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Report to the Chairman, Subcommittee on Wheat, Soybeans, and Feed Grains, Committee on Agriculture, House of Representatives

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FOOD SAFETY AND QUALITY

Existing Detection and Control Programs Minimize Aflatoxin

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The Honorable Dan Glickman
Chairman, Subcommittee on Wheat,
Soybeans, and Feed Grains
Committee on Agriculture
House of Representatives

Dear Mr. Chairman:

As you requested, this report examines the risks posed by the presence of aflatoxin in the domestic food supply and efforts to detect and control aflatoxin levels.

As arranged with your office, we are sending copies of this report today to Representative Jim Jontz. Copies are also being sent to the Secretary of Agriculture; the Secretary of Health and Human Services; the Commissioner, Food and Drug Administration; interested congressional committees; and other interested parties upon request.

Major contributors to this report are listed in appendix III. If you have any questions about this report, please call me at (202) 275-5138.

Sincerely yours,

John W. Harman
Director, Food and
Agriculture Issues

Executive Summary

Purpose

Higher than normal levels of aflatoxin, a naturally occurring, mold-pro duced toxin, were found in the Midwest's 1988 corn crop, in some corn in Illinois and Texas in 1989, and again in some Texas corn in 1990, federal and state officials reported. Aflatoxin can cause illness or even death if enough is eaten. Although the long-term effects of consuming small amounts of aflatoxin are less certain, some scientists believe that over time it could cause cancer.

Concerned about the effectiveness of efforts to monitor aflatoxin and prevent aflatoxin-contaminated foods from reaching the public, the Chairman of the Subcommittee on Wheat, Soybeans, and Feed Grains, House Committee on Agriculture, asked GAO to report on the (1) risk that aflatoxin presents, particularly when compared with other domestic food safety hazards, and (2) existing federal, state, and industry efforts to detect and control aflatoxin. GAO also assessed several federal, state, and industry proposals to develop more systematic and comprehensive data on aflatoxin outbreaks and impose more stringent aflatoxin limits.

Background

Aflatoxin can form on crops in the field or in storage, and even after processing into foods or animal feeds. Crops under stress from drought and high temperatures, or weakened by insect or other damage, are more susceptible to aflatoxin contamination. Corn and peanuts are among the most susceptible crops, and foods and feeds processed from them pose a higher aflatoxin risk.

Several federal agencies have oversight responsibilities for aflatoxin. The Food and Drug Administration (FDA) has established limits on the amounts of aflatoxin allowable in foods and feeds, and it samples and tests susceptible commodities to monitor and enforce industry compliance with its limits. The U.S. Department of Agriculture also has programs to detect and help control aflatoxin: The Federal Grain Inspection Service tests corn for aflatoxin, and the Agricultural Marketing Service and Agricultural Stabilization and Conservation Service test peanuts (as well as other nuts and processed nut products), in conjunction with industry. The states and industry have also instituted their own aflatoxin detection and control programs.

GAO examined Georgia's and Iowa's efforts to detect and control aflatoxin in corn, peanuts, and milk in detail.

Results in Brief

Aflatoxin poses less of a domestic food safety risk than other hazards such as salmonella poisoning and environmental contaminants, according to regulators and food scientists. High aflatoxin levels in domestic foods are believed unlikely because conditions in the U.S. agricultural environment are not generally conducive to the development of aflatoxin. Moreover, federal and state agencies, as well as industry, have effective detection and control programs. Commercial milling/processing techniques and food preparation can also reduce aflatoxin. Although available test results cannot be generalized to the overall food supply, FDA's limited testing of suspect food items after the 1988 drought shows few instances where aflatoxin exceeded FDA limits.

Multiple federal and state agencies as well as industry itself are involved in aflatoxin detection and control efforts. In general, federal and state regulatory programs routinely monitor and test susceptible commodities where aflatoxin is a recurring problem. However, where aflatoxin problems are infrequent, detection and control efforts fluctuate, depending on weather conditions, perceptions about the extent of an aflatoxin outbreak, and how the affected commodity will be used. Also, the corn destined for human food purposes tends to be tested more than corn destined for animal feed purposes. Industry has strong economic incentives to minimize aflatoxin contamination and plays a key role in ensuring the safety of the food supply. While some gaps and overlaps may occur in these programs, in aggregate they appear effective at minimizing aflatoxin in the food supply. Also, technical and practical limitations in state-of-the-art sampling and testing techniques mean that some aflatoxin will enter the food supply despite the most stringent detection and control programs.

Proposals have been made to more systematically and comprehensively collect information on the extent of aflatoxin outbreaks in corn, for use as an alternative method to trigger the detection and control efforts of federal and state regulators, farmers, and industry. California is currently establishing a statewide aflatoxin limit for food products. More stringent limits have also been proposed for various bulk commodities and/or foods by the peanut industry and some members of U.N. Food and Agriculture/World Health Organization committees. Comprehensive information on aflatoxin might prove useful for export sales if used to enhance perceptions about the quality of the U.S. corn crop. However, additional resources would be required to develop these proposals, and given the effectiveness of existing programs, it is uncertain whether new programs or limits would ultimately result in less aflatoxin in the food supply.

Principal Findings

Risk of Food-Related Hazards

No cases of illness and/or death from aflatoxin poisoning have been documented in the United States. In contrast, the Centers for Disease Control and FDA estimate that food-borne microbial pathogens such as salmonella and listeria cause as many as 33 million illnesses and about 9,000 deaths in the United States each year.

The aflatoxin limits established for human foods are based on the potential concern that small amounts consumed over time might cause cancer. Federal and state test results, though limited, show few instances where these standards were exceeded following the 1988 drought. For instance, FDA's testing of 601 milled corn-based products found only 2.2 percent in excess of the 20-parts-per-billion (ppb) limit. According to FDA, these products all required further processing or preparation before consumption, which further reduces aflatoxin levels. None of the ready-to-eat corn-based products had levels exceeding FDA's limits. Similarly, out of a total of 2,276 milk samples tested by FDA and 7 states, only 17 (.75 percent) exceeded the 0.5-ppb limit.

Federal, State, and Industry Efforts

In aggregate, federal, state, and industry efforts to detect and control aflatoxin appear effective at minimizing aflatoxin in the food supply. On the basis of its testing, combined with that of the states, FDA believes that the food supply is generally safe from aflatoxin, even during periods of drought when its occurrence is more widespread.

States with recurring aflatoxin problems generally test susceptible commodities and foods routinely for aflatoxin. For example, Georgia routinely tests corn, pecans, peanuts, and milk for aflatoxin. In contrast, the efforts of states with only occasional aflatoxin problems fluctuate from year-to-year. This situation is particularly true in the Midwest, which produces most of the nation's 8-billion-bushel corn crop. While fluctuating efforts tend to contribute to an overall lack of comprehensive information on the incidence of aflatoxin in U.S. corn, the variable approach taken by midwestern states appears reasonable given the sporadic nature of their problems.

Economic incentives motivate industry to test susceptible commodities repeatedly throughout the marketing process—from bulk commodity to final product—depending on how widespread aflatoxin problems are believed to be. Also, in some cases, the aflatoxin standards imposed by industry are more stringent than federal limits. For example, one milling company requires a 10-ppb aflatoxin limit for the corn it buys (rather than the 20-ppb federal limit) and tests it upon delivery, during processing, and in the final product stage.

Proposals to Improve Aflatoxin Control

Several proposals have been made to improve data gathering and make some of the mechanisms used to initiate detection and control efforts more proactive—particularly in the Midwest. California is establishing a statewide aflatoxin limit for food. More stringent limits have also been proposed by the peanut industry and some members of the international community. However, existing federal and state efforts appear to be effective at minimizing aflatoxin in the domestic food supply. Industry's efforts are particularly important for minimizing aflatoxin. In addition, technical as well as practical limitations associated with sampling and testing mean that some aflatoxin will enter the food and feed supply despite the most stringent detection and control programs. Consequently, while improved data gathering may prove beneficial for other purposes, it is questionable whether significantly reduced aflatoxin levels would result from the investment of the additional resources needed to improve data.

Recommendations

GAO is making no recommendations.

Agency Comments

The information contained in this report was discussed with responsible FDA, USDA, Georgia, and Iowa officials, and they agreed with the facts as presented. Where appropriate, changes were made on the basis of these discussions to clarify some of the information. However, as your office requested, GAO did not obtain official agency comments on a draft of this report.

Contents

Executive Summary		
Chapter 1 Introduction		[illegible]
	Sources of Dietary Aflatoxin	[illegible]
	Regulatory Strategy	[illegible]
	Objectives, Scope, and Methodology	1[illegible]
Chapter 2 Aflatoxin Is Considered Less of a Health Risk Than Other Food Hazards		13
	Health Effects of Aflatoxin	13
	Aflatoxin Does Not Seriously Threaten Domestic Food Safety	14
	Milling, Processing, and Food Preparation Can Reduce Aflatoxin in Some Foods	16
	Sampling and Testing Limits Affect Detection and Control	20
	Conclusions	22
Chapter 3 Existing Regulatory and Industry Programs to Detect and Control Aflatoxin		24
	Federal Efforts	24
	State Efforts	27
	Industry Efforts	30
	Conclusions	32
Chapter 4 Proposals to Improve Aflatoxin Detection and Control		34
	Iowa Aflatoxin Task Force Proposal	34
	FGIS and Grain Industry Proposal	36
	FDA and Others Are Reviewing Existing Aflatoxin Limits	36
	Conclusions	38
Appendixes	Appendix I: Georgia's Programs to Detect and Control Aflatoxin	40
	Appendix II: Iowa's Programs to Detect and Control Aflatoxin	44
	Appendix III: Major Contributors to This Report	47
Tables	Table I.1: Aflatoxin Test Results for Corn Sampled in Georgia, Fiscal Years 1989 and 1990	41

Table I.2: Aflatoxin Test Results for Corn, Pecan, and Peanut Food Products Sampled Between October 1988 and November 1989 42
Table I.3: Aflatoxin Test Results for Milk Sampled in Calendar Year 1989 43

Abbreviations

AMS	Agricultural Marketing Service
ARS	Agricultural Research Service
ASCS	Agricultural Stabilization and Conservation Service
CAST	Council of Agricultural Science and Technology
CDC	Centers for Disease Control
FDA	Food and Drug Administration
FGIS	Federal Grain Inspection Service
FSIS	Food Safety and Inspection Service
GDA	Georgia Department of Agriculture
IDALS	Iowa Department of Agriculture and Land Stewardship
NASS	National Agricultural Statistics Service
PAC	Peanut Administrative Committee
ppb	parts-per-billion
USDA	United States Department of Agriculture

Introduction

The Food and Drug Administration (FDA) and state regulators found higher than normal amounts of aflatoxin (a naturally occurring, mold-produced toxin) in corn from the Midwest in 1988, Illinois in 1989, and Texas in 1989 and 1990. Federal and state officials, as well as others, were concerned because aflatoxin can adversely affect human and animal health and contaminate other commodities as well; it remains in the food and feed products processed from them. Consequently, following these higher than normal occurrences, existing controls to prevent aflatoxin-contaminated food from reaching the public were questioned.

Sources of Dietary Aflatoxin

Aflatoxin is a potent natural toxin formed by two common molds that occur throughout agricultural and non agricultural areas worldwide. These molds are present in soil and plant debris and are spread by wind currents, insects, and rain.

Aflatoxin becomes more prevalent, and therefore more of a food safety concern, during a drought because low rainfall and high temperatures encourage the growth and survival of the molds that produce it. Also, crops stressed by drought and high temperatures, and/or weakened by insect or other damage (i.e., hail or frost) are more susceptible to mold growth and subsequent aflatoxin contamination. The aflatoxin-producing molds can grow on crops in the field, poorly dried harvested crops in storage, and processed food and feed products. Aflatoxin can cause illness or even death if large enough amounts are eaten. Some authorities also believe that the long-term consumption of smaller amounts of aflatoxin may cause cancer.

According to the Council for Agricultural Science and Technology (CAST),[1] commodities having a high risk of direct aflatoxin contamination include corn, peanuts, cottonseed, brazil nuts, pistachio nuts, and copra (dried coconut meat).[2] Milled corn and peanut products such as corn meal, corn grits, and peanut butter are the primary sources of dietary aflatoxin in the United States. Milk, meat, and eggs can also be indirectly contaminated with a less potent, metabolized form of aflatoxin

[1] CAST is a consortium of scientific societies whose primary mission is to provide scientific information on food and agricultural issues of national importance.

[2] CAST, Mycotoxins:Economic and Health Risks, Report No. 116, (Ames, Iowa: Nov. 1989).

when animals eat aflatoxin-contaminated feeds. However, research indicates that meat and eggs are not likely sources of dietary aflatoxin and dietary exposure to aflatoxin from milk is reported to be negligible.[3]

Aflatoxin was first recognized as a food safety concern during the early 1960s. Since then, federal, state, and private organizations have instituted an array of programs and cooperative agreements to detect and control aflatoxin in the food and feed supply.

Regulatory Strategy

While the aflatoxin contained in foods and feeds can be minimized, it cannot be entirely eliminated. Limitations in the accuracy of the state-of-the-art sampling techniques and analytical testing methods mean that even with the most stringent of modern detection and control programs some aflatoxin will find its way into the food and feed supply. Furthermore, since the testing process destroys the commodity tested, testing 100 percent of a susceptible crop would not be practical—even if it were possible. Therefore, as the principal federal agency responsible for ensuring the safety of the domestic food supply, FDA establishes and enforces limits[4] on the quantity of aflatoxin allowable in foods and feeds under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

FDA limits aflatoxin in food and feed because of its suspected ability to cause cancer in humans and/or its potential to otherwise adversely affect animals. The limits themselves, however, are set taking into account sampling and analytical testing reliability; FDA's ability to legally defend its actions; and the feasibility of reducing aflatoxin without totally eliminating susceptible commodities from the food supply. FDA's aflatoxin limit for corn destined for human food purposes, dairy feed, or export is 20 parts per billion (ppb).[5] Aflatoxin limits for nondairy feed corn vary between 20 and 300 ppb, depending on the species of consuming animal, its maturity, and whether the animal involved is to be used for breeding purposes. FDA has also set an aflatoxin limit of 20 ppb for processed peanuts and peanut products (25 ppb for raw peanuts) and requires a 0.5-ppb limit for milk because large quantities are

[3]The Committee on Diet, Nutrition, and Cancer, Assembly of Life Sciences, National Research Council, Diet, Nutrition, and Cancer (Washington, D.C.: National Academy Press, 1982). Also, research performed by U.S. Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS) indicates that meat, poultry, and eggs are not likely to be significant sources of dietary aflatoxin.

[4]The aflatoxin levels set by FDA are referred to as "limits" for the purposes of this report.

[5]According to the Iowa Corn Growers Association, most exported corn is used for animal feed. FDA will allow aflatoxin levels higher than 20 ppb in corn for export if the higher levels are approved by the importing nation and the exporter documents the approval.

consumed by infants and children. FDA regulates aflatoxin as an added substance, rather than as a naturally occurring poisonous and deleterious substance, because it can be avoided or minimized with proper agricultural and manufacturing practices.

The U.S. Department of Agriculture (USDA) also has programs to detect and help control aflatoxin. Its Federal Grain Inspection Service (FGIS) tests corn for aflatoxin and, in conjunction with industry, its Agricultural Marketing Service (AMS) and Agricultural Stabilization and Conservation Service (ASCS) test peanuts. In addition, some states have implemented their own programs to test commodities and food products for aflatoxin. Also, industry, in cooperation with USDA and FDA, voluntarily established aflatoxin detection and control programs to cover imported and domestic tree nuts.[6] FDA monitors these crops to ensure that effective industry-implemented quality control procedures continue. More detailed information on federal, state, and industry detection and control programs for aflatoxin is provided in chapter 3.

USDA and private industry have considerable research underway on the prevention, detection, and control of aflatoxin. However, aflatoxin remains a naturally occurring phenomenon that cannot be totally eliminated from the food and feed supply without eliminating the susceptible commodities themselves.

Objectives, Scope, and Methodology

The Chairman, Subcommittee on Wheat, Soybeans, and Feed Grains, House Committee on Agriculture, asked us to examine (1) the relative risk that aflatoxin presents to food safety when compared with other food supply contaminants and (2) approaches taken by selected states to detect and control aflatoxin.[7] We also assessed several federal, state, and industry proposals to make (1) aflatoxin limits more stringent and (2) data gathering on aflatoxin outbreaks more systematic and comprehensive. We reported our preliminary findings in testimony before the Subcommittee on April 2, 1990.[8] This report presents our final results.

[6]In conjunction with FDA and USDA, affected industries voluntarily established aflatoxin detection and control programs for imported Brazil and pistachio nuts in 1968 and 1973, respectively, and for domestic tree nuts in 1971.

[7]Information concerning USDA aflatoxin research projects was provided in our report entitled Food Safety And Quality: USDA Initiatives Regarding Aflatoxin Research (GAO/RCED-90-205FS, Aug. 15, 1990).

[8]Observations on Aflatoxin Detection and Control Activities of Federal, State, and Private Organizations (GAO/T-RCED-90-60, Apr. 2, 1990).

To get information on aflatoxin's relative importance as a food safety risk, we interviewed and obtained documentation from officials at FDA and USDA, as well as other knowledgeable government and industry officials. We obtained information on the incidence of aflatoxin in field crops following the 1988 drought from ASCS, FGIS, the National Agricultural Statistics Service (NASS), the Federal Crop Insurance Corporation, and various states. We obtained information from FDA's compliance program reports for fiscal year 1986 and for October 1988 through June 1989, and compared the aflatoxin levels found in corn-based foods for the 1986 non-drought and 1988-89 drought periods. We also reviewed USDA's aflatoxin test results for corn-based surplus commodities for January through December 1989.

We gathered information on the extent of aflatoxin in peanuts and peanut products from AMS and the Peanut Administrative Committee (PAC). PAC membership includes elected peanut handlers and producers who, along with AMS, administer the peanut marketing agreement. We obtained data regarding aflatoxin in meat and poultry products from FSIS officials. We did not verify the FDA, USDA, or state data bases.

We attended symposiums held by USDA's Agricultural Research Service (ARS) and the Institute of Food Technologists and Intercollegiate Nutrition Consortium, where aflatoxin and other food safety issue priorities were discussed. We also reviewed pertinent studies and literature regarding food safety risks.

We used a case study approach to develop information on selected state programs to detect and control aflatoxin. We chose the AMS program for peanuts, and Georgia and Iowa programs for corn and milk for study, following discussions with USDA scientists and agreement with Subcommittee staff. We selected Georgia because (1) its environmental conditions encourage aflatoxin formation, (2) it is the largest U.S. producer of peanuts, and (3) it has had an aflatoxin detection and control program since the late 1960s. We selected Iowa because it (1) has sporadic aflatoxin problems, (2) is the largest U.S. corn producer, and (3) had an aflatoxin outbreak in 1988.

We interviewed and obtained data from Georgia and Iowa state officials, representatives of the Corn Refiners Association, American Corn Millers Federation, National Peanut Council, and several corn marketers and processors. We also observed sampling and testing procedures at a limited number of locations to document corn, peanut, and milk industry aflatoxin detection and control practices. We supplemented our case study approach by interviewing officials responsible for aflatoxin detection control in foods or feeds in California, Illinois, Minnesota, North Carolina, Pennsylvania, Texas, and Wisconsin.

Finally, we monitored FDA efforts to establish limits for aflatoxin under the Administrative Procedures Act, and California's efforts to establish its own aflatoxin limits.

We conducted our review from September 1989 through November 1990, at FDA, USDA, and other locations in the Washington, D.C., metropolitan area and in Georgia, Illinois, Iowa, Minnesota, North Carolina, and Texas. The review conformed to generally accepted government auditing standards. We discussed the information in this report with responsible FDA, USDA, Georgia, and Iowa officials, and they agreed with the facts as presented. Where appropriate, we made changes on the basis of these discussions to clarify some of the information. However, as your office requested, we did not obtain official agency comments on a draft of this report.

Aflatoxin Is Considered Less of a Health Risk Than Other Food Hazards

Aflatoxin can cause serious health effects if large enough amounts of it are eaten. However, in the domestic food supply, aflatoxin levels high enough to cause illness or death are unlikely and pose less of a health risk than do some other domestic food-related concerns, according to food scientists and regulators. Furthermore, commercial processing methods help to reduce the levels of aflatoxin contained in foods made from susceptible commodities, thereby decreasing any health risks associated with its long-term consumption.

Health Effects of Aflatoxin

Heavy consumption of aflatoxin can cause vomiting, abdominal pain, liver damage, and even death. Although rare, there have been documented instances where people in underdeveloped African and Asian countries have become ill and/or died from aflatoxin poisoning after eating visibly molded foods during food shortages. However, these nations have environmental conditions--high temperatures and drought,, that foster mold growth in agricultural crops and commodities, and they lack regulatory systems for aflatoxin monitoring and control. These conditions do not normally exist in the United States,[1] and experts are not aware of cases of domestic illness and/or death from eating aflatoxin-contaminated foods.

The long-term effects of consuming low levels of aflatoxin are not as well documented. Although some scientists think aflatoxin may contribute to human liver cancer, cause/effect relationships have not been proven.

Controversy Over Whether Aflatoxin Causes Cancer

Liver cancer is a suspected human health effect of long-term dietary exposure to low levels of aflatoxin contamination, but direct, causal evidence is absent. FDA and other scientists have questioned the validity of laboratory animal experiments and human population studies used to determine whether such a relationship exists. Scientists have also differed on how to interpret study results and how they should be used.

In laboratory studies, scientists have fed high doses of aflatoxin to experimental laboratory animals, documented the formation of liver cancer, and used the results to extrapolate the probable risk to humans for long-term, low-level exposure. However, some scientists believe that the animals used in these studies may be more susceptible to aflatoxin

[1]CAST, Mycotoxins: Economic and Health Risks, Report No. 116 (Ames, Iowa, Nov. 1989).

than humans. Specifically, CAST reported that monkeys are more resistant to aflatoxin's effects than laboratory rats, and according to metabolic and biochemical evidence, humans are also less sensitive to aflatoxin's effects.[2] Some have also questioned the mathematical extrapolation of human risk from laboratory animal results.[3]

Similarly, some scientists question whether some human population studies used to link aflatoxin and cancer are valid. These authorities believe that the carcinogenic effects of herbal medicines and the hepatitis B virus were and are important factors in Africa and Asia, where these studies were conducted, but were not adequately considered. CAST questions whether these studies have any applicability to the U.S. population. It believes that differences in food quality and variety between these countries and the United States are significant and that aflatoxin may not be an important contributor to domestic liver cancer.

Different interpretations of data from a study done in the United States have also added to confusion over the possible carcinogenicity of aflatoxin. For instance, one human population study[4] compared the incidence of death from liver cancer and dietary exposure to aflatoxin between rural white males from the southeastern, northern, central, and western regions. On the basis of the study's results, the researcher concluded there was no correlation between dietary exposure and liver cancer. CAST agreed. However, using the same study data, the International Agency for Research on Cancer concluded that aflatoxin was a possible human carcinogen.

Aflatoxin Does Not Seriously Threaten Domestic Food Safety

The short-term effects of eating food contaminated with large amounts of aflatoxin have been documented in underdeveloped African and Asian countries; the effects, if any, of eating low-level amounts over the long term are less clear. Nevertheless, scientists and regulators agree that other food-related issues pose more serious threats to the domestic food supply. In addition, commercial food processing and preparation prior to consumption can further reduce aflatoxin levels.

[2]CAST, Mycotoxins: Economic and Health Risks, Report No. 116 (Ames, Iowa: Nov. 1989).

[3]Committee on Diet, Nutrition, and Cancer, Assembly of Life Sciences, National Research Council, Diet, Nutrition, and Cancer (Washington, D.C.: National Academy Press, 1982).

[4]Leonard Stoloff, "Aflatoxin As a Cause of Primary Liver-cell Cancer in the United States: A Probability Study," Nutrition Cancer, vol. 5, pp. 165-186 (1983).

Available Test Results Indicate the Food Supply Is Safe From Aflatoxin

Limitations associated with FDA and state sampling procedures preclude statistically valid national estimates of aflatoxin levels in the food supply. However, on the basis of combined results of federal and state testing, FDA believes that the food supply is generally safe from aflatoxin—even during drought years. FDA officials also believe that their test results overstate the aflatoxin problem because their sampling is intentionally biased towards geographical areas suspected of having aflatoxin and firms with a prior history of food and drug law violations.

During fiscal year 1986—a non-drought year for the corn-producing Midwest—FDA sampled 148 whole corn lots, 139 milled corn products, and 23 manufactured corn-based products nationwide. About 6.8 percent of the whole corn lots sampled and 4.3 percent of the milled corn products had aflatoxin levels over FDA's human consumption limit of 20 ppb. No aflatoxin above the 20 ppb limit was found in manufactured, ready-to-eat, corn-based foods such as corn chips, tortillas, and hush puppies.

Following the 1988 midwestern drought, FDA sampled 1,240 whole corn lots, 601 milled corn products, and 139 manufactured corn-based products, nationwide. About 5.5 percent of the whole corn lots sampled and 2.2 percent of the milled corn products had aflatoxin in excess of the 20-ppb limit. According to FDA officials, all of the manufactured corn-based products found to contain excess aflatoxin were types that required additional processing and/or preparation before being eaten, which can further reduce aflatoxin levels. None of the manufactured, ready-to-eat, corn-based products tested contained aflatoxin in excess of FDA's limit. In addition, between January and December 1989, USDA tested 3,359 corn-based commodities, such as corn meal and grits acquired through price-support programs, and none were found to contain excessive aflatoxin levels.

Regarding milk, FDA found no aflatoxin above the 0.5-ppb limit in the 182 milk samples it tested during fiscal year 1986. During the 1988 drought, FDA found that 5, or .8 percent of the 608 milk samples it tested contained aflatoxin in excess of the 0.5 ppb limit. Similarly, test results volunteered by 7 states showed that 12, or .7 percent of 1,668 milk samples tested exceeded the 0.5-ppb limit. On the basis of the combined federal/state testing results, FDA officials believed that aflatoxin was effectively kept out of the milk supply.

Other Hazards Thought to Present Greater Risks

Although no precise way of ranking food safety concerns exists, food scientists and regulators generally believe that microbiological pathogens, malnutrition, and environmental contaminants (i.e., mercury and lead), present greater domestic food safety risks than does aflatoxin. For instance, despite the overall safety of the domestic food supply, the Centers for Disease Control (CDC) and FDA estimate that food-borne microbial pathogens such as campylobacter, salmonella enteritidis, and listeria cause between 6.5 million and 33 million illnesses and about 9,000 deaths in the United States each year.

Conversely, no cases of illness and/or death from eating aflatoxin have been documented in the United States. Amounts of aflatoxin in the U.S. food supply large enough to cause immediate illness and/or death are believed unlikely because conditions in the U.S. agricultural environment are generally not conducive to the development of aflatoxin. In addition, federal and state agencies, as well as industry, have effective detection and control programs. Milling and processing techniques also reduce the aflatoxin levels that may be contained in some commercially manufactured foods. Domestic concerns therefore focus more on whether long-term dietary exposure to small amounts of aflatoxin can cause cancer in humans.

The FDA Commissioner has stated that, although it is really not possible to compare chronic (long-term) carcinogenic risks to acute (immediate, short-term) health effects, the hazards created in our own kitchens from food-borne diseases outrank dangers from chemicals like aflatoxin and pesticides. The Commissioner also stated that the occasional consumption of the very few corn products that contain a measurable amount of aflatoxin are of little lifetime health consequence, because only repeated exposure to relatively high levels of aflatoxin over a number of years presents a significant safety risk. Nevertheless, FDA's regulatory approach is to keep aflatoxin levels in the food supply as low as possible (i.e., 20 ppb or less), because of uncertainty over whether eating small amounts could eventually cause human cancer.

Milling, Processing, and Food Preparation Can Reduce Aflatoxin in Some Foods

Some of the commercial processing methods used to manufacture corn and peanut food products can significantly reduce the aflatoxin contained in them. Final preparation before consumption can further reduce/dilute the remaining aflatoxin in some corn-based foods. Pasteurization processes used for milk are less effective in reducing aflatoxin levels. However, the aflatoxin that milk may contain is a less potent, metabolized form and is regulated to 0.5 ppb or less. Therefore, dietary exposure to aflatoxin from milk is relatively small. Cultured milk products such as yogurt and buttermilk have about the same level of aflatoxin as in the original milk. Concentrated dairy products such as cheese may actually contain higher levels of aflatoxin than the milk from which they are made.

Corn

Domestically, about 16 percent of the annual U.S. corn crop is used for human consumption; about 24 percent is exported; and about 60 percent of the remaining crop is used domestically for animal feed. Generally, corn is processed into food and food ingredients using either wet or dry milling methods.[5] About 75 percent of the corn crop used for human consumption is processed by wet milling; the remaining 25 percent is processed at dry mills.

ARS scientists believe that very little aflatoxin will be found in wet milled corn-based food products, compared with the original corn. Industry-sponsored research shows that the starch component used to make food products such as cornstarch, corn sugar, corn syrup, and alcohol contains very little aflatoxin when compared with the level contained in the original corn.[6] Essentially, all of the aflatoxin present in the original corn has been found to concentrate in the by-products of the wet milling process used to produce animal feed.[7]

Similarly, in dry milling, according to ARS and FDA reviews of industry research, low-fat flour, meal, and grits produced by tempering/degerming—the most common of the three dry milling methods—contain lower levels of aflatoxin than the original corn.[8] However, the research also shows that aflatoxin levels for higher fat content food products are likely to exceed those of the original corn. Reviewing the

[5]Wet and dry milling methods involve separating the corn kernel into parts by physical or chemical means. In wet milling, corn kernels are soaked in water and separated into their starch, gluten, hull, and germ components. The starch and germ components are used for food products, the hull and gluten are generally used for animal feed. The tempering-degerming dry milling method uses less water but separates the corn kernel into basic components. The stone grinding and alkaline cooking dry milling methods do not separate out the germ component, and most of the corn kernel is used in consumer foods.

[6]K.R. Yahl, S.A. Watson, R.J. Smith, R. Barabolok, "Laboratory Wet-Milling of Corn Containing High Levels of Aflatoxin and a Survey of Commercial Wet-Milling Products," Cereal Chemistry, Vol. 48 (Jul.-Aug. 1971).

[7]Glenn A. Bennett and Roy A. Anderson, "Distribution of Aflatoxin and/or Zearalenone in Wet-Milled Corn Products: A Review," Journal of Agricultural Food Chemistry, Vol. 26, No. 5 (1978).

[8]O.L. Brekke, A.J. Peplinski, G.E. Nelson, and E.L. Griffin, Jr., "Pilot-Plant Dry Milling of Corn Containing Aflatoxin," Cereal Chemistry, Vol. 52 (Mar. - Apr. 1975).

industry-sponsored research results, ARS and FDA scientists concluded that the lowest levels of aflatoxin would be found in the corn kernel components used as food ingredients and the highest would be in components used for animal feed.[9] FDA scientists also conducted an independent study of milled corn products at 82 dry milling establishments and generally corroborated the earlier dry milling research results.[10]

The other dry milling processes—stone-grinding and alkaline cooking—are not as successful as tempering/degerming in reducing aflatoxin levels. Also, research has shown that while alkaline cooking may reduce between 20 to 90 percent of the original aflatoxin, aflatoxin may chemically reform in the stomach when the food is exposed to stomach acids.[11]

Preparation May Further Reduce/Dilute Aflatoxin

Preparing dry-milled products for eating can further reduce aflatoxin. FDA scientists reported that boiling grits destroyed about 28 percent of the aflatoxin. When boiled grits were fried, an additional 34 to 53 percent of the aflatoxin was destroyed, depending on the moisture content of the grits. Similarly, 13 percent of the aflatoxin found in corn meal was destroyed when made into corn muffins.[12]

Peanuts

About 53 percent of the annual peanut crop is used domestically for human food, about 19 percent is exported for food use, about 17 percent is crushed for oil, and about 11 percent is used for feed, seed and other non-food purposes. The aflatoxin in peanuts is reduced when they are milled and processed into consumer products such as peanut butter and oil. During the milling process, peanut millers and processors use electronic eye sorting and hand picking to remove the smaller, darker kernels, which are more likely to be contaminated with aflatoxin. According to ARS scientists, the sorting process can remove significant amounts of aflatoxin. Peanuts removed through sorting are frequently

[9]O.L. Shotwell, "Aflatoxin in Corn," Journal of American Oil Chemistry Society, Vol. 54 (Mar. 1977).

[10]L. Stoloff, B. Dalrymple, "Aflatoxin and Zearalenone in Dry-Milled Corn Products," Journal of the Association of Analytical Chemists, Vol. 60 (1977).

[11]Ralph L. Price, Karen V. Jorgensen, "Effects of Processing on Aflatoxin Levels and on Mutagenic Potential of Tortillas Made From Naturally Contaminated Corn," Journal of Food Science, Vol. 50 (1985).

[12]Leonard Stoloff, Mary Truckness, "Effect of Boiling, Frying, and Baking on Recovery of Aflatoxin From Naturally Contaminated Corn Grits or Cornmeal," Journal of the Association of Official Analytical Chemists, Vol. 64, No. 3 (1981).

crushed for oil. The oil is then refined to eliminate impurities, which removes the aflatoxin as well.

Further reductions in aflatoxin may occur in blanching, which removes the peanut skins, and in roasting. Blanching and roasting are done before peanuts are ground into butter. FDA scientists reviewed research on the effects of dry and deep-fat roasting and reported that these methods reduced aflatoxin by 40 to 80 percent.

Milk

Two grades of milk are produced in the United States—grades A and B.[13] About 90 percent of the milk produced each year is grade A, which is used for drinking and in milk products such as cream, yogurt, and ice cream. Grade B (and surplus grade A) milk is used in manufactured products such as cheese, butter, and dry milk. Laboratory research on whether certain pasteurization processes can reduce aflatoxin in milk has yielded conflicting results. Some industry research has shown reductions in aflatoxin of between 6 and 64 percent, depending on the pasteurization process used and whether the milk was contaminated naturally or was artificially contaminated for research purposes. However, University of Wisconsin scientists who reviewed FDA and industry research concluded that pasteurization had only a small effect on reducing aflatoxin.[14] This finding supports 1970s FDA studies that concluded aflatoxin in milk was not reduced through pasteurization. The University of Wisconsin scientists concluded that the difference between natural and artificial aflatoxin contamination and variations in analytical techniques used might explain the variability in different researchers' results.

The University of Wisconsin scientists also concluded that if raw milk contains aflatoxin, milk products that are more concentrated, such as natural cheese, processed cheese, and butter, will generally have higher aflatoxin levels—as much as eight times higher than the original milk.[15] However, assuming the original milk contained 0.5-ppb aflatoxin or less, an eight-fold concentration would yield, at most, a 4-ppb aflatoxin level

[13] Farmers producing grade A milk must adhere to higher sanitation requirements than for grade B milk.

[14] Rhona S. Applebaum, Robert E. Brackett, Dana W. Wiseman, and Elmer H. Marth; "Aflatoxin: Toxicity to Dairy Cattle and Occurrence in Milk and Milk Products—A Review," Journal of Food Protection, Vol. 45 (June 1982).

[15] Dana W. Wiseman and Elmer H. Marth; "Behavior of Aflatoxin M_1 in Yogurt, Buttermilk, and Kefir;" Journal of Food Protection, Vol. 46 (Feb. 1983).

in the processed products manufactured from it. Also, while FDA has not set an aflatoxin limit for processed dairy products, the limit established for other processed foods is 20 ppb.

Sampling and Testing Limits Affect Detection and Control

Determining the specific level of aflatoxin in a commodity generally involves (1) collecting a representative sample; (2) making the sample more uniform through grinding, mixing, etc.; (3) drawing a representative sub-sample for testing; and (4) analyzing the sub-sample using chemical and other means. This process is imprecise—even when standard procedures are followed. Additional efforts can be taken to minimize the errors associated with each of these steps. However, there are practical limits to the extent of sampling and testing that can be done.

Sampling Error

CAST reports that sampling is the largest source of error in aflatoxin testing. The Iowa Aflatoxin Task Force also reported that it is difficult to obtain a representative sample when corn is in its kernel state. Errors arise in sampling whole corn because (1) aflatoxin is concentrated in less than 0.1 percent of the kernels; (2) contaminated kernels may not be evenly distributed throughout a bulk load; (3) there are differences in the aflatoxin level of individual kernels; and (4) aflatoxin is measured in exceedingly small quantities. For example, a rail hopper car containing 300 million corn kernels would have a composite aflatoxin level of 20 ppb if only 6,000 of those kernels had an aflatoxin concentration of 0.1 percent by weight. The Iowa Aflatoxin Task Force estimated that the odds of 1 or more of the 6,000 kernels being selected following typical sampling procedures was about 11 percent.

It is therefore difficult to determine the actual aflatoxin level for a load of whole corn with certainty. The small number of contaminated kernels, uneven distribution, and the range of aflatoxin concentration among them can cause significant differences between samples selected from the same load. It is possible that aflatoxin in a load may not be detected by sampling and testing or, once detected, may not be detected in a subsequent sampling. FGIS currently requires the selection of a 10-pound random sample to test corn for aflatoxin. Sampling error, according to CAST, might be reduced by increasing the sample size.

Sub-Sampling Error

Whole corn samples must be ground and mixed before they can be analyzed. The grinding and mixing makes the sample more uniform in consistency and better ensures that the aflatoxin contained in it will be evenly distributed. A smaller sub-sample is then selected from the mixture for detailed analysis.

It is presumed that the distribution of contaminated particles in the sub-sample is similar to the distribution of contaminated kernels in the bulk load. However, as discussed earlier, aflatoxin may not be uniformly distributed in the bulk load and the sub-sample, like the sample from which it was selected, may not be representative. Furthermore, even with grinding and mixing, aflatoxin may not be uniformly distributed in the mixture, and there may be differences between sub-samples selected from it. According to CAST, these differences can be minimized by grinding and mixing the sample more and increasing the size of the sub-sample.

Analytical Testing Error

Several methods are used to analyze commodities for aflatoxin. Some laboratory procedures require a number of complicated steps, such as solvent extraction, centrifugation, drying, dilutions, and visually matching the sample extract color (or fluorescence) to a control standard, to estimate the level of contamination. However, according to CAST, each of the steps involved in these analytical procedures introduce variations in the final test results and repeated analyses on the same sub-sample sometimes produce different results. New "quick-test" methods are also available for analyzing aflatoxin that are less involved, and FGIS has found several of them to be generally reliable. Although simpler to use, an official of the Association of Official Analytical Chemists[16] believes that some degree of training is required for analysts to produce consistent and reliable results with some quick test kits. Analytical variability can be reduced by increasing the number of tests performed.

Practical Limitations

Approximately 8 billion bushels of corn are produced in the United States each year. Unlike the smaller, centrally located peanut crop, the huge crop of whole corn is marketed at about 8,000 locations throughout the country. The rudimentary facilities at some of these locations are not suited for detailed aflatoxin testing and analysis. Also, during the harvest rush, farmers must frequently wait in line in order to deliver their corn to these locations. The additional time required to properly select representative samples, coupled with the time required to analyze

[16]This organization judges the suitability and reproducibility of analytical methods by conducting collaborative studies whereby a number of different analysts carry out specific procedures on identical samples.

the samples taken—even with quick-test methods—would add between 25 and 35 minutes to the delivery time for each load of corn. Also, given delivery load sizes of between 300 and 500 bushels, and an average quick-test kit cost of $10, it would cost between $160 and $260 million each year for the quick test kits needed to perform this testing. Efforts to reduce sampling, sub-sampling, and analytical error, such as increasing sample sizes, numbers, and grinding, could add considerably to the time and expense involved. Consequently, testing every load of corn delivered to these facilities during the harvest may not be feasible.

However, corn is processed into food at about 100 mills. Sampling and testing is routinely conducted at these locations to check quality factors such as starch and oil content and kernel damage from molds and aflatoxin contamination. Theoretically, samples taken and tested at these locations during the manufacturing process would tend to yield more accurate results because the entire load of corn (or a substantial portion of it) has been uniformly ground and mixed and the aflatoxin contained in it is more evenly distributed.

Conclusions

Sustained regulatory efforts are necessary to ensure that aflatoxin in the food and feed supply is minimized because aflatoxin can cause illness and/or death if eaten in large enough amounts. It is not known whether adverse health effects can result from consuming smaller amounts over time.

However, while the potency of aflatoxin is recognized, experts do not know of any documented cases of acute aflatoxin poisoning in the United States. Large amounts of aflatoxin contamination are not considered likely in the domestic food supply because conditions in the U.S. agricultural environment are generally not conducive to aflatoxin formation and there are several layers of detection and control. Indeed, many food scientists and regulators rank aflatoxin as a lower domestic food safety risk than microbiological pathogens, malnutrition, and environmental contaminants. Some commercial food processing methods also tend to reduce the levels of aflatoxin found in susceptible commodities.

Test results show that aflatoxin has occasionally entered the food supply in amounts exceeding FDA's limits. FDA does not believe that these instances posed a significant health threat. In addition, on the basis of its compliance monitoring data and state data, FDA does not believe that aflatoxin has presented a significant problem to the domestic food supply—even with its occurrence in midwestern corn during the 1988 drought. However, practical and technical limitations in sampling and testing capabilities mean that some aflatoxin will ultimately find its way into the food and feed supply despite the most stringent detection and control programs.

Existing Regulatory and Industry Programs to Detect and Control Aflatoxin

Federal and state programs have been established to detect and control aflatoxin in susceptible commodities and food products. Regulatory programs have been established to routinely test susceptible commodities and foods where aflatoxin is a persistent, recurring problem. In situations where aflatoxin is only an occasional problem, detection and control efforts fluctuate from year-to-year. However, industry has strong incentives to minimize the aflatoxin contained in its products, and it plays a key role in protecting the food and feed supply from aflatoxin, assisted by the federal government and the states. In fact, to ensure quality control, some industries set aflatoxin limits that are more stringent than the federal government's. While some gaps and overlaps may occur in these programs, in aggregate they appear to be effective at minimizing aflatoxin in the food supply.

Federal Efforts

FDA is the principal federal agency responsible for ensuring that a multitude of food, drug, medical, and cosmetic items marketed in the United States are safe, pure, and properly labeled. It relies heavily on the regulatory efforts of other federal and state agencies and private industry to keep contaminants, such as aflatoxin, out of the domestic food and feed supply. FDA has set limits for aflatoxin in food and feed products, and through compliance programs evaluates industry manufacturing practices and quality control procedures implemented to detect and control aflatoxin.

FDA also monitors aflatoxin levels in the food supply by sampling and testing a limited number of raw and processed commodities each year. This testing generally focuses on areas where monitoring by states and private industry may be inadequate and/or on firms that have previously violated regulations. FDA increases its testing when weather conditions make aflatoxin contamination more probable. FDA conducts compliance programs to establish a background of data on the occurrence and levels of aflatoxin and to remove from interstate commerce products containing excessive aflatoxin levels.

FGIS, AMS, and ASCS also have programs to detect and help control aflatoxin. Private companies may ask FGIS to sample and test grain and grain products for aflatoxin, under authority of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.). Also, recent amendments to the Grain Standards Act (7 U.S.C. 77), require FGIS to test all exported corn unless the sales contract stipulates that aflatoxin testing should not be performed.[1] AMS and PAC jointly administer a peanut marketing agreement,[2] and ASCS administers the peanut price support program—which are two major means, in addition to industry programs, of preventing aflatoxin-contaminated peanuts from entering the food supply.

Corn

FDA periodically conducts on-site "establishment" inspections to determine whether elevators, warehouses, and manufacturing plants are meeting their responsibilities for producing safe products. Establishments are selected for inspection on the basis of such factors as the type of products handled or manufactured, the violation rate of the facility or industry, and/or whether it has been previously inspected. In some instances, FDA contracts with state regulatory agencies to have the inspections performed for them and relies on the states for follow-up on violations by firms not involved in interstate commerce. FDA follows up on violations by firms involved in interstate commerce.

Although FGIS's objective is to facilitate grain marketing, it has agreed, through a memorandum of understanding, to inform FDA when it detects aflatoxin in corn lots that it has both sampled and tested.[3] Many of the requests for FGIS services are for export shipments. For example, FGIS was asked to perform aflatoxin sampling and testing on about 98.5 percent of the corn exported in fiscal year 1990 and on 99.8 percent exported in fiscal year 1991 to date.

Peanuts

The industry-initiated peanut marketing agreement requires that all peanuts be inspected for aflatoxin. The agreement requires the following:

[1]The Food, Agriculture, Conservation, and Trade Act of 1990 (P.L. 101-624) amended the U.S. Grain Standards Act (7 U.S.C. 77) to authorize and require FGIS to test exported corn for aflatoxin unless the contract between the buyer and seller specifically states that aflatoxin testing should not be performed.

[2]Marketing agreements can be used to keep agricultural products of poor quality from entering the market and depressing price levels. The peanut marketing agreement is a voluntary contract between peanut handlers (handlers) and the Secretary of Agriculture and is authorized under the Agricultural Marketing Agreement Act of 1937 (7 U.S.C. 601-674). Before the 1990 crop, USDA's peanut marketing agreement covered about 68 peanut handlers and 95 percent of all peanuts marketed. Amendments to the Agricultural Marketing Agreement Act (P.L. 101-220) now require that all U.S. handlers comply with the marketing agreement's aflatoxin testing and other quality requirements.

[3]FGIS does not inform FDA when it detects aflatoxin in samples submitted by other parties for analysis because, since it did not sample the corn, FGIS does not know from what lot the sample was drawn.

- All harvested peanuts brought to handlers—firms that buy and sell peanuts—are sampled and visually inspected for aflatoxin-producing mold. Contaminated loads are diverted to nonedible uses such as seed or animal feed.
- All milled peanuts intended for human consumption are analyzed for aflatoxin content by a USDA- or PAC-approved laboratory. Peanuts with more than 20 ppb[4] aflatoxin are diverted for nonedible uses or remilled and then retested before being sold for edible uses.
- Peanut warehouses and equipment are inspected by PAC officials to ensure that storage conditions are not conducive to the growth of aflatoxin-producing mold.
- To prevent contamination, peanuts for human consumption are stored separately from lower quality peanuts.

Under a memorandum of understanding with AMS, FDA is notified of milled peanuts testing positive so it can examine products made from such peanuts.

USDA's peanut price support program supplements the marketing agreement's activities. ASCS administers this program, which advances support loans to farmers, arranges storage for loan peanuts, and records producer peanut sales. Producer marketing associations assist ASCS. The program is primarily intended to manage producer price support benefits. However, the following aflatoxin detection and control requirements have also been established under the program:

- Federally licensed state inspectors sample all peanuts delivered for price support and visually inspect them for the aflatoxin-producing mold.
- Peanuts found to be aflatoxin-contaminated must be sold to handlers, placed under price support loan (contaminated peanuts receive a lower support rate), or returned to the farm for seed.
- Contaminated peanuts sold to handlers or placed under price support are stored separately in ASCS-inspected warehouses and are diverted to nonedible uses.
- Peanuts purchased from the price support program for export for food purposes must be tested for aflatoxin.

FDA also collects and analyzes peanuts and peanut products for aflatoxin through its compliance program and inspects milling and processing plants through its establishment inspection program. However, FDA

[4]This industry standard became 15 ppb, as of Aug. 23, 1990.

limits its peanut-monitoring efforts because of extensive USDA and industry involvement.

Milk

FDA oversees the safety and purity of the nation's milk supply through a collaborative federal/state milk safety program that dates back to the mid-1920s. Most milk is produced and marketed under the Grade A Pasteurized Milk Ordinance—the basic sanitation standard used today in the voluntary, cooperative, interstate milk safety program by the states and the District of Columbia (states). Although the ordinance does not specifically require that milk be tested for aflatoxin, it stipulates that no adulterated milk may be marketed for human consumption.

FDA monitors this program and provides technical assistance and additional testing when needed. The states themselves provide day-to-day oversight and, according to officials' perceptions of aflatoxin risk, individually decide whether to test raw and/or processed milk for aflatoxin contamination and/or enforce their own dairy laws and regulations. FDA relies heavily on state authorities for the inspection of milk for aflatoxin (as well as other contaminants) and has enforcement jurisdiction over milk products shipped in interstate commerce. FDA also annually collects and analyzes a limited number of milk products for aflatoxin and, during periodic inspections of dairy processing plants, reviews the processors' procedures for avoiding contaminants such as aflatoxin.

FDA has an interagency agreement with the Environmental Protection Agency, which provides approximately 800 milk samples to FDA for analysis each year. FDA analyzes these samples to assess the health risks presented by levels of aflatoxin (and environmental contaminants) in the nation's milk supply.

State Efforts

State aflatoxin detection and control activities vary depending on the commodity involved and whether widespread and/or recurring problems are perceived to exist.

Corn

State programs to detect and control aflatoxin in corn vary by geographic area, commodity use, and perceptions regarding the extent of an aflatoxin outbreak. Most of the approximately 8 billion bushels of corn produced by the United States each year are grown in the midwestern "Corn Belt" states including Illinois, Indiana, Iowa, Minnesota, Nebraska, and Ohio. Generally, the cooler weather and adequate rainfall in these states mean that aflatoxin is only a sporadic problem, so that efforts to check corn for aflatoxin depend on whether a problem is perceived to exist. Sampling and testing efforts are generally less extensive during favorable crop years but intensify to deal with a perceived problem. Conversely, drought-prone southeastern states routinely monitor corn for aflatoxin because the hotter, dryer, climatic conditions there promote recurring aflatoxin problems with corn-based food and feed products.

States may monitor aflatoxin in their own program or under contract to FDA. States analyze samples for aflatoxin risks and may inspect corn and corn products for aflatoxin in production areas, at grain elevators, and manufacturing establishments, as well as in those samples submitted to them for testing. They also follow up on violations by intrastate firms as requested by FDA.

For example, in response to the increased aflatoxin risk from the 1988 drought, FDA's Kansas City district office initiated a special sampling effort to draw 10 samples from each state under its jurisdiction—Iowa, Kansas, Missouri, and Nebraska. Before sampling began, FDA officials contacted state regulatory agency and private industry officials to identify growing areas with the greatest risk of aflatoxin occurrence. State and industry contacts and Nebraska's prior analyses indicated that Nebraska and Kansas were less likely to have aflatoxin because weather conditions were less severe and farmers there are more likely to irrigate their corn crops. Accordingly, FDA district officials focused their efforts on Iowa and Missouri.

FDA officials kept the respective state regulatory agencies informed about their sampling activities and identified warehouses where corn was sampled. When sample test results showed aflatoxin levels in excess of 20 ppb, FDA officials provided states with copies of documents detailing the sampling method used and analytical test results. When FDA officials believed the firm was not an interstate shipper, it requested state regulators to conduct follow-up activities.

In response to FDA referrals, Iowa state officials, for example, sampled and tested warehouses' corn. If Iowa regulators verified FDA's results, they reviewed the warehouse's corn handling and storing procedures and, where needed, required changes. They then monitored the warehouse's compliance with these changes. FDA officials told us that other states in the district conducted similar follow-up activities. More detailed information on Georgia and Iowa aflatoxin detection and control efforts is provided in appendixes I and II.

Peanuts

Most of the approximately 4 billion pounds of peanuts produced in the United States each year are grown by nine states—Alabama, Florida, Georgia, New Mexico, North Carolina, Oklahoma, South Carolina, Texas, and Virginia. These states are more prone to higher temperatures and drought than the Midwest, and aflatoxin in peanuts is a recurring problem. However, ever since aflatoxin was discovered to be a food safety risk in the 1960s, peanuts have been subjected to extensive detection and control procedures to ensure that peanuts containing more aflatoxin than allowed by FDA do not enter the food supply.[5]

Under a joint federal government/industry peanut marketing agreement, all peanuts must be inspected for aflatoxin. States support these detection and control activities by providing personnel to sample and inspect peanuts. AMS has a cooperative agreement with each peanut-producing state, whereby each state provides inspectors whom AMS trains, licenses, and supervises. All work is performed on a user fee basis. In addition, states may periodically test processed peanut products for aflatoxin. For example, Georgia routinely tests processed peanut products for aflatoxin and Iowa tests occasionally.

Milk

The states, through their dairy laws and regulations, serve as the front line defense in monitoring the milk supply for aflatoxin and in preventing contaminated milk from entering the market. States' monitoring efforts vary according to how they perceive the magnitude of an aflatoxin problem, resource availability, and other factors. However, all states participate in the Interstate Milk Shippers Program—a voluntary federal/state program for ensuring a safe and wholesome supply of grade A pasteurized milk. The states have also adopted the Pasteurized Milk Ordinance and are responsible for its enforcement under their dairy laws and regulations. States sample and test their raw milk supply and periodically collect finished milk products from processors for aflatoxin analysis.

[5]FDA lowered its aflatoxin limit from 30 ppb to 20 ppb (25 ppb for raw peanuts) with improved sampling and testing abilities.

The United States produces about 145 billion pounds of milk each year. The majority of this milk is produced in five states—California, Minnesota, New York, Pennsylvania, and Wisconsin. California considers feed testing to be its first line of defense against aflatoxin in the milk supply, but draws and tests about 200 samples each year from silos where large quantities of milk are comingled. Since 1988, California has found only one instance where aflatoxin in milk exceeded the FDA limit, according to a state official. Similarly, aflatoxin is not considered to be a milk supply problem in Minnesota, New York, Pennsylvania, or Wisconsin, and the testing programs of these states ebb and flow, depending on weather conditions and news of an aflatoxin outbreak. On the other hand, Arizona, Florida, Georgia, Iowa, North Carolina, and Virginia all have programs to routinely monitor milk for aflatoxin contamination, according to an FDA official.

We reviewed the programs established by Georgia, Iowa, and North Carolina to detect and control aflatoxin in milk. The state efforts were similar and included sampling of grade A and B milk at dairy farms, bulk-milk tankers, and processing plants. If aflatoxin is found in a sample drawn from a bulk-milk tanker, state officials collect follow-up samples to identify the contamination source. Depending on the level of aflatoxin found, the state may warn or suspend identified producers from selling milk until aflatoxin is purged from their dairy cows. Milk that tests above FDA's 0.5-ppb limit is disposed of or directed to nonedible uses. These states also periodically sample and test finished milk products for aflatoxin.

Industry Efforts

Firms that buy, sell, process, and/or manufacture products from commodities that are susceptible to aflatoxin contamination have strong economic incentives for incorporating aflatoxin testing into their quality control programs. These incentives include avoiding costs associated with customer rejections, product recalls, possible seizures by FDA or state regulatory agencies, and the potential loss of market share from adverse publicity. The extent to which an individual firm takes action to detect and control aflatoxin depends on its assessment of the risk of not testing and the desire to preserve its image as a supplier of wholesome ingredients or foods.

Corn

Industry efforts to detect and control aflatoxin in corn may take place at any point in the marketing process, depending on how widespread the aflatoxin problems for a given crop year are thought to be. Sampling and testing may start with the harvested corn and continue through the manufacture and sale of finished products. For example, one quality control director says his food manufacturing company requires vendors to have quality control systems to ensure corn products are within FDA aflatoxin limits. At the onset of the harvest in the 1988 drought year, the company reviewed vendors' aflatoxin sampling and testing programs and required some vendors to make modifications to satisfy its requirements. After its review, the company implemented a program to sample and test high-risk ingredients from selected vendors for compliance.

Similarly, according to an official of a wet milling organization, 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 geographical areas producing aflatoxin-contaminated corn. Testing is then decreased for corn purchased from areas not having aflatoxin contamination. In drought years testing is increased to cover all incoming corn.

Officials of a wet milling company stated that they limit aflatoxin in purchased corn to 10 ppb, or one-half of FDA's limit for aflatoxin in food products. The corn is tested when delivered, during processing, and in final products. This extensive testing is done to avoid excessive aflatoxin in the feeds the company produces, some of which are exported for dairy animals. These officials believe that if customers found aflatoxin in the final feed or milk products, their company might lose its market share.

Also, according to officials of a dry milling firm, every load of corn delivered to their plants since 1965 has been tested for aflatoxin, and they reject any load exceeding 15 ppb.

Aflatoxin testing has been part of the corn milling industry's quality assurance program for many years, according to trade organization officials. In addition, according to a representative of the National Grain and Feed Association, purchase contracts typically require grain to be in compliance with FDA aflatoxin limits. The Office of Technology Assessment has also reported that limits on mycotoxins (such as aflatoxin) were one of the characteristics most often specified in purchase contracts by domestic millers and major feed companies.[6]

[6]U.S. Congress, Office of Technology Assessment, Enhancing the Quality of U.S. Grain for International Trade, OTA-F-399 (Washington, D.C.: U.S. Government Printing Office, Feb. 1989).

Peanuts

Manufacturers of peanut products impose quality requirements on their suppliers that in some cases are more stringent than government regulations. For instance, a peanut handler told us that one food manufacturer his plant supplies not only requires him to have a quality control program that limits aflatoxin, but also specifies the quality control method to be employed and instructs him in how to use it. Moreover, this manufacturer monitors its suppliers' compliance with contract specifications and, at the end of the year, ranks the suppliers against each other. Those at the bottom of the list may be dropped as suppliers. The plant manager told us that the manufacturer previously purchased peanuts from 14 millers and now buys from only 4.

In addition, the National Peanut Council, which represents all segments of the industry, publishes a voluntary code of good management practices that provides guidance for minimizing aflatoxin levels in peanuts and peanut products. The code emphasizes that manufacturers have ultimate responsibility for ensuring that only wholesome peanuts enter the consumer market. Effective August 1990, PAC unanimously decided to lower the industry aflatoxin standard for raw peanut lots from 20 to 15 ppb. More information on this change is provided in chapter 4 of this report.

Milk

The dairy industry has quality control programs to check milk for residues, microorganisms, flavor characteristics, and shelf life. It also plays a contributory role in monitoring the milk supply for aflatoxin contamination. For instance, Georgia and Iowa state officials estimate that about 50 and 100 percent of their milk processors, respectively, screen for aflatoxin. Also, representatives from two producer cooperatives told us that they work to prevent aflatoxin-contaminated milk from entering the market. For instance, an official of one cooperative, which is the third largest milk producer association in the United States, told us that the cooperative performs aflatoxin testing on every tanker truck of milk delivered to any of its branches throughout the southeastern states. Loads with more than 0.5 ppb aflatoxin are rejected. An official of another cooperative told us that while his cooperative does not itself sample or test for aflatoxin, the processor to whom they sell all their milk samples and tests each incoming tanker truck and rejects any with more than 0.5 ppb aflatoxin.

Conclusions

In general, regulatory detection and control programs exist to routinely test susceptible commodities and foods where aflatoxin is a recurring problem. In areas where aflatoxin presents only occasional problems—the Midwest in particular—the extent of detection and control activities depends on perceptions regarding the seriousness of an outbreak. While variable detection and control efforts appear reasonable given the intermittent nature of the midwestern aflatoxin problem, the fluctuating nature of these programs contributes to a general lack of comprehensive information regarding the extent of aflatoxin outbreaks in midwestern corn.

Proposals to Improve Aflatoxin Detection and Control

Aflatoxin presents only occasional problems for the Midwest. Detection and control efforts there fluctuate according to the perceived seriousness of an outbreak. However, the information available on midwestern aflatoxin outbreaks is consequently limited—particularly with respect to corn. Following the 1988 midwestern drought, several proposals were made to establish a formal, systematic means of gathering information regarding aflatoxin outbreaks in midwestern corn. Potentially, such information could provide a more proactive alternative to the anecdotal information now used to recognize and act on aflatoxin problems. However, additional development work would be required before these proposals could be implemented, and they might not result in appreciably less aflatoxin in the food supply.

FDA's aflatoxin limits are generally accepted and used by federal and state agencies as a baseline for possible regulatory action and by industry itself in setting quality standards. However, a 1987 Appeals Court decision declared that FDA's aflatoxin limits were not legally binding because correct procedures were not followed in establishing them. FDA is now establishing legally binding limits. California is establishing its own statewide limit for aflatoxin in foods. The peanut industry and the international community have also initiated actions to set more stringent aflatoxin limits. However, the extent to which these actions might actually result in lower aflatoxin levels in foods is unknown.

Iowa Aflatoxin Task Force Proposal

In some areas, aflatoxin is only a sporadic or isolated problem and the amount of testing done each year varies. In particular, initial regulatory and industry decisions to test midwestern corn for aflatoxin are based on anecdotal information regarding how widespread an aflatoxin outbreak may be. State government and corn industry officials, as well as grain scientists, notice when weather patterns are conducive to aflatoxin formation, and their observations become the impetus for detection and control efforts. Producers are subsequently involved, and plans of action are developed. Differences in the methods used to gather and confirm this information usually preclude reliable estimates regarding the extent of an aflatoxin problem. Several proposals have been made to establish a systematic and consistent means of collecting data to identify when aflatoxin is likely to be present in the corn crop and to initiate more sampling and testing to determine its extent.

For example, during the 1988 drought, Iowa state government and industry officials and grain scientists began alerting producers that weather conditions were conducive to aflatoxin formation. The Iowa Corn Growers Association formed the Iowa Aflatoxin Task Force—producers, operators of farmer-owned and private elevators, land-grant university scientists, and government officials. Task force members conducted workshops and seminars to inform growers and elevator operators of the potential aflatoxin problem and the steps they could take to minimize it. Task force members also initiated sampling of early harvested corn to confirm aflatoxin's presence in the state. Similar government and industry efforts evolved in some other midwestern states.

The Iowa Aflatoxin Task Force concluded that a more formal and systematic means for identifying and quantifying the occurrence of aflatoxin was needed. It believed that such a system (1) would make the actions taken to minimize an aflatoxin outbreak more timely and (2) was needed to standardize state approaches to aflatoxin problems.

The Task Force proposed establishing (1) a national, pre-harvest weather monitoring and early warning system to predict high-, medium-, and low-risk areas of aflatoxin formation and (2) sampling at harvest to confirm or deny advance warning data. Using the monitoring and sampling results, information about aflatoxin and how to mitigate its effects would be gathered and disseminated; regulatory agencies and legislators would be advised of the problem and how to handle it; and state contingency plans could be activated if needed.

The information might also be used by

- FDA and state regulators to focus their monitoring/testing efforts, instead of relying on general perceptions of where and what was best to test,
- dairy farmers to decide whether to test locally grown or purchased feeds for aflatoxin,
- processors/manufacturers to select locations from which to purchase their raw ingredients, and
- export sales negotiators as evidence of overall crop quality.

Monitoring Before and After Harvest

According to the Task Force proposal, the National Agriculture Statistics Service (NASS) would establish high-, medium-, and low-risk geographical areas using temperature and moisture information reported by the State Crop Reporting Services. Relationships between aflatoxin formation and temperature and moisture conditions during critical periods in corn's development would be established, and regulators and the grain industry would be alerted to the possibility of aflatoxin in crops. However, this proposal requires specific criteria not yet developed for determining when weather conditions would trigger aflatoxin formation.

Physical sampling to substantiate advance warning data, the second part of the Iowa Aflatoxin Task Force proposal, would be accomplished by modifying the existing NASS at-harvest crop sampling program. The program, which relies on drawing and testing samples in major corn producing-states, was designed to give state-by-state estimates of average yield and corn quality factors. NASS has turned down earlier requests to estimate aflatoxin in corn, according to a NASS official, because its system relies on farmer cooperation for its existing crop surveys, and NASS is concerned that it may lose farmer cooperation because aflatoxin is a controversial issue.

FGIS and Grain Industry Proposal

Both FGIS and a grain industry trade group have proposed actions to provide additional information on aflatoxin levels in corn. This information could then be used to trigger additional sampling and testing. FGIS supported the development of a system to identify aflatoxin risk areas using USDA and National Oceanic and Atmospheric Administration data. It also offered, on a fee basis, to assist FDA in determining the extent of aflatoxin contamination by sampling crops in the field and at harvest time. FDA declined the FGIS offer. Although it was interested in obtaining additional information on the incidence of aflatoxin, FDA did not believe data collected through such an effort would allow it to estimate the extent of contamination nationwide. FDA also declined because of funding constraints.

FDA and Others Are Reviewing Existing Aflatoxin Limits

FDA's aflatoxin limits are currently not legally binding because they were not established through the public notice and comment procedures required by the Administrative Procedures Act (5 U.S.C. 553).[1] FDA is currently reviewing its aflatoxin limits and plans to establish legally binding aflatoxin limits through the formal administrative rule-making procedure. FDA will make its decision on the basis of laboratory animal exposure studies; human population studies; human exposure information; existing sampling, analysis, manufacturing capabilities and public comments. FDA intends to propose aflatoxin limits for public comment in

[1]Currently, in order to take regulatory action, FDA must show, on a case-by-case basis, that amounts of aflatoxin in a food "may be injurious to health."

about 1 year. However, preliminary review results indicate the controversy regarding toxicological information has widened, according to an FDA official.

California Is Establishing Its Own Aflatoxin Limits

The California Safe Drinking Water and Toxic Enforcement Act of 1986 requires warning labels on foods containing chemicals known to cause cancer or provide reproductive toxicity. Under this act, California is establishing a state limit for aflatoxin. As proposed, California's limit would apply only to food products, rather than the agricultural commodities from which they are made. California is now in the process of reviewing and modifying its draft proposal. Whether California's aflatoxin limit will ultimately be more or less stringent than FDA's, or how it will affect the food products marketed in or by that state, cannot be determined at this time.

Lower Aflatoxin Limit Proposed for Peanuts

At its 1990 annual meeting, PAC unanimously agreed to lower the industry aflatoxin standard for raw peanut lots intended for human consumption from 20 to 15 ppb. An AMS official said the reduction was proposed because (1) the industry has a continuing interest in improving peanut quality, (2) some countries that import U.S. peanuts have more stringent standards for aflatoxin, and (3) peanut processors are interested in having the lowest possible level of aflatoxin in their finished products. The rule was made final by USDA under the public rule-making process and became the effective standard under the peanut marketing agreement on August 23, 1990.

More Stringent International Standards Proposed

Committees of the Codex Alimentarius Commission—an organization of the U.N. Food and Agriculture Organization and the World Health Organization—are deliberating on more stringent international standards for aflatoxin. The Codex Committee on Food Additives and Contaminants may propose an aflatoxin limit for foods in international commerce, once it has obtained and reviewed information from various governments regarding national aflatoxin regulations, sampling plans, toxicological data, etc. The Cereals, Pulses, and Legumes Committee proposed a 15-ppb aflatoxin limit for raw peanuts and a 10-ppb limit for processed peanut products and specified both sample size and analytical methods. However, the Committee decided against making a recommendation for corn until more is known about sampling accuracy.

Conclusions

Although aflatoxin does not seriously threaten the domestic food supply, several proposals have been made to improve data gathering and the mechanisms used to initiate detection and control efforts—particularly in the Midwest. More stringent limits have also been proposed. While improved data gathering might prove beneficial for other purposes, existing federal and state efforts, and industry efforts in particular, appear to be effective at minimizing aflatoxin in the domestic food supply. Consequently, it is questionable whether significantly reduced aflatoxin levels in foods would result from the investment of additional resources.

Georgia's Programs to Detect and Control Aflatoxin

The four commodities grown or produced in Georgia at risk for aflatoxin contamination are peanuts, pecans, corn, and milk. Georgia is the largest producer of peanuts and pecans each year. About 95 percent of the corn produced in Georgia, according to Georgia Department of Agriculture (GDA) officials, is used for animal feed. However, Georgia does not produce enough corn to meet its own needs and must import corn from other states.

Georgia has recurring aflatoxin incidences because it is prone to drought conditions. Recognizing this, Georgia instituted detection and control measures for corn, pecans, and peanuts in the 1960s and began similar activities for milk in the 1970s. GDA aflatoxin detection and control efforts are both a regulatory activity and a quality control service.

Detection and Control for Corn Includes Field Crops and Foods

At producers' and marketers' request, the GDA tests whole corn for aflatoxin to control corn quality. The GDA also tests food products made from corn under a regulatory program to prevent the marketing of aflatoxin-contaminated foods.

Aflatoxin Testing at Farms and Elevators Is Performed Upon Request

The GDA offers aflatoxin testing at farms and elevators upon request. The services are provided so contaminated corn can be diverted from food production and selectively used for animal feed. The GDA's aflatoxin-testing services include both collecting and testing samples or testing samples that have been submitted to them. These services are offered in conjunction with grain inspection performed on behalf of FGIS.

Aflatoxin in corn shipments is generally controlled through purchase contract specifications. According to a GDA official, aflatoxin testing is also requested for over 95 percent of the truck and rail car shipments sampled and inspected for grading. This official said that the industry uses the test results to determine whether the corn meets contract specifications before it is shipped.

The grain industry also controls aflatoxin in purchases by screening corn with blacklight, which indicates the presence of the mold that produces aflatoxin. According to a GDA official, some elevator operators also perform analytical tests to confirm the presence of aflatoxin and determine its specific level. Corn not meeting contract specifications for aflatoxin is either cleaned or diverted to appropriate nonedible use.

In fiscal years 1989 and 1990, about 8 and 5 percent of the corn tested by the GDA, respectively, had aflatoxin greater than 100 ppb. Table I.1 shows the aflatoxin test results for all samples drawn by or submitted to the GDA.

Table I.1: Aflatoxin Test Results for Corn Sampled in Georgia, Fiscal Years 1989 and 1990

	FY 1989 Samples (July 1988-June 1989)		FY 1990 Samples (July 1989-Jan. 1990)	
Parts per billion	**Number**	**Percent of total samples**	**Number**	**Percent of total samples**
0-20	861	62	1,257	81
20-40	268	19	142	9
40-100	146	11	77	5
100 or more	115	8	72	5
Total	**1,390**	**100**	**1,548**	**100**

Source: Plant Industry Division, GDA.

Under the Georgia Commercial Feed Law,[1] the GDA is authorized to prohibit the sale of animal feed by issuing a stop sale when feed is found to be harmful to livestock. Whole grain corn, however, is not covered under this law until it is ground and mixed with other feed ingredients.

Food Products Are Monitored at the Processor and Retail Levels

The GDA monitors food manufacturing plants and retail markets to prevent aflatoxin-contaminated products from reaching consumers under authority provided by the Georgia Food Act.[2] The act authorizes the GDA to stop the sale of or to embargo any commodity found to be adulterated or contaminated. To do this, the GDA collects corn, pecan, and peanut products from about 50 food processing plants and an unspecified number of retail stores for aflatoxin analysis. According to a GDA official, the GDA focuses its sampling efforts at processing plants and increases its sampling efforts in years when the risk of aflatoxin contamination is high.

The GDA informs manufacturers of test results, and if the product is in violation (over 20 ppb), issues stop-sale orders and requests the firms involved to recall the product. A GDA official told us that state efforts are sometimes coordinated with FDA and that test results are routinely shared.

[1]Ga. L. 1972.

[2]Ga. L. 1956.

Table I.2 shows the GDA's test results for food samples collected primarily at processing plants between October 1, 1988, and November 30, 1989.

Table I.2: Aflatoxin Test Results for Corn, Pecan, and Peanut Food Products Sampled Between October 1988 and November 1989

	Number of samples		
Type	Collected	In violation[a]	Percent
Corn (for food)	46	6	13
Corn products	111	0	0
Pecans	62	0	0
Peanut butter	1	0	0
Total	**220**	**6**	

[a]Over 20 ppb

Source: Consumer Protection Division, GDA.

According to a GDA official, the quality control procedures established by food processors in compliance with FDA's good manufacturing practices requirements also include aflatoxin testing. Also, a Georgia corn mill official told us that aflatoxin detection and control practices have been in place at his firm for about 17 years and include

- restricting corn purchases to areas having low aflatoxin risk,
- screening incoming corn with blacklight,
- testing incoming corn at the start of harvest and all corn arriving by rail cars, and
- randomly sampling and testing finished products.

Any load testing over 20 ppb is rejected.

Milk Monitoring Efforts Depend on the Extent of Aflatoxin Problems

The GDA is authorized to monitor the milk supply for aflatoxin under the Georgia Dairy Act of 1980.[3] The act adopted the 1978 Grade A Pasteurized Milk Ordinance, the basic standard for grade A milk and milk products adopted by all states. To monitor the milk supply for aflatoxin, the GDA collects milk samples from dairy farms, milk tankers, and milk processing plants. The amount of testing performed varies each year, depending on the extent to which aflatoxin contamination is found in the corn crop through its sampling activities.

The GDA's activities are coordinated with and supplemented by FDA and dairy industry efforts. The GDA, according to officials, provides its

[3]No. 1087 (Senate Bill No. 415).

aflatoxin test results to FDA each month, along with information on the actions initiated to deal with any violative aflatoxin levels found.

Table I.3 shows the results of the GDA's aflatoxin testing at fluid milk[4] processing plants, dairy farms, and tankers.

Table I.3: Aflatoxin Test Results for Milk Sampled in Calendar Year 1989

		Violative	
Sample type	**Collected**	**Number**	**Percent**
Dairy farm	51	2	3.9
Tanker	43	0	0
Finished product	256	1	0.4
Total	**350**	**3**	

Source: Dairy Division, GDA.

Other Activities

In addition to the aflatoxin programs for corn, food products, and milk, the GDA provides inspection staff for USDA's peanut marketing agreement and price support programs.

[4]Only grade A milk is produced in Georgia.

Iowa's Programs to Detect and Control Aflatoxin

Corn and milk are the two commodities grown or produced in Iowa that are most susceptible to aflatoxin contamination. Iowa is the largest U.S. producer of corn, growing about 18 percent of the total annual domestic crop. Aflatoxin occurs in Iowa corn only occasionally, with drought conditions. Since corn represents a significant portion of the value of state agricultural products, state government and industry officials consider aflatoxin to be a serious, but sporadic, problem. Therefore, the intensity of programs to detect and control it fluctuates from year to year. The most recent aflatoxin outbreaks in Iowa occurred in 1977, 1983, and 1988.

Detection and Control Efforts for Corn

Iowa's Department of Agriculture and Land Stewardship (IDALS) established a regulatory policy for corn following the 1988 drought, after higher than normal levels of aflatoxin contamination were found. The policy was specific to the 1988 crop and was sent to all state-licensed grain warehouses. The policy required warehouse operators to test for aflatoxin in corn that they intended to ship out of state, disclose levels of aflatoxin in excess of 20 ppb on invoices and bills of lading, and maintain records of sales, which were subject to state and/or FDA audit for 1 year. The IDALS also created control programs for improperly stored contaminated corn found in state-licensed grain warehouses and advised warehouse operators and other industry members on how to properly handle contaminated corn.

The IDALS, industry officials, and Iowa State University scientists all played key roles in the detection and control of aflatoxin in Iowa during 1988. Industry officials—representatives of producer and grain marketing organizations—worked with Iowa State University scientists to inform the industry of the aflatoxin risk and advised them on how to mitigate its effects. They also conducted workshops and seminars for the industry and prepared written materials for distribution through the media and producer and marketing organizations.

An Aflatoxin Task Force was also formed through the Iowa Corn Growers Association, which analyzed the benefits and costs of various detection and control efforts and made recommendations concerning aflatoxin regulation. The Task Force concluded that aflatoxin testing should be the warehouse operator's decision and that mandatory testing was neither economically nor politically feasible. It recommended the following:

- Aflatoxin testing should include sampling by FGIS's prescribed procedures; scanning samples by an approved blacklight; and either the segregation of corn lots testing positive until a quantitative test can be run or, instead, rejection of suspect corn;
- Food products should be sampled and tested by the state at the processor and consumer level; and
- A national policy should be established to specify warehousemen's responsibilities regarding aflatoxin-contaminated corn to ensure uniform state and federal requirements.

State Aflatoxin Control Activities

The IDALS's principal activities to detect and control aflatoxin in corn were (1) establishing the state regulatory policy for intra-interstate movement of aflatoxin-contaminated corn, (2) verifying FDA reports of warehouses storing contaminated corn and taking necessary regulatory action, and (3) analytically testing corn samples submitted by farmers and other interested parties.

Although determining compliance with the state regulation was not part of IDALS's normal activities, IDALS officials determined whether individual warehouses were in compliance if FDA reported that the warehouse had stored corn with violative aflatoxin levels. If the IDALS's sampling and testing confirmed FDA's findings, it determined a market value for the contaminated corn and whether the warehouse could still meet its obligations to producers and traders whose corn it was storing. The warehouse operator was required to correct any shortage within 24 hours by (1) posting a bond or letter of credit in an amount equal to any shortage, (2) buying grain to replace the contaminated bushels, or (3) using warehouse-owned bushels to cover the warehouse obligations.

In addition, IDALS officials required the operator to

- check incoming corn for aflatoxin and record any aflatoxin found on the warehouse receipts issued;
- segregate aflatoxin-contaminated corn from aflatoxin-free corn;
- disclose aflatoxin levels on shipment documents; and,
- maintain proper inventory records.

Milk Detection and Control Efforts

In addition to increased efforts for detecting aflatoxin in corn, the IDALS established a program to monitor milk for aflatoxin following the 1988 drought. The IDALS's monitoring efforts include both fluid and manufacturing grade milk, and supplement the aflatoxin testing done by the dairy industry itself. IDALS inspectors periodically draw milk samples from tankers, processing plants, and finished milk products. If tankers are found to have more than 0.3-ppb aflatoxin, but less than the 0.5-ppb FDA action level, state inspectors sample milk at each dairy farm on the tankers' route to determine the source. The state then tests the dairy farmers' feed to identify and remove the source of contamination. If 0.5-ppb aflatoxin or more is found, the milk is diverted to non-edible uses. Also, if milk samples drawn at processing plants or finished products are found to have 0.5-ppb aflatoxin or more, the state can require the processor to dump or divert the milk for non-edible uses or recall finished products.

The IDALS's monitoring efforts and the fear of losing market share provided strong incentive for the dairy industry to perform its own testing. An IDALS official estimated that virtually all milk processors have acquired the equipment necessary to test incoming milk for aflatoxin.

Test Results Indicated Iowa Food Supply Safe

Corn and corn product samples tested by the IDALS for aflatoxin following the 1988 drought showed that 68 percent contained 20 ppb or less aflatoxin and 93 percent contained 100 ppb or less. IDALS officials believed that these results overstated the occurrence of aflatoxin because the samples were not randomly selected but were collected by or submitted to them because aflatoxin contamination was suspected.

Lastly, according to FDA officials, their special and routine monitoring of the region that included Iowa showed that state regulatory and private industry efforts were working. However, state officials believed that FDA's testing of Iowa consumer foods was limited and were considering expanding state testing to supplement it.

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