
Aflatoxin

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.

GIPSA's Role in Aflatoxin Testing. GIPSA provides aflatoxin testing service as official criteria for corn, sorghum, wheat, and soybeans, 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 (AMA). Additionally, all corn exported from the United States is required to be tested for aflatoxin. 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.

Testing Methods. The GIPSA approved test kits use enzyme linked immunosorbent assay (ELISA), monoclonal antibody affinity chromatography, lateral flow strip or fluorescence technology. The test kits approved by GIPSA and used in the official inspection system are: Charm Science - ROSA® Aflatoxin Quantitative, ROSA® Aflatoxin P/N, Envirologix - QuickTox, Neogen - AgriScreen, Veratox, Veratox AST, Reveal for Aflatoxin, R-Biopharm - Aflacard T20, RIDASCREEN Fast Aflatoxin SC, Romer - AflaCup, AgraStrip, Fluoroquant, Strategic Diagnostics Inc. - Myco✓, and Vicam - Aflatest. To further assist the grain industry, GIPSA also provides, on a limited basis, a complex chemical testing method, High Performance Liquid Chromatography (HPLC) testing 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 directive by authorized employees of GIPSA or licensed delegated/designated agency personnel.

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

The FDA will consider action if aflatoxin levels exceed:

- 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.

Reporting lots exceeding FDA action levels: GIPSA and FDA, having certain related objectives in carrying out their respective regulatory and service functions, have an agreement (Memorandum of Understanding) 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 Memorandum of Understanding (MOU), GIPSA and officially delegated/designated agencies report to FDA, on a lot-by-lot basis, each lot that, during the course of an official sample-lot inspection, exceed the action limits as listed above.

Aflatoxin testing fees: GIPSA's fee for aflatoxin testing performed under the provisions of the USGSA depends on the site of the GIPSA laboratory where the testing is performed. GIPSA's fees for original and appeal aflatoxin testing services performed at an applicant's facility in an onsite GIPSA laboratory using the ELISA test kits are \$10.00 per test for qualitative or quantitative analysis. An hourly inspection and sampling fee is also charged to applicants in addition to the unit fee listed above.

Fees for aflatoxin analysis initiated as an original or appeal inspection service at other than an applicant's facility in a GIPSA laboratory are \$30.00 per test for qualitative or quantitative analysis. An hourly inspection and sampling fee may also be charged to applicants, when appropriate.

HPLC testing for Board Appeal inspections under the USGSA is billed at the applicable USGSA noncontract hourly rate.

GIPSA'S Objective: GIPSA will continue to monitor the official aflatoxin testing program in place and work with the FDA to safeguard the public's health, and provide the market with rapid, accurate aflatoxin testing services.