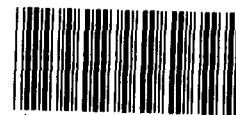


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**Observations on Aflatoxin Detection and
Control Activities of Federal, State, and
Private Organizations**

Statement of
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Before the
Subcommittee on Wheat, Soybeans, and
Feed Grains
House Committee on Agriculture



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Mr. Chairman and members of the Subcommittee:

We are pleased to be here today to discuss the preliminary results of ongoing work we are doing at your request on aflatoxin -- a naturally occurring toxin produced by a common fungus on crops such as corn and peanuts. You asked us to develop information on (1) the relative food safety risk of aflatoxin, (2) methods for detecting and controlling it, and (3) the extent of aflatoxin in the U.S. corn crop.

In summary, our work shows that (1) food safety experts consider aflatoxin a serious food safety concern but do not consider it as serious as other food safety risks and the Food and Drug Administration (FDA), the principal agency that regulates aflatoxin in food and feed, considers the overall food supply to be safe from aflatoxin; (2) aflatoxin detection and control occurs through the collective efforts of various federal, state, and industry groups; and (3) information is inadequate to determine the extent of aflatoxin in the U.S. corn crop.

AFLATOXIN IS NOT AS SERIOUS
AS OTHER FOOD SAFETY RISKS

Aflatoxin can enter the food supply directly in products such as peanut butter, corn meal, and corn grits. Less potent forms of aflatoxin can enter the food supply indirectly in the milk, meat, or eggs of animals that eat aflatoxin-contaminated feeds. Crops are more susceptible to aflatoxin contamination when stressed by drought conditions like those experienced in the midwest in 1988

and in parts of Illinois and Texas in 1989. Aflatoxin was subsequently found in corn grown in those areas.

Although the presence of aflatoxin in food products is undesirable, aflatoxin is not considered as serious as other food safety risks. Although there is no precise way to rank food safety risks, experts like FDA and the American Association of Cereal Chemists generally rank microbial contaminants such as salmonella and listeria as the major health hazard associated with food because of their potential to kill humans after one exposure. Malnutrition -- the consumption of an improper mix of nutrients, excessive amounts of fats and salts, etc. -- and environmental contaminants such as lead and mercury are also considered more serious than aflatoxin. Pesticide residues and additives are usually ranked as less serious than aflatoxin.

Because aflatoxin occurs naturally and cannot be entirely eliminated, FDA allows small amounts, referred to as action levels, to be present in foods and feeds. FDA set the action levels at 20 parts per billion (ppb) for food, 0.5 ppb for milk because infants and children drink large quantities, and varying levels up to 300

ppb for feeds.¹ If aflatoxin exceeds these levels, FDA considers whether action is needed to control the contaminated product.²

Although FDA's surveillance sampling of corn-based products has shown a small number of instances where aflatoxin made its way into consumer channels at levels exceeding regulatory limits, FDA does not consider the food supply to be at risk. At fiscal year 1990 hearings before the Subcommittee on Rural Development, Agriculture and Related Agencies of the House Committee on Appropriations, the FDA Commissioner said that FDA was confident that there was no risk associated with the commercial food supply as a result of the 1988 drought. He stated that occasional consumption of the very few corn products that contain small amounts of aflatoxin is of little lifetime health consequence, because only repeated exposure to relatively high aflatoxin levels over a number of years presents a significant safety risk.

¹Higher levels of contamination in feed are allowed because research has shown that animals, depending on their size, maturity, or whether they are used for breeding stock, can eat higher levels of aflatoxin without ill effects.

²In 1987, the United States Court of Appeals for the District of Columbia Circuit found that action levels, because they were not established through the notice and comment procedure of the Administrative Procedure Act (5 U.S.C. 553) were not legally binding and that FDA had to establish new regulatory limits through the notice and comment process. Until FDA establishes new limits it must prove on a case-by-case basis that the amounts of aflatoxin in a food "may be injurious to health" in order to take regulatory action such as seizing the product. Thus, FDA is now in the process of establishing new regulatory limits.

FDA's surveillance activities -- which increased significantly in 1989 because of the drought -- showed that a small percentage of food products exceeded the action levels. Between October 1988 and June 1989, FDA sampled 2,097 food products and found that 5.5 percent of the whole corn shipments and 2.2 percent of the milled corn products contained aflatoxin in excess of the 20 parts per billion limit. The products in which aflatoxin was found would have to be further processed or prepared which would further reduce the aflatoxin levels before they were eaten.

In comparison, for fiscal year 1986 (not a midwest drought year), FDA sampled about 300 food products and found a slightly higher incidence of aflatoxin than in fiscal year 1989 (6.8 percent of the whole corn samples and 4.3 percent of the milled corn products had levels exceeding 20 parts per billion). FDA said that the 1986 and 1989 sample results were biased towards geographic areas suspected of having aflatoxin and firms with a prior history of Food and Drug Law violations.

AFLATOXIN DETECTION AND CONTROL EFFORTS

Testing for aflatoxin, particularly for corn, is difficult because of the large volume of grain involved (about 8 billion bushels annually) and because of testing problems. Obtaining representative samples is a problem at all of the about 8,000 locations where whole corn is traded--including whole corn deliveries at mills because, (1) aflatoxin is concentrated in individual kernels of corn, (2) infected kernels may not be evenly

distributed through a bulk lot, (3) there are differences in the aflatoxin level of individual kernels, and (4) aflatoxin is measured in exceedingly small quantities.

Only about 16 percent of the annual corn crop (about 1.2 billion bushels) is used for human food and most of that is processed at about 100 mills. Sample variability is less of a problem after corn has been milled because it has been ground and mixed, and any aflatoxin in it is more evenly distributed. Consequently, representative samples are more easily obtained.

Further, testing all corn marketed, including that used for commercial feed, will not always ensure that aflatoxin will be eliminated from the food supply. While recent USDA research shows that the meat, poultry, and eggs from animals eating aflatoxin are not likely to be a food safety threat, the milk from dairy cows fed aflatoxin contaminated feeds can contain aflatoxin residues in excess of FDA's action levels. Contaminated milk has been traced to both commercial feeds and those grown and fed on farms.

Despite these difficulties, aflatoxin detection and control occurs through the efforts of various federal, state, and private groups. Each organization has its own testing objectives such as assuring food safety, market efficiency, and profitability.

FDA does not monitor all affected foods and feeds for aflatoxin. Instead, FDA requires food and feed manufacturers to follow regulations commonly referred to as good manufacturing practices. These regulations require food processors to have quality control procedures that ensure food products are safe, wholesome, and suitable for human consumption. Manufacturers are required to use only raw materials and ingredients that are within FDA's action levels. Manufacturers may either purchase ingredients that are guaranteed or certified to be within the action levels or may test the ingredients themselves. As I mentioned, FDA annually samples a small number of susceptible raw materials and food products to monitor industry compliance with its regulations and obtain data on the level and frequency of aflatoxin contamination.

Food manufacturers and firms that mill corn, shell peanuts, or otherwise prepare raw commodities used in food manufacturing contribute to aflatoxin detection and control and have economic incentives to do so as part of their quality control procedures.

One food manufacturing company's quality control director told us his company requires its suppliers to have quality control systems that ensure products are within FDA's action levels. At the onset of the 1988 harvest, his company reviewed its suppliers' sampling and testing program and required some suppliers to make changes to satisfy his company's requirements. Subsequently, the

manufacturer implemented a program to sample and test dry milled³ products for compliance. The manufacturer did not focus on wet milled⁴ food products because research has shown that most of the aflatoxin is removed during the wet milling process.

Although we did not determine the extent of industrywide testing, milling trade association officials told us that aflatoxin testing has been standard procedure in their industry for years. An official of a dry milling industry organization said current industry efforts may involve testing of whole corn as it is delivered to plants or removed from storage for processing, as well as testing of finished products. An official of a wet milling organization said that, in favorable growing years, a statistical sampling plan may be used to determine the extent of testing needed. Testing is increased as the corn crop enters the market so that companies can identify and avoid geographic areas producing aflatoxin-contaminated corn. During the drought, testing was increased to cover all incoming corn.

At the federal level, FDA works with other federal agencies to extend its monitoring of susceptible commodities. The principal federal agencies with whom FDA works are USDA's Agricultural Marketing Service (AMS) and USDA's Federal Grain Inspection Service

³Dry milled products include corn meal, corn flour, grits, alcohol, and corn oils for human use, and animal feeds.

⁴Wet milled products include starches, sugars, oils, and animal feeds.

(FGIS). AMS oversees a peanut marketing agreement that requires all peanuts sold by farmers to be sampled and visually inspected for the mold that produces aflatoxin, and all peanuts, before they are sold to food manufacturers, are sampled and tested for aflatoxin. Unlike the peanut program, FGIS's sampling and testing of grain and grain products is on a request basis.

At the state level, aflatoxin detection and control activities vary with state interests and for reasons such as the frequency of aflatoxin's occurrence. For example, some states, such as Georgia and North Carolina, have annual programs to monitor susceptible food and feed products for aflatoxin. They, and other states, assist the AMS by providing inspectors to carry out the detection and control program for peanuts. In other states, aflatoxin control activities are less extensive.

FDA coordinates with states to avoid duplication and, to the degree that FDA has confidence in a state's control efforts, FDA limits its activity to spot checks. FDA shares its aflatoxin surveillance results with state regulatory agencies and encourages them to reciprocate. In this way, FDA supplements its information on the extent of aflatoxin in food and feeds.

INFORMATION ON THE EXTENT OF
AFLATOXIN IN CORN IS LIMITED

Information on the incidence of aflatoxin in the corn crop is inadequate for determining whether aflatoxin is a widespread problem. Although individual states monitor field corn for

aflatoxin their results do not show how widespread aflatoxin is because state surveys may not be done in a statistically reliable manner. Generalizations about the incidence of aflatoxin are difficult because aflatoxin is a localized problem even in years of widespread drought. For example, one state study showed that although the average level of aflatoxin in the state's crop was 21 parts per billion, 65 percent of the crop had no detectable level of aflatoxin. However, limited state testing results are sometimes reported by the media as estimates of the extent of aflatoxin for the entire state without recognizing the limitations of the state study or the variability of aflatoxin across the state.

A recent proposal by the Iowa Aflatoxin Task Force -- consisting of representatives from state government, producer organizations, grain trade, and academia -- offers a proactive approach to gathering additional information on the occurrence of aflatoxin in the corn crop. The proposal calls for (1) a pre-harvest weather monitoring and early warning system to predict high-, medium-, and low-risk areas of aflatoxin formation and (2) physical sampling at harvest time to confirm or deny advance warning data. It is intended to alert regulators and the grain industry to the possibility of aflatoxin contamination and reduce its impacts by allowing (1) FDA and state regulators to focus their aflatoxin control efforts on locations with the highest risk; (2) dairy farmers to decide whether the feeds they grow or purchase

should be tested for aflatoxin; and (3) food processors to select locations from which to purchase their raw ingredients.

USDA's National Agricultural Statistics Service (Service) would, according to the Iowa proposal, establish risk areas using temperature and moisture information reported by the State Crop Reporting services. Some additional research would be required to develop specific criteria for relating weather information to aflatoxin formation. Sampling to substantiate advance warning data would be accomplished by modifying the Service's existing at-harvest crop sampling program. Adding aflatoxin testing would require that larger samples be drawn, dried immediately to stop further aflatoxin formation, and then sent for laboratory analysis. Since the Service relies on farmer cooperation for its surveys, it has turned down earlier requests to estimate aflatoxin in corn because it is a controversial issue with farmers, and may cause the Service to lose farmer cooperation.

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In summary, aflatoxin is a serious food safety concern, but it is not as serious as several other food safety risks. An infrastructure of federal, state, and industry groups exist to test and control the incidence of aflatoxin in the overall food supply. At this time, FDA considers that supply to be safe from aflatoxin. Nevertheless, the adequacy of testing procedures and whether

increase testing. If it is decided more testing is necessary, a logical point for additional testing is the approximately 100 mills where corn is processed into food. This is at the point of greatest risk. The Iowa Aflatoxin Task Force's proposal also offers one approach for making this testing and control process more proactive and thereby possibly improving monitoring of aflatoxin.

Mr. Chairman, this ends my prepared statement. I would be glad to respond to any questions.