Chapter 6

Mycotoxin Hazards and Regulations

Impacts on Food and Animal Feed Crop Trade

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Summary

The risk of contamination by mycotoxins is an important food safety concern for grains and other field crops. Mycotoxins are toxic byproducts of mold infestations affecting as much as one-quarter of global food and feed crop output. Food contaminated with mycotoxins, particularly with aflatoxins, a subcategory, can cause sometimes-fatal acute illness, and are associated with increased cancer risk.

To protect consumers from these health risks, many countries have adopted regulations to limit exposure to mycotoxins. As with many food safety regulations, domestic and trade regimes governing mycotoxins often take the form of product, rather than process, standards. The World Trade Organization's Sanitary and Phytosanitary Agreement states that these standards must be based on sound risk assessments. However, diverging perceptions of tolerable health risks—associated largely with the level of economic development and the susceptibility of a nation's crops to contamination—have led to widely varying standards among different national or multilateral agencies. For example, of the 48 countries with established limits for total aflatoxins in food, standards ranged from 0 to 50 parts per billion.

In the United States, aflatoxins are not commonly cited as a reason for import "refusals" by the Food and Drug Administration (FDA), the Federal agency that enforces mycotoxin regulations. In 2001, only 4 of 1,781 FDA import detentions of cereals (grain) and cereal products (which include consumer-ready processed products) were due to aflatoxins, although detentions were more common for contamination of nut and seed imports. Nevertheless, several studies indicate that the economic costs of enforcing standards, and the lost trade opportunities stemming from unharmonized global product standards on mycotoxins, are substantial:

- One study estimated that crop losses (corn, wheat, and peanuts) from mycotoxin contamination in the United States amount to $932 million annually, in addition to losses averaging $466 million annually from regulatory enforcement, testing, and other quality control measures (CAST, 2003).
- Wilson and Otsuki (2001) estimated that, for a group of 46 countries—including the United States—the adoption of a uniform aflatoxin standard based on international Codex Alimentarius Commission (Codex) guidelines would increase trade of cereals (grains) and nuts by more than $6 billion, or more than 50 percent, compared with the divergent standards in effect during 1998.

There are several reasons why trade disputes related to the setting of regulatory standards on mycotoxins could persist, or even worsen. First, mycotoxin contamination is recognized as an unavoidable risk. Codex, for example, notes that many factors that influence the level of contamination in cereals and grains are environmental—such as weather and insect infestation—and therefore are difficult or impossible to control. Second, perceptions of tolerable health risks are not likely to narrow significantly in the near future since they appear to hinge largely on the level of economic development and the susceptibility of a nation's crops to contamination. Finally, under the "precautionary principle," some countries may set new standards on certain mycotoxins for which scientific evidence of a health risk is unclear.[2]

One strategy to lower both the health risks and the economic costs associated with mycotoxins is to increase awareness among food producers and handlers of practices which would minimize mycotoxin contamination, and to encourage the adoption of process-based guidelines such as good agricultural practices (GAPs) or good manufacturing practices (GMPs).

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[2] The "precautionary principle" is a term referring to the use of environmental or health precautions in situations where the extent or source of a particular risk is unclear.

Introduction

Concerns about human health arise when grains and other field crops are found to contain unsafe chemicals, additives, or other contaminants. Many countries have established sanitary and phytosanitary (SPS) regulations to protect consumers from these health risks, while seeking to balance health benefits with the potential trade disruptions, economic losses, and market uncertainties that regulations can cause. Among grains and other field crops, perhaps the most prevalent—if publicly unrecognized—source of food-related health risks are naturally occurring poisonous substances called mycotoxins. Consuming grains or other foods contaminated with certain mycotoxins can be fatal if the toxins are present at very high levels. Long-term exposure to mycotoxins can increase cancer risk, and suppress the immune system, among other health problems.

Although humans face health risks stemming from the contamination of grains with other naturally occurring substances, mycotoxins are unique in that they are produced naturally on the grain, and their presence (at least initially) is usually associated with uncontrollable factors such as climatic conditions.[3] The presence of mycotoxins can also be distinguished from plant infestations that affect grains—such as TCK smut and Karnal bunt infestations which are still subject to SPS-related import controls designed to protect the quality of domestically produced crops—but pose no food safety risk.

Mycotoxins are produced by certain fungi (e.g., *Aspergillus* ssp., *Penicillium* ssp., and *Fusarium* ssp.) that grow on human food and animal feed ingredients such as corn, sorghum, wheat, barley, peanuts, and other legumes and oilseeds. Five broad groups of mycotoxins—aflatoxin, vomitoxin, ochratoxin A, fumonisin, and zearalenone—are commonly found in food and feed grains (table 6.1). Among mycotoxins, probably the most widely recognized risk comes from aflatoxins. Aflatoxins are extremely potent carcinogenic and mutagenic substances that first came into the public spotlight—and were formally identified—in the early 1960s following the deaths of more than 100,000 young turkeys on a poultry farm in England. The so-called Turkey X disease was eventually tied to high levels of aflatoxin in Brazilian peanut meal imported as a feed ingredient. Aflatoxin contamination is most common in African, Asian, and South American countries with warm and humid climates, but also occurs in temperate areas of North America and Europe. These five groups of mycotoxins all pose health concerns and are subject to SPS or other regulatory measures.

The fungi (mold) that produce mycotoxins can emerge either in the field (in soil, decaying vegetation, and grains undergoing microbiological deterioration) or during postharvest transportation or storage. Temperature stress is an important cause of fungi growth on crops in the field, and high moisture content (water activity) and temperature are associated with the growth of fungi in stored grain. Detection and control of the fungi is a continuous concern since the fungi can become established and remain with the commodity anywhere along the production, storage, transportation, and processing chain. A further concern is that the absence of visible mold does not guarantee the grain is free from mycotoxin, and cooking or processing the food product does not necessarily rid it of mycotoxin contamination. For example, molds contaminated with aflatoxins have been isolated in processed food products such as bread, macaroni, cooked meat, cheese, and flour (Guerzoni, 1999).

For the consumer, a food safety concern is potential exposure to mycotoxins through consumption of food from contaminated crops, which can produce acute and/or long-term health problems. Consuming food products that contain high levels of certain mycotoxins can cause the rapid onset of mycotoxicosis, a severe illness characterized by vomiting, abdominal pain, pulmonary edema, convulsions, coma, and in rare cases, death. Although lethal cases are uncommon, acute illnesses from mycotoxins, particularly aflatoxins (aflatoxicosis), have been reported from many parts of the world, usually in developing countries. Some notable outbreaks include the deaths of 3 Taiwanese in 1967, and the deaths of more than 100 people in Northwest India in 1974. Both outbreaks were attributed to aflatoxin contamination, of rice in Taiwan and corn in India. Vomitoxin was responsible for another large-scale incident of mycotoxicosis in India in 1988.

Although more difficult to directly associate with mycotoxin contamination, an equal, or perhaps even greater, food safety concern than acute illness is the long-term effects of lower-level mycotoxin consumption, particularly the risks of cancer and immune deficiency. Aflatoxin B1 was placed on the list of known human carcinogens by the International Agency for

[3] For example, dioxins also occur naturally—sometimes as a result of forest fires or volcanic eruptions—but they are often the byproduct of industrial processes (see chapter 8).

Table 6.1—Common mycotoxins, commodity affected, and health effects

Mycotoxin	Commodities	Fungal source(s)	Effects of ingestion
Aflatoxin B1, B2 G1, G2	Corn, peanuts, and many other commodities	*Aspergillus flavus* *Aspergillus parasiticus*	Aflatoxin B1 identified as potent human carcinogen by IARC.[1] Risk of human toxicosis. Adverse effects in various animals, especially chickens.
Deoxynivaleno[1] Nivalenol (Vomitoxin)	Wheat, corn, and barley	*Fusarium graminearum* *Fusarium crookwellense* *Fusarium culmorum*	Human toxicoses in India, China, Japan, and Korea. Toxic to animals, especially pigs.
Zearalenone	Corn, wheat	*Fusarium graminearum* *Fusarium culmorum* *Fusarium crookwellense*	Identified by the IARC as a possible carcinogen. Affects reproductive system in laboratory animals and pigs.
Ochratoxin A	Barley, wheat, and many other commodities	*Aspergillus ochraceus* *Penicillium verrucosum*	Suspected by IARC as human carcinogen. Carcinogenic in laboratory animals and pigs.
Fumonisin B1	Corn	*Fusarium moniliforme* plus several less common species	Suspected by IARC as human carcinogen. Toxic to pigs and poultry. Cause of equine eucoencepha-lomalacia (ELEM), a fatal disease of horses.

[1]International Agency for Research on Cancer.

Source: adapted from GASCA, "Mycotoxins in Grain." Group for Assistance on Systems Relating to Grain after Harvest. Technical Center for Agricultural and Rural Cooperation (CTA), the Netherlands, Technical Leaflet No. 3. 1997. *www.fao.org/inpho/vlibrary/x0008e/X0008E00.htm#Contents*.

Research on Cancer (IARC) in 1988, and other mycotoxins are suspected or known to be carcinogenic or to have other adverse health consequences (table 6.1).[4] Aflatoxins are a particular concern for populations with a high incidence of hepatitis B because the relative rate of liver cancer in people with hepatitis B is up to 60 times greater than normal when those people are exposed to aflatoxin (Miller, 1996, p. 4).

In addition to direct risks to humans from consumption of mycotoxin-contaminated grains, there are indirect health risks to those who consume animal products containing residues of carcinogenic mycotoxins. Mycotoxins can be detected in meat, milk, and eggs from animals that have consumed feed ingredients containing mycotoxins, and many countries have tolerance standards for mycotoxin residues in these products.

Another concern related to the consumption of mycotoxin-contaminated feed by livestock is the potential for economic losses from animal health and productivity problems. Aflatoxins in feed are known to be associated with liver damage in animals, reduced milk and egg production, poor weight gain, and recurrent infections due to immunity suppression. The young of any particular species are most vulnerable, but the degree of susceptibility varies by species.

Regulatory Actions

As with many public food safety regulations, domestic and trade regimes governing mycotoxins in most countries take the form of product, rather than process, standards. That is, tolerance levels for the amount of mycotoxin in a product are established rather than regulating the production or treatment of the commodity along the marketing chain (Henson and Caswell, 1999).

The United States began regulating the concentration of mycotoxins in food and feed in 1968, following some of

[4] Specifically, “mycotoxins may be carcinogenic (e.g., aflatoxin B1, ochratoxin A, fumonisin B1), estrogenic (zearalenone and I and J zearalenols), nephrotoxic (ochratoxins, citrinin, oosporeine), dermonecrotic (trichothecenes), or immunosuppressive (aflatoxin B1, ochratoxin A, and T-2 toxin)…. Much of the published information on toxicity comes from studies in experimental animals, and these may not reflect the effects of mycotoxins on humans and other animals…. [Nevertheless] residues in animal products of carcinogenic mycotoxins, such as aflatoxin B1, M1, and ochratoxin A, pose a threat to human health, and their levels should be monitored” (Orriss, 1997, p. 2).

the early incidents of animal and human health problems related to mycotoxins. A study by the United Nations' Food and Agriculture Organization (FAO) on worldwide regulations for mycotoxins revealed that at least 77 countries now have specific regulations for mycotoxins. Thirteen countries are known to have no specific regulations, and no data are available for about 50 countries, many of them in Africa (Van Egmond, 1999).[5] Survey data by the FAO also reveal that the number of countries adopting mycotoxin regulations grew significantly from the mid-1980s to mid-1990s, and that the range of tolerance levels vary widely (Van Egmond, 1999). In 1996, for example, 48 countries had established tolerance levels for total aflatoxins in food—up from 30 in 1987—with standards ranging from 0 parts per billion (ppb) to 50 ppb. For the 21 countries with total aflatoxins standards on animal feeds, the tolerance levels ranged from 0 ppb to 1,000 ppb (table 6.2).

According to the Joint FAO/World Health Organization (WHO) Expert Committee on Food Additives (JECFA), the scientific body that develops advisory international standards on food additives and contaminants for the Codex Alimentarius Commission, reaching consensus on maximum levels for aflatoxin (and other mycotoxin) standards is complicated by the fact that:

> levels of contamination of foodstuffs vary tremendously around the world, and … with respect to trade, the perspectives of delegations differ profoundly. Those representing countries in which aflatoxin contamination is not prevalent want low standards because they do not wish to see the quality of their food supply degraded. Those delegations from countries in which aflatoxin contamination is a problem because of their climatic conditions naturally wish to have standards in which higher levels of contamination are permitted so that they can trade their products on world markets (Hermann, 1999, p. 3).

Thus, for a large number of countries, the risks associated with mycotoxin contamination are generally recognized and the levels entering the food chain subject to limitations. Enforcing these limitations naturally imposes costs on domestic producers and consumers (e.g., of monitoring, testing, destroying the crop or diverting it to lower valued use). At the same time, when the cost and benefit analyses—or risk assessments—underlying domestic regulations lead countries to set different tolerance standards, these divergent standards can also affect producers in other countries, disrupt trade, and result in trade disputes.

U.S. Regulatory Provisions

In the United States, authority to regulate mycotoxins (i.e., aflatoxin, fumonisins, and vomitoxin) is established by the Federal Food, Drug and Cosmetic Act (FFDCA), which is enforced by the Food and Drug Administration (FDA). The FDA has established specific "action" levels for aflatoxin present in food or feed and "advisory" levels for other mycotoxins. The action and advisory levels are designed to provide an adequate margin of safety to protect human and animal health (Robens, 2001; USDA, 1998). The standard for aflatoxins is 20 ppb for human food and animal feeds (corn and other grains) intended for immature animals or unknown destinations. Except for mandatory aflatoxin testing on U.S. corn exports, however, mycotoxin testing for domestically produced or imported foods and feed ingredients is not required by law. That is, testing for mycotoxins in grains that are not exported is voluntary, and contamination levels are not considered part of official grading standards for agricultural commodities. The FDA does have a monitoring program, however, and "reserves the right to take appropriate enforcement actions when circumstances warrant such actions" (CAST, 2003, p. 109).

The U.S. Department of Agriculture's Grain Inspection, Packers and Stockyards Administration (GIPSA) also offers aflatoxin testing for corn, sorghum, wheat, and soybeans as "official criteria" under the United States Grain Standards Act, and has an official understanding with the FDA that it will report to them samples that exceed established action levels. In the event this occurs, any action by the FDA on a lot sample that tests above that level is taken on a case-by-case basis, and can involve diverting the commodity to alternative uses with less stringent standards (e.g., corn for ethanol production or "finishing" beef cattle), and will only rarely require disposal (table 6.3).

In addition, purchasers may regularly test grains as part of their routine quality control efforts (Lijewski, 2002), and contracts between buyer and seller may be contingent upon achieving an aflatoxin (or other mycotoxin)

[5] Most of the existing mycotoxin regulations concern aflatoxins in food, and in fact all countries with mycotoxin regulations at least have tolerances for aflatoxin B1 (considered the most toxic aflatoxin) or the sum of the aflatoxins B1, B2, G1, and G2 in foods and/or animal feed.

Table 6.2—Medians and ranges of maximum aflatoxin tolerance levels and number of countries with regulations (1987, 1996)

	1987			1996		
Category	Median	Range	No. of countries	Median	Range	No. of countries
	— Parts per billion —		*Number*	*— Parts per billion —*		*Number*
B1 in foodstuffs	4	0-50	29	4	0-30	33
B1+B2+G1+G2 in foodstuffs	7	0-50	30	8	0-50	48
B1 in foodstuffs for children	0.2	0-5.0	4	0.3	0-5.0	5
M1 in milk	0.05	0-1.0	13	0.05	0-1.0	17
B1 in feedstuffs	30	5-1,000	16	20	5-1,000	19
B1+B2+G1+G2 in feedstuffs	50	10-1,000	8	50	0-1,000	21

Source: Adapted from Van Egmond, Hans, "Worldwide Regulations for Mycotoxins." Third Joint FAO/WHO/UNEP International Conference on Mycotoxins. MYC-CONF/99/8a, March 1999.

Table 6.3—Product standards for aflatoxins (United States, European Union, and Codex Alimentarius)

United States[1]		European Union[2]	
Product	Standard	Product	Standard
	Parts per billion		*Parts per billion*
Raw peanuts (industry standard).	15	Peanuts, nuts, dried fruit, and processed products thereof, intended for direct human consumption.	4 (2)
Human food, corn, and other grains intended for immature animals (including poultry) and for dairy animals or when its destination is not known.	20	Peanuts to be subjected to sorting or other physical treatment, before human consumption or use as an ingredient in food.	15 (8)
For animal feeds, other than corn or cottonseed meal.	20	Nuts and dried fruit to be subjected to sorting or other physical treatment, before human consumption or use as an ingredient in food.	10 (5)
For corn and other grains intended for breeding beef cattle, breeding swine, or mature poultry.	100	Cereals and processed products thereof intended for direct human consumption or an ingredient in food.	4 (2)
For corn and other grains intended for finishing swine of 100 pounds or greater.	200		
		Feed materials and complete feedstuffs with the exception of:[3]	(50)
For corn and other grains intended for finishing beef cattle and for cottonseed meal intended for cattle, swine, or poultry.	300	- feed materials from peanuts, copra, palm-kernel, cottonseed, corn and products processed thereof,	(20)
		- complete feedstuffs for dairy cattle	(5)
		- complete feedstuffs for pigs and poultry (except young animals)	(20)
Codex			
Peanuts intended for further processing.	15	- other complete feedstuffs.	(10)

[1] Food and Drug Administration (FDA) standard unless otherwise noted.
[2] Numbers in parentheses refer to separate standard for aflatoxin B1 alone.
[3] Additional standards exist for "complementary feedingstuffs."
Sources: USDA (GIPSA), 1998; Otsuki et al., 2001; EC, 1999.

level at, or even below, FDA-established action or advisory levels.[6] According to a private commodity analyst, most grain purchase contracts of corn processors specify aflatoxin levels below the FDA standard, often 10 ppb or less (Brenner, 2002). Under industry guidelines developed by the U.S. Peanut Administrative Committee, mandatory testing and a separate industry standard of 15 ppb does exist for aflatoxins in raw peanuts.

Testing for aflatoxins in imported foods is not required, but the FDA does test samples of food and feed imports on a regular basis, and import refusals are authorized under the FFDCA. Between 1987 and 1997, the FDA inspected an average of about 500 samples of imported foods and feed per year for aflatoxins, with about 4 percent of samples testing above the 20 ppb level, almost exclusively in food products (CAST, 2003, p. 43). In 2001, the FDA recorded more than 2,100 detentions of imported cereals (grains), cereal products, nuts, and seeds due to food safety concerns, although just 29 of the detentions were due to aflatoxins.

Multinational Standard Setting and the SPS Agreement

At the international level, the Codex Alimentarius Commission of the United Nations (henceforth "Codex") has, since 1963, developed general principles of food safety and hygiene designed to promote food safety and facilitate trade, including the setting of advisory standards on natural and environmental toxins such as mycotoxins (FAO, 2002).

Codex standards are advisory, not mandatory, and the data in table 6.2 demonstrate that national standards vary widely, with aflatoxin standards for foods fluctuating from zero tolerance to more than three times the Codex standard of 15 ppb.[7] Nevertheless, within the regulatory framework of the World Trade Organization (WTO), the Sanitary and Phytosanitary (SPS) Agreement—while not ceding authority over food safety standards from national governments—maintains that measures which conform to Codex standards, guidelines, or other recommendations are science-based, appropriate, and nondiscriminatory (Park et al., 1999).

Henson and Caswell (1999) point out that the SPS agreement essentially requires WTO members to justify the food safety regulations that they apply and demonstrate that any trade distortive effects (costs) are proportionate to the potential health benefits. Food safety regulations can be justified either by simply adopting international standards (i.e., Codex standards), which are assumed to be unchallengeable, or by conducting a scientific risk assessment of the health concerns addressed by the food safety regulation.[8]

Thus, the SPS agreement represents an effort to promote transparency in the establishment of food safety regulations and, if possible, to harmonize regulations based on sound risk assessment principles. Ultimately, the goal is to facilitate trade without compromising consumer protection.

However, the idea that there can be a uniform assessment of how to balance human safety concerns with "proportionate" impacts on trade can be both problematic and controversial. Some argue that food safety regulations, particularly standards stricter than those proposed by Codex, impose unfair economic, and even safety, burdens on lower-income food exporting countries. The argument is that such standards limit export opportunities because compliance is either too costly or unachievable given a lack of technical capacity, infrastructure, and food hazard management experience. Stricter regulations in importing countries are even cited as an additional health risk burden on the exporting country population since only the best quality foods leave the country, leaving commodities with higher levels of mycotoxin contamination for the domestic population (Cardwell et al., 2001).

[6] Testing is also provided for processed products such as corn meal, corn gluten meal, corn/soy blend, popcorn, rice, and other products governed by the Agricultural Marketing Act of 1946.

[7] It should be noted that the only crop for which Codex has adopted a mycotoxin standard is peanuts, with a total aflatoxin (B1+B2+G1+G2) standard of 15 ppb. Codex has also established a standard for aflatoxin M1 in milk and a 50 ppb standard for the mycotoxin patulin in apple juice and apple juice ingredients. It is also considering a proposed maximum of 5 ppb for ochratoxin A in raw wheat, barley, rye, and derived products.

[8] The adoption of stricter standards than those prescribed by the Codex Alimentarius to achieve a lower level of risk is allowed under the SPS agreement, but according to Henson and Caswell (1999, p. 599), the setting of national standards are supposed to meet certain criteria. Risk assessment should involve generally recognized techniques, must be supported by currently available scientific evidence (or "pertinent information"), must demonstrate that the level of protection is appropriate given the level of risk that the country aims to achieve, and must show that actions taken to achieve the desired level of protection do not impede trade unnecessarily.

Economic Impact on International Trade

The economic losses associated with mycotoxin contamination are difficult to assess in a consistent and uniform way, and no comprehensive analysis of the costs to U.S. and foreign crop and livestock producers is available. The lack of information on the health costs and other economic losses from mycotoxin-induced human illness is partly due to the difficulty of establishing cause-and-effect relationships between the mycotoxins and the chronic diseases they are suspected of causing. However, with an estimated 25 percent to 50 percent (Miller, 1995) of the world's food crops affected by mycotoxins, the economic costs are likely to be considerable.[9] Numerous reports focusing on different countries/regions, commodities, toxins, and cost categories (e.g., costs of regulations, testing, production loss, trade losses) offer some indication of these losses.

For the United States, one study using FDA sample data and computer simulations estimated that crop losses from mycotoxin (aflatoxin, fumonisin, and deoxynivalenol) contamination of corn, wheat, and peanuts averaged $932 million annually (CAST, 2003). Additional losses averaging $466 million stem from efforts to prevent or reduce contamination (through regulatory enforcement, testing, and other quality control efforts). In this study, livestock losses were estimated at only $6 million annually. However, an earlier report estimated that, in some years, production losses to the U.S. poultry and swine industries have surpassed $100 million (CAST, 1989).

Numerous other reports of economic losses to specific commodities in selected years—due to complete loss of the crop value or diversion into discounted markets such as feed or ethanol use—indicate that for the U.S., economic losses from mycotoxins are primarily confined to domestic crop producers and their potential downstream users, including export markets.[10]

[9] Alternatively, Park et al. (1995) estimate that the actual global production of commodities at "high risk," including corn, peanuts, copra, palm nuts, and oil seed meal, comes to about 100 million metric tons, a significant but smaller proportion of global production than cited by Miller (1995).

[10] Some other examples of estimated losses in the U.S. include: peanuts - $25 million/year (1993-96); cottonseed - $20-$50 per ton discount (Arizona); barley - $406 million between 1993 and 1998 (Minnesota, N. Dakota, S. Dakota); wheat - $300 million (1996) in Red River Valley (Minnesota, N. Dakota, S. Dakota) (Robens, 2001).

As for imports into the United States, data on import refusals by the FDA during 2001 reveal that the presence of aflatoxins was not a commonly invoked reason for detaining food product imports into the United States that year—because contaminated products were detected and diverted to other uses before exportation, or perhaps because the U.S. does not import a large volume of products most susceptible to aflatoxins (e.g., peanuts or corn). In 2001, there were 1,781 import detentions of cereals (grain) and cereal products (which include consumer-ready processed products), and another 387 detentions of nuts and edible seeds. However, only 29 of the detentions were due to aflatoxins, only 4 in the cereal and cereal product category. Of the 1,781 detentions in this category, only 52 were due to "naturally occurring" safety concerns (other than "filth"): 47 detentions for *Salmonella*, 4 for aflatoxins, and 1 for *Listeria*. The majority of detentions were due to labeling or branding issues, or the presence of unsafe additives.

For developing countries, lost export opportunities to developed countries—which typically have more stringent mycotoxin limitations—appear significant. The potential for disruptions to developing-country food exports resulting from regulatory actions in high income markets is underscored by the fact that the majority—nearly 70 percent—of developing Middle East and African country food exports are destined for high-income countries.[11]

In some cases, developing countries have experienced market losses due to persistent mycotoxin problems or the imposition of new, stricter regulations by importing countries. Thailand was once among the world's leading corn exporters, regularly ranking among the top five exporters during the 1970s and 1980s. But partly due to aflatoxin problems, Thai corn regularly sold at a discount on international markets, costing Thailand about $50 million per year in lost export value (Tangthirasunan, 1998). According to FAO estimates, the direct costs of mycotoxin contamination of corn and peanuts in Southeast Asia (Thailand, Indonesia, and the Philippines) amounted to several hundred million dollars annually, with most of the losses accounted for by corn (Bhat and Vasanthi, 1999). India also saw exports of peanut meal to the European Union (EU) drop by more than $30 million a year when the EU imposed new mycotoxin regulations in the early 1980s (Bhat and

[11] Otsuki et al., 2001. Data are from the mid-1990s. Only 16 percent of Middle East and African country food trade was intraregional.

Vasanthi, 1999). Total peanut meal imports by the current 15 EU member countries fell from over 1 million tons in the mid-1970s to just 200,000-400,000 tons annually after 1982.

Balancing Food Safety Costs and Benefits From Trade: The Case of EU Mycotoxin Regulations

Several recent studies have helped to crystallize the fact that the setting of tolerance levels for mycotoxins involves clear, but controversial, tradeoffs between human health and economic opportunity. One study measured the potential health impacts on cancer death rates from the adoption of two alternative standards for aflatoxin. Motivated by a proposed harmonization of EU mycotoxin standards at a level lower (more stringent) than advisory standards set by Codex Alimentarius, several other studies looked at the trade impacts of different aflatoxin standard harmonization scenarios.

In 1997, the JECFA—which provides scientific advice to Codex—evaluated the potential risks of aflatoxins and considered the possible impact of two alternative aflatoxin standards (10 and 20 ppb) on human health. Two examples were developed, a European diet with 1 percent of the population testing positive for hepatitis and a Far Eastern diet with 25 percent testing positive for hepatitis. The JECFA study concluded that, for the first example (European diet), implementation of a 20-ppb standard would lead to a risk of 41 cancer deaths per year per 1 billion persons. Adoption of the lower 10-ppb standard would reduce the risk to 39 cancer deaths per year per 1 billion persons, or 2 lives per year for a population of 1 billion persons. The same change in standards would lower cancer deaths by about 300 persons per year per 1 billion people for the Asian diet (and high incidence of hepatitis) scenario (Herrman and Walker, 1999).

Also in 1997, the EU proposed a new harmonized standard for aflatoxins, provoking a number of complaints by nonmember countries. The proposal recommended establishing a standard of 4 ppb of total aflatoxins (B1+B2+G1+G2)—2 ppb for B1 alone—in cereals (grains), edible nuts, dried and preserved fruits, and groundnuts (peanuts) intended for direct human consumption. This level represented a stricter standard than the standards in effect in most EU countries at the time, and considerably lower than Codex recommendations and standards in many developing countries (table 6.3). Codex, for example, has a recommended standard of 15 ppb for total aflatoxins in peanuts, and the average African standard for peanuts was as high as 44 ppb—14 ppb for aflatoxin B1 (Otsuki et al., 2001).

The originally proposed standard was relaxed for some categories of use following complaints by Argentina, Australia, Bolivia, Brazil, Canada, India, Mexico, Pakistan, Peru, and Uruguay. These countries argued that "the EC [European Commission] requirements not only departed from the Codex Alimentarius recommendations, but also had considerable social and economic impacts on the concerned countries" (WTO, 1998, p. 3). The subsequently proposed standards, implemented in March 2001 (and amended in 2002), were nevertheless still more stringent than those previously in place for eight of the EU countries, and the standards for cereals and nuts intended for direct human consumption were not relaxed from the originally proposed level (Otsuki et al., 2001).

A widely cited journal article by Otsuki et al. (2001) found that cereal (and cereal preparations) exports by 9 African countries to the EU during 1998 would have declined by 59 percent, or $177 million, if the EU had harmonized their aflatoxin regulations at the proposed limit and enforced this limit on all shipments. Alternatively, the adoption of the somewhat more lax Codex standard by the EU would increase the African country cereal (and preparations) exports to the EU by $202 million, a 68-percent increase. For edible nuts and dried and preserved fruits, the estimated decline in African exports to the EU would be $220 million (47 percent) if the EU harmonized its regulations at the proposed level, but would increase $66 million (14 percent) if the Codex standard was adopted.

Another study by the World Bank (Wilson and Otsuki, 2001) broadened the analysis to evaluate the impact on grain and tree nut trade among 15 importing and 31 exporting countries, including the United States. Among the countries studied, the uniform adoption of a Codex standard of 9 ppb for aflatoxin B1 would increase cereal and nut trade by $6.14 billion, or more than 50 percent, compared with the (1998) status quo.[12]

[12] The study assumes that, for all cereals and nuts, the countries would adopt standards based on the current Codex advisory standard for peanuts. The Codex standard for peanuts is 15 ppb for all aflatoxins combined, but Wilson and Otsuki assume that aflatoxin B1 comprises, on average, about 60 percent of the total level of aflatoxin contamination (or about 9 ppb).

The impact on the United States would amount to more than $700 million in increased exports.[13]

Similarly, adoption of a proposed European Union standard of 2 ppb for aflatoxin B1 by all countries included in the study would reduce trade by $6.05 billion, compared with status quo regulations. The results also show that, since less developed countries generally have less stringent standards for aflatoxin, less developed countries that conduct trade with one another will lose more export opportunities than developed countries. Under a scenario where all countries adopt a uniform standard that maintains global trade at baseline (1998) levels, the distribution of trade shifts to favor developed-country exports and reduces less developed country exports by 10 percent.

Process Standards Complement Product Standards and Can Accomplish Similar Goals

The studies cited earlier clearly illustrate that food safety regulations—particularly product standards such as specific tolerance levels—have significant economic consequences, and that different perceptions about appropriate tradeoffs between health and economic losses are the source of potential conflict between countries. With this in mind, what strategies can be used to diffuse trade frictions, and at the same time help reduce economic losses from mycotoxin contamination and divergent standards?

A common method of minimizing food safety risks is the adoption of good agricultural practices (GAPs) at the preharvest level and good manufacturing practices (GMPs) at the processing and distribution stages. These strategies—implemented independently by private groups, or required by public agencies—can be used to control and minimize risk throughout the production, handling, and processing chain. These can complement product standards, and potentially reduce overall economic losses. In the United States, for example, a standard practice among grain processors is to clean corn before any manufacturing process in order to sift out broken kernels and screenings that are more susceptible to mycotoxin infestation. Grain purchasers also conduct a regular program of testing following harvest to determine whether there are any mycotoxin problems in particular supply areas (Brenner, 2002).

In its 34th session held in March 2002, a Codex Committee on Food Additives and Contaminants (CCFAC) report recommended that GAPs and GMPs be used to establish formal hazard analysis and critical control point (HACCP) food safety systems to identify, monitor, and control mycotoxin risks all along the food production chain (Codex, 2002). Park et al. (1999) suggest steps that can be taken at five stages of food production to lower mycotoxin contamination. At the preharvest stage, for example, insect control, adequate irrigation, crop rotation, and other practices can help minimize initial contamination in the field (table 6.4). During storage, properly dried crops should be protected from moisture, insects and rodents, and monitored for temperature, moisture, and humidity changes. Electronic or hand-sorting can be conducted before processing.

HACCP principles are thus likely to be among the most effective means of lowering risks and economic losses, especially since prevention of mycotoxin contamination is widely considered more practicable than decontamination.[14] However, an effective long-term strategy for controlling and monitoring mycotoxin risks in developing countries most susceptible to the problem may require technical assistance from public agencies and improved adherence to quality control measures and HACCP principles by private actors. In India, for example, one report noted that more than one-quarter of tested corn samples exceeded the Indian tolerance limit of 30 ppb, and that if Codex standards were applied, nearly one-half (47 percent) of the samples would have to be rejected (Van Egmond, 1995, in Bhat and Vasanthi, 1999)—indicating high levels of contamination most likely caused by improper drying or storage.

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[13] This compares to a survey-based estimate that places the impact of "questionable" SPS-related food safety regulations on U.S. agricultural exports at $2.29 billion. Of this, $1.02 billion of the trade impact was to grain and feed grains, with "the Americas" accounting for the major share (69 percent) of the losses, followed by East Asia (14 percent), Europe (11 percent), and Africa (6 percent). No information on the specific nature of the SPS barriers was given (Thornsbury et al., 1997).

[14] According to Codex (1997), "to date there has been no widespread government acceptance of any decontamination treatment intended to reduce aflatoxin B1 levels in contaminated animal feedingstuffs."

Table 6.4—Possible HACCP application stages for agricultural commodities, food products, and animal feeds

Stage	Commodity	Hazard	Corrective action
Preharvest	Cereal grains, oil seeds, nuts, fruits	Mold infestation with subsequent mycotoxin formation	-use crop resistant varieties -enforce effective insect control programs -maintain adequate irrigation schedules -perform good tillage, crop rotation, weed control, etc.
Harvesting	Cereal grains, oil seeds, nuts, fruits	Increase in mycotoxin formation	-harvest at appropriate time -maintain at lower temperature, if possible -remove extraneous material -dry rapidly to below 10 percent moisture.
Postharvest, storage	Cereal grains, oil seeds, nuts, fruits	Increase and/or occurrence of mycotoxin	-protect stored product from moisture, insects, environmental factors, etc. -store product on dry, clean surface.
Post-harvest, processing and manufacturing	Cereal grains, oil seeds, nuts, fruits	Mycotoxin carryover or contamination	-test all ingredients added -monitor processing/manufacturing operation to maintain high-quality product -follow good manufacturing practices.
Animal feeding	Dairy, meat and poultry products	Transfer of mycotoxin to dairy products, meat and poultry products	-monitor mycotoxin levels in feed ingredients -test products for mycotoxin residues.

Source: Park, Douglas, H. Njapau, and E. Boutrif. “Minimising [sic] Risks Posed by Mycotoxins Utilising [sic] the HACCP Concept.” Third Joint FAO/WHO/NEP International Conference on Mycotoxins, Tunis, Tunisia. MYC-CONF/99/8b, 1999.

Conclusion

Although not publicly prominent, food safety issues related to international trade in cereals and grains and other crops—particularly those pertaining to mycotoxin regulations—are economically important. Most countries do recognize that placing standards on the level of mycotoxins entering the food chain is prudent, but diverging perceptions of how to balance economic costs and health benefits have become a source of trade friction between countries. For export-reliant developing countries lacking the means to implement stronger quality control measures, the issue is especially relevant.

For several reasons, trade disputes related to the setting of regulatory standards on mycotoxins are likely to persist. First, mycotoxin contamination is recognized as an unavoidable risk. Codex (2002) notes that, in the field, many factors that influence the level of contamination in cereals and grains are environmentally related—such as weather and insect infestation—and are therefore difficult or impossible to control. Second, perceptions of tolerable health risks are not likely to narrow significantly in the near future since they appear to hinge largely on the level of economic development and the susceptibility of a nation’s crops to contamination. Finally, using the precautionary principle, some countries may set new mycotoxin standards which lack internationally accepted risk assessments.

To minimize the initial risk of mycotoxin contamination and consequently lessen the likelihood that tolerance levels will be exceeded, private sector actors or public agencies can consider implementing process standards based on GAPs, GMPs, and HACCP principles. Developing countries are likely to require technical assistance and economic support to implement these strategies.

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