologist.

Minimizing Aflatoxin in Corn

Mississippi State University Extension Service

Aflatoxin is a naturally occurring toxic chemical by-product from the growth of the fungus *Aspergillus flavus* on corn and other crops such as peanuts and cottonseed. Grain containing aflatoxin is toxic to animals, especially young animals and poultry; therefore, facilities that handle grain routinely test loads before accepting delivery.

Aflatoxin problems are more likely in Mississippi than in the Corn Belt, because the state's hot, humid climate is ideal for fungal growth. Also, little hybrid resistance exists and few if any decontamination methods have proven successful and been granted federal approval.

Stressful Conditions

The Midsouth's climatic conditions dictate that aflatoxin potential will continue to threaten corn producers until control measures are identified. Aflatoxin problems have historically developed during years with severe high-temperature stress, particularly when coupled with water deficiency and insect ear and stalk damage. In 1977 and 1998, Mississippi had severe problems with aflatoxin-contaminated corn.

You can minimize the likelihood of developing a problem by using sound agronomic practices, properly storing and drying grain, maintaining grain quality, and sanitizing grain-handling equipment.

Aflatoxin can infect corn by airborne spores in the field during grain filling or during storage and handling. Kernel infection may occur through the silk, cob, or direct contact. Fungus spores overwinter on plant residue on the soil. However, management practices intending to reduce the inoculum level have little impact on aflatoxin development in subsequent years, because the fungus is abundant in the Midsouth nearly every year.

Management Practices

Aflatoxin develops in the field when corn is exposed to severe environmental conditions known to stress kernel development and promote fungal infection within the ear. Management practices that improve plant health strongly discourage aflatoxin development.

Timely planting, adequate fertility, good weed and insect control, supplemental irrigation, suitable plant population, and hybrid selection should help reduce aflatoxin potential. Although hybrid evaluations conducted in Mississippi in 1998 indicated little aflatoxin resistance in commercially available hybrids, hybrids that perform well in drought conditions generally have lower aflatoxin concentration than hybrids that yield poorly in drought conditions.

Harvest Timing

Producers may reduce the likelihood of aflatoxin buildup in the field by harvesting corn before it reaches the industry standard of 15.5 percent moisture.This system reduces duration when ears may be exposed to unfavorable drying conditions that promote aflatoxin development in the field. Corn reaches physiological maturity at about 30 percent moisture and can be harvested any time thereafter. Mississippi research indicates corn will normally lose around 0.6 percent moisture per day during the dry-down period. This rate is not influenced much by hybrid maturity. Thus, you can reduce field exposure by at least 1 to 2 1/2 weeks by harvesting corn at 20 to 25 percent moisture, compared to letting the corn dry in the field to 15 percent moisture.

The disadvantage of early harvest is that wet, warm grain is an ideal environment for rapid aflatoxin escalation if it is not handled properly. Dry your high-moisture grain (16-30 percent) to below 15 percent moisture within 24 hours after harvest or immediately haul the grain to an elevator (that will dry the grain).

Storage

Do not store grain in trucks, combines, bins, or any nonaerated site for more than 4 to 6 hours. These conditions quickly escalate aflatoxin levels and deteriorate grain quality, because fungal growth and grain respiration will rise quickly in high-moisture grain, particularly with normal Mississippi August and early September air temperatures.

Conversely, aflatoxin approaches dormant levels when grain moisture drops to about 12 percent, especially when air temperatures decline to around 55 ºF. If you plan to dry the grain yourself, do not harvest more corn than you can dry within these constraints.

Aflatoxin problems often develop in grain bins being used to dry corn. You must minimize grain

depth (commonly 3-6 feet deep) to quickly dry high-moisture corn using in-bin drying system. Stirring devices may assist drying but cannot overcome aeration problems that limit the drying rate in deep-layered grain. Other drying systems, such as continuous flow and portable batch driers, normally dry grain within these constraints, if harvest capacity does not exceed volume of the drying system.

Harvest and Handling Practices

You may improve grain quality by altering harvest and handling procedures. Fungi readily invade kernels with cracked or damaged seed coats. If you suspect a problem, keep obviously stressed, stunted, or damaged areas and field edges from healthy corn.

Increasing fan speed, opening sieves, and reducing ground speed help enhance grain quality collected by a combine. Postharvest screen cleaners and gravity separators help reduce moderate aflatoxin levels (50 to 100 ppb) below the FDA standard (20 ppb).

Daily clean out corn and debris left in combines, trucks, pits, grain carts, and augers; clean bins before use because these are potential contamination sources. Spores from fungi on infected grain may readily disperse during handling, contaminating subsequent grain. A chlorine cleaning solution (3/4 cup bleach/gallon of water) kills fungal growth on handling facilities.

Detection

Methods historically used for aflatoxin detection range from visual observations to complex lab analyses. A "black light" test uses long-wave ultraviolet light to illuminate a bright yellow-green fluorescence indicative of a fungal metabolism product that often preludes aflatoxin. This product is called Kojic acid and should not be confused with aflatoxin. The "black light" test has limited use; use only as a preliminary test to a more accurate chemical analysis.

Elevators or grain markets should use chemical analyses to determine aflatoxin content. You may also submit samples for analysis to the State Chemical Lab or buy an aflatoxin test kit from chemical supply companies.

Sampling and Testing

Substantial aflatoxin testing variability is common because few kernels are normally contaminated with aflatoxin (less than 0.1 percent), but concentration in individual kernels is often very high.

You may improve sampling by increasing the sample size and using proper sampling techniques. Chemical extraction of aflatoxin requires grinding the grain sample.

Testers should grind the original sample before a subsample is removed. This improves distribution of contaminated particles to the subsample. Testers may also grind particles finer, increase the size of the subsample, and increase number of analyses per sample to reduce variability. The latter two recommendations, however, will increase the time and expense involved with the analytical procedure and may be impractical in some situations.

Action Levels

The United States Food and Drug Administration action levels for corn contaminated with aflatoxin establish guidelines for specific uses. Research indicates that aflatoxin-contaminated corn within these action levels will not injure the health of specific animals listed or humans consuming foods derived from these animals.

FDA action levels for aflatoxin-contaminated corn include the following:

Maximum level	Use
20 ppb:	**Human food, feed for immature animals (including poultry) or dairy animals, or unknown destination**
100 ppb:	**Feed for breeding cattle, breeding swine, or poultry**
200 ppb:	**Feed for finishing swine of greater than 100 pounds**
300 ppb:	**Feed for finishing beef cattle**

www.ext.msstate.edu

By **Dr. Erick Larson**, Extension Corn Specialist

Information Sheet 1563

Extension Service of Mississippi State University, cooperating with U.S. Department of Agriculture. Published in furtherance of Acts of Congress, May 8 and June 30, 1914. RONALD A. BROWN, Director (rev-1M-3-00)

Web Sites: www.extension.iastate.edu/Publications/PM1800.pdf
http://aes.missouri.edu/delta/croppest/aflacorn.stm

Aflatoxins in Corn

Aflatoxins are a group of chemicals produced by certain mold fungi. These fungi, *Aspergillus flavus* and *Aspergillus parasiticus*, can be recognized by yellow-green or gray-green, respectively, on corn kernels, in the field or in storage (Figure 1). Although aflatoxins are not automatically produced whenever grain becomes moldy, the risk of aflatoxin contamination is greater in damaged, moldy corn than in corn with little mold. Aflatoxins are harmful or fatal to livestock and are considered carcinogenic (cancer-causing) to animals and humans. In the Midwest, aflatoxin levels are highest during hot, dry summers. The prime conditions for the fungus to produce toxin are warm August nights in a period of drought.

In high-risk years, aflatoxin screening may be done at the elevator or where the corn is marketed. Rapid, on-site tests can determine the possible presence of aflatoxin, but they do not provide specific quantitative results. The toxins are produced inside the corn kernels and their presence can be determined only by specific analytical tests. Because aflatoxin levels can vary greatly from kernel to kernel, sampling the load, bin, or unit of grain is the most critical step in determining actual levels of aflatoxin.

How to sample corn for aflatoxin testing

Because aflatoxin does not occur uniformly through a lot of grain and is usually localized in a small area, the best approach is to make a composite sample consisting of subsamples from every part of a load, bin, or unit of corn. The recommended procedure is to sample periodically from a moving stream, combining these samples to obtain a composite sample of at least 10 lb of corn. An alternative is to sample with a probe through a storage unit (five perimeter samples and one center sample for each 6 feet of bin height). In the field, sample individual fields or parts of fields separately. Grain in trucks can probed in the same way to collect samples of at least 5 lb per truck.

Fields that vary in cropping history, tillage practices, planting date, soil type, or hybrid can differ greatly in aflatoxin vulnerability. Sample a minimum of 10 to 30 locations within each field. To reach the same sampling frequency as testing grain in trucks, collect one sample (5-10 lb) for about every 5 acres. Immediately dry samples to 12–14 percent moisture to prevent aflatoxin development during transit or storage. High-moisture samples should be frozen and delivered to the laboratory in the frozen state. Dried samples maintain their quality best if shipped in cloth or paper containers.

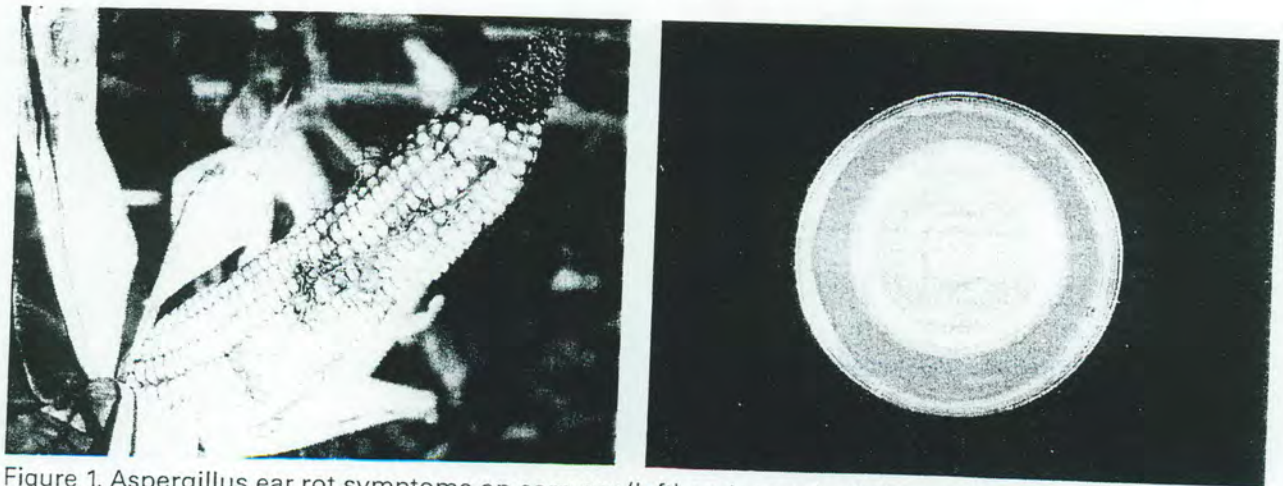

Figure 1. Aspergillus ear rot symptoms on corn ear (left) and growth of *Aspergillus flavus* in artificial culture (right).

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How to test for aflatoxin

Currently, two types of screening tests are available: blacklight tests and commercial test kits. The blacklight (also called ultraviolet light) test is a visual inspection for the presence of a greenish gold fluorescence under light at a wavelength of 365 nm (nanometers). The greenish gold fluorescence looks like a firefly glow. More than four glowing particles per 5-pound sample (before grinding) indicate a likelihood of a +20 ppb (parts per billion) level of aflatoxins. However, remember that this test is an initial screening for the presence of aflatoxin and the results should be verified by laboratory analysis. If there are less than four glowing particles per 5 lb sample, this does not guarantee that the sample is free of aflatoxins.

Commercial test kits with immunoassay or ELISA techniques are available for on-site tests for aflatoxin. Immunoassay analysis is based on the detection of specific proteins found in aflatoxins using antibodies to identify these proteins. The tests are very specific for aflatoxin, but they require operator training and practice to be accurate. Some tests determine only the presence or absence of aflatoxin; others can quantify, within a range, the amount of aflatoxin present. If a lot of corn is rejected based on the results of an immunoassay test kit, the results also should be confirmed by laboratory analysis. The entire sample should be ground before removing a subsample for the test kit.

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Consequences of high concentrations of aflatoxin in corn

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Unfortunately, the most abundant aflatoxin, aflatoxin B1, is a carcinogen. This raises human health concerns because aflatoxin can appear in the milk of dairy cows fed contaminated corn.

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The amount of aflatoxin produced in storage is determined by storage conditions. The most important factors are grain moisture content and temperature. Optimum storage temperatures for *A. flavus* to grow are 80–90°F; optimum grain moisture content is 18 percent. Damaged corn also favors the growth of *A. flavus*. Importantly, aflatoxin concentration never decreases in storage; it only increases or remains the same.

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   If extensive infection is observed, a sample should be collected, as described on page 1, for aflatoxin analysis. Decisions on handling moldy grain should be made before the field is combined. Depending on the toxin results, the field should be harvested as soon as possible and the corn dried immediately to prevent further toxin development. After harvest, spoilage can occur quickly if delays result from indecision.

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4. Clean bins and grain-handling equipment and remove fines from the corn before storing. Old corn residue is frequently a source of contamination.

5. After the harvest, **clean** corn can be kept at 16 or 17 percent moisture during the winter. Moldy corn should be dried immediately to 15 percent moisture or less. Holding grain for even a short time can allow significant mold and mycotoxin development. For long-term storage, all corn should be dried to 14 percent, depending on the duration of storage. Moldy corn is not suitable for long-term storage.

6. Cool grain after drying, and maintain it at 35–40°F for the duration of the winter. Aeration can be used for temperature control. If the corn will be stored during the summer, use aeration to warm it to 50–60°F in the spring. Use aeration to control moisture and temperatures during cool periods in the summer. Next to moisture content, temperature is the most important factor in preventing the development of molds and toxins.

7. Control storage insects.

8. Check grain every 2 weeks in storage (more often if quality is suspect) for temperature, crusting, hot spots, moisture, and mold. If any of these conditions are detected, steps should be taken immediately to reduce the temperature, aerate the bin, break up hot spots, or remove spoiled grain.

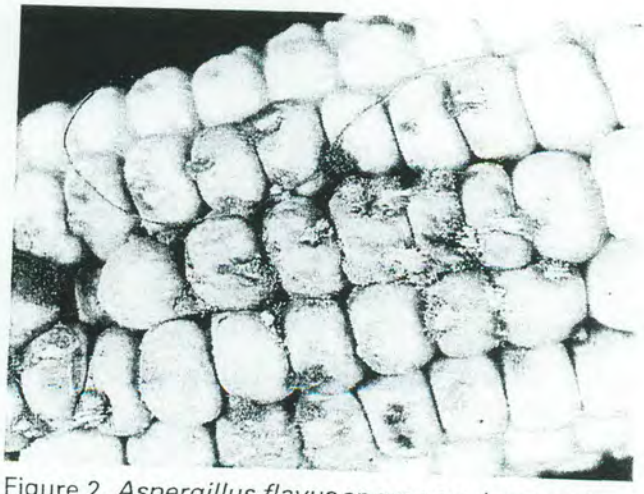

Figure 2. *Aspergillus flavus* spores on damaged corn kernels.

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