

# FDA Regulatory Guidance for Toxins and Contaminants

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The Food and Drug Administration has issued regulatory guidance for two toxins and contaminants that may be present in raw grains and finished feed: Aflatoxin and deoxynivalenol (vomitoxin).

This memo is not intended as legal advice; it is provided for information purposes only.

## 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)**.

■ **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 toxins or contaminants 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 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 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 the 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 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, did 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. Further, the agency increased its advisory levels for commodities intended as feed to the following levels:

Vomitoxin Level <small>(in parts per million)</small>	Intended Use
5 p.p.m.:	For grain and grain byproducts destined for swine. (FDA advises that commodities containing this level of vomitoxin not exceed 20 percent of the ration.)
10 p.p.m.:	For grain and grain byproducts destined for beef cattle and feedlot cattle older than four months, as well as for chickens. (FDA recommends that commodities containing this level of vomitoxin not exceed 50 percent of the ration for these species.)
5 p.p.m.	For grain and grain byproducts destined for all other animal species. (FDA recommends that commodities containing this level of vomitoxin not exceed 40 percent of the ration.)

## FDA 'Draft Guidance' to Industry on Fumonisin

FDA on June 6, 2000 issued a “draft 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.”

Fumonisin are mycotoxins produced by molds.

Importantly, the FDA “draft 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 “have been linked to a variety of significant adverse health effects in livestock and experimental animals.” The agency noted that “human epidemiological studies are inconclusive at this time, (but) based on a wide variety of significant adverse animal health effects, FDA believes that an association between fumonisins and human disease is possible.”

For corn and corn products intended for **human food**, the FDA-recommended maximum levels for total fumonisins ( $FB_1$ ,  $FB_2$  and  $FB_3$ ) are shown in Chart 1.

For **animal feeds**, FDA-recommended maximum levels for total fumonisins ( $FB_1$ ,  $FB_2$  and  $FB_3$ ) are shown in Chart 2.

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 1**

Product	Total Fumonisin ( $FB_1 + FB_2 + FB_3$ ) parts per million
Degermed dry milled corn products (e.g., flaking grits, corn grits, corn meal, corn flour with fat content of <5 %, dry weight basis)	2 ppm
Whole or partially degermed dry milled corn products (e.g. flaking grits, corn grits, corn meal, corn flour with fat content of < 2.25% dry weight basis)	4 ppm
Dry milled corn bran	4 ppm
Cleaned corn intended for masa production	4 ppm
Cleaned corn intended for popcorn	3 ppm

**CHART 2**

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

<sup>1</sup> total fumonisins =  $FB_1 + FB_2 + FB_3$ .

<sup>2</sup> fraction of corn or corn by-product mixed into the total ration.

<sup>3</sup> includes asses, zebras and onagers.

<sup>4</sup> cattle, sheep, goats and other ruminants that are  $\geq 3$  months old and fed for slaughter.

<sup>5</sup> fed for pelt production.

<sup>6</sup> turkeys, chickens, ducklings and other poultry fed for slaughter.

<sup>7</sup> includes laying hens, roosters, lactating dairy cows and bulls.

<sup>8</sup> includes dogs and cats.

## 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:

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 (as occurred in 1988) or in response to state-specific requests to address local outbreaks (as occurred with the state of Missouri in 1993).

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 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. can 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.

■ **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

### Aflatoxin

Aflatoxin Level	Commodities and Species
<i>(in parts per billion)</i>	
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 below, or when the intended use is not known.
20 p.p.b.:	For corn, peanut products and other animal feeds and feed ingredients, but excluding cottonseed meal, intended for immature animals.
100 p.p.b.:	For corn and peanut products intended for breeding beef cattle, breeding swine or mature poultry (e.g., laying hens).
200 p.p.b.:	For corn and peanut products intended for finishing swine (100 pounds or more).
300 p.p.b.:	For cottonseed meal intended for beef cattle, swine or poultry (regardless of age or breeding status).
300 p.p.b.:	For corn and peanut products intended for finishing beef cattle (e.g., feedlot cattle).

- 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, and has an ongoing rulemaking open to consider the effectiveness and safety of similar technology for detoxifying corn.

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 “*Memo to the Manager*”.

Also attached as an appendix to this “*Memo to the Manager*” is the most recent FDA Compliance Policy Guide for Aflatoxins in Animal Feed and Feed Ingredients -- *Compliance Policy Guide 7126.33, Chapter 28 - Animal Feed*.

# Food and Drug Administration Compliance Policy Guide

## Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds (Compliance Policy Guide 7126.33)

### 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 ppb 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 ppb 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 ppb 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 ppb for corn and peanut products intended for finishing (i.e., feedlot) beef cattle;
- 300 ppb for cottonseed meal intended for beef cattle, swine, or poultry (regardless of age or breeding status);
- 200 ppb for corn or peanut products intended for finishing swine of 100 pounds or greater;
- 100 ppb for corn and peanut products intended for breeding beef cattle, breeding swine, or mature poultry;
- 20 ppb for corn, peanut products, and other animal feeds and feed ingredients, but excluding cottonseed meal, intended for immature animals;
- 20 ppb 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 derivative 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 ppb.

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\*

Issued: 11/21/79

Reissued: 10/01/80

Revised: 8/15/82, 5/18/89, 8/28/94



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.]*

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### PART I: DOMESTIC GRAIN

1. **NGFA: What are FDA's general rules governing aflatoxin present in corn in domestic commerce:** not be exported if the food or feed is adulterated due to aflatoxin contamination. (*Emphasis added.*)

**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

<b>FDA Regulatory Policy on Aflatoxin</b>	
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

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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 subplot 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 subplot 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 subplot 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**

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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.