

Produce, Food Safety, and International Trade

Response to U.S. Foodborne Illness Outbreaks Associated with Imported Produce

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Summary

Outbreaks of foodborne illness in the United States associated with imports of fresh produce affect not only consumers and the growers of the contaminated product, but also frequently other suppliers to the U.S. market, including U.S. producers. Because most produce is highly perishable, the United States depends on seasonal imports for a year-round supply of some items. Often by the time someone falls ill from an imported product and an investigation identifies both the product and its origin, that country may no longer be exporting the product to the United States. For example, a foreign grower may just supply the United States for a brief market window before the U.S. season begins. Of course, many foreign suppliers have much longer seasons. The negative publicity about an outbreak will often affect whichever suppliers are selling their product at that time—often U.S. producers—whether they had anything to do with the outbreak or not.

The impact of a foodborne illness outbreak on trade depends on whether foreign producers can quickly correct the contamination problem and convince buyers that their product no longer poses a risk. This chapter reviews outbreaks of foodborne illnesses associated with Guatemalan raspberries, Mexican strawberries (contaminated either in Mexico or the United States), and Mexican cantaloupe. In the Mexican strawberry case, after just one outbreak and an initial collapse of trade, strawberry trade rebounded in the following years. In the Guatemalan raspberry and Mexican cantaloupe cases, the U.S. Food and Drug Administration (FDA) refused to accept these products into the United States after outbreaks in consecutive

years. The Guatemalan raspberry industry has never really recovered from the experience although it is now free to ship to the United States under a rigorous food safety program. The impact of the ongoing cantaloupe problem on future trade is still unknown.

FDA, the Centers for Disease Control and Prevention, the produce industry, retailers, and foreign governments have worked together to keep unsafe produce off the market and resolve food safety problems. The FDA's voluntary guidelines for good agricultural practices (GAPs) provide recommendations to growers, both domestic and foreign, on how to reduce microbial hazards. FDA emphasizes that GAPs only reduce the risk of microbial contamination and cannot eliminate the risk. If invited by a foreign government, FDA will often visit an area associated with an outbreak to try to identify practices that are inconsistent with GAP guidelines. FDA also provides training in foreign countries on GAPs.

Many individual growers have responded to increased concern about foodborne illnesses (and attendant financial losses) by improving their food safety systems. Grower organizations have been instrumental in developing better food safety and traceback systems to protect the reputation of their particular crops. While individual farmers might not want a contamination problem traced to their operation, the industry as a whole is more concerned with accountability. Retailers, who face unwanted publicity in a foodborne illness outbreak, have also taken the initiative by demanding more stringent food safety programs from their suppliers. Some demand that their produce suppliers have third-party audits to verify that they are complying with GAP guidelines.

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Introduction

The U.S. food supply is one of the safest in the world (Crutchfield and Roberts, 2000). In the mid-1990s, however, outbreaks of foodborne illnesses linked to microbial contamination of both domestic and imported produce focused attention on the potential for contamination at the grower and shipper level (Tauxe, 1997).² For example, in 1996 the potentially dangerous bacterium *Escherichia coli* O157:H7 was linked to California lettuce associated with farm-level contamination. In the same year, a very large foodborne illness outbreak was linked to imported Guatemalan raspberries contaminated at the farm level with the parasite *Cyclospora*. The economic impacts of outbreaks made it clear to the produce industry, particularly those sectors associated with contaminated produce, that improved food safety programs were necessary. The U.S. government also became more involved in produce food safety at the farm and shipper level.

In the United States, responsibility for food safety of imported foods resides with USDA's Food Safety and Inspection Service (FSIS) and the U.S. Food and Drug Administration (FDA). FSIS deals with meat, poultry, and some egg products, and FDA covers all other food products, including produce. Both agencies require imported foods to meet domestic food standards. FSIS allows only imports from countries with food safety systems it deems to be equivalent to those in the United States, thus putting the burden for safety on the exporting country. Unlike FSIS, FDA does not have legal authority to require that imports of the products it covers be produced with food systems equivalent to those in the United States.

Food safety concerns can focus on pesticide residues, microbial and chemical contamination, and the effects of biotechnology. FDA randomly tests both imported and domestic produce for pesticide residues. FDA also randomly tests chemical residues, although this testing is much more limited in scope. Concern about microbial contamination is relatively new. Biotechnology, an important determinant of trade flows for other agricultural products, is not yet a central concern for fruit and vegetables. Traditionally,

² Shippers are the first marketers in the produce distribution chain and are often involved with harvesting and packing produce, a stage at which contamination may occur. Many shippers are vertically integrated grower-shippers.

FDA has relied on inspections at the port of entry to ensure safety of the products. While this worked well for food safety issues such as detecting pesticide residues exceeding U.S. tolerance levels, testing for microbial contamination is a completely different challenge. The FDA tolerance for microbial pathogens is zero, so it would deny entry to any produce with contamination that could be detected, but testing for microbial contamination is not very successful. Microbial contamination is often low level and sporadic so it can be difficult to detect. Also, if perishable produce is held at the border while microbial tests are completed, it may deteriorate in quality to the point where it cannot be sold. In comparison, if produce has pesticide residues that exceed the legal tolerance, it is likely to be pervasive and contamination would show up in random testing. FDA does targeted sampling for microbial contamination when there are concerns about a specific product.

In 1997, President Clinton announced the Produce and Imported Food Safety Initiative, which called for additional resources to improve domestic standards and to ensure that imports were equally safe (Crutchfield, 1999). Three broad areas of action were identified. First, the President directed FDA to seek new legal authority to require equivalence in food safety systems in foreign countries (but there has been no change in legislation). Second, the initiative targeted more resources at improving inspection activities abroad by providing technical assistance. This has been an important means of improving food safety abroad. Third, the initiative focused on providing guidance to both domestic and foreign producers on good agricultural practices (GAPs).

In 1998, FDA published voluntary guidelines for both domestic and foreign producers on GAPs for reducing microbial contamination (FDA, 1998). Although voluntary, GAPs are now an important part of the produce industry. FDA does not have mandatory food safety requirements with respect to microbial contamination for the fresh produce industry. This situation provides incentives to the produce industry to voluntarily adopt GAPs and ensure that food safety does not become a bigger issue. FDA and the produce industry have developed a good working relationship and have made important improvements in food safety. FDA could impose mandatory food safety standards for fresh produce if deemed appropriate. For example, in the late 1990s, there were three foodborne illness outbreaks associ-

ated with fruit juice—one *E. coli* O157:H7 outbreak associated with apple juice and two *Salmonella* outbreaks associated with orange juice. Two people died. In 2001, FDA published a final rule requiring juice processors to use hazard analysis and critical control point (HACCP) principles (FDA, 2001b). FDA also requires HACCP for seafood processors. These mandatory requirements also apply to imported products.

FDA promotes adoption of GAPs as a means to minimize microbial contamination, instead of relying on relatively ineffective testing at the border to detect problem produce. According to FDA, even with GAPs it is not possible to eliminate microbial contamination for produce although it is possible to reduce the risk. For fresh and fresh-cut produce, there is no effective microbial elimination step such as pasteurization for milk.

GAPs provide growers with a structure to evaluate different practices and their potential to reduce microbial food safety hazards so they can develop a food safety program tailored to their own operations (see box 5.1). Many grower practices—such as water sampling or worker hygiene programs—could reduce the risk of microbial contamination. Each grower must evaluate the benefits and costs of investing in risk-reducing practices. This assessment will vary by crop, environmental conditions, and individual grower situation.

It is not always clear how much additional investment in food safety practices is enough. A foodborne illness outbreak may occur if a farmer cuts corners and fails to adopt a practice considered standard in the local industry. Other outbreaks may represent cases where growers and scientists misjudge what is required to prevent problems and growers underinvest in food safety practices. The science and tools available to growers to reduce the risk of contamination are still evolving. Of course, with uncertainty, growers may also overinvest in food safety precautions. There is always the concern that a practice may be a technical but not an economic success. Some segments of the produce industry are undoubtedly more advanced than others in their efforts to reduce these risks, but there is no systematic survey of growers to identify their progress.

This chapter examines one aspect of the food safety issue, the private and public responses to U.S. foodborne illness outbreaks due to microbial contamination

associated with imported produce.³ Even when the contaminated product is imported, the U.S. industry is often affected and both domestic and foreign growers need to take action to protect their economic well being. The chapter begins with information on microbial contamination of produce and the role of produce imports in U.S. consumption. Three examples of foodborne disease outbreaks follow which demonstrate how growers, grower organizations, governments in the United States and abroad, and retailers responded to contamination problems. The analysis also includes a brief look at the impact of contaminated imports on trade. The three examples are: (1) imports of Guatemalan raspberries associated with *Cyclospora*, (2) imports of Mexican strawberries associated with hepatitis A (contaminated either in Mexico or the United States), and (3) imports of cantaloupe from Mexico associated with *Salmonella*.⁴ In each case, the contamination occurred, or may have occurred, at the grower or shipper level. Then the analysis turns to a comparison of the private and public responses to food safety problems demonstrated by the three case studies. Concluding comments focus on lessons learned and areas for future research.

Foodborne Illness Outbreaks

Despite heightened concern about food safety, the vast majority of growers for the U.S. market, both domestic and foreign, has never been involved in food safety

³ This study does not examine pesticide residue contamination. A study of U.S. winter vegetable imports from Mexico showed that pesticide residue violations were relatively infrequent (Calvin and Barrios, 1998). In 1997, FDA tested 3 percent of total shipments through Nogales, Arizona, and only about 3 percent of the tested products were in violation of pesticide residue standards. Of the winter vegetables—tomatoes, bell peppers, cucumbers, eggplant, summer-type squash, and snap beans—only snap beans had any violations. Of course, the winter vegetable industry in Mexico is well established. When Guatemala began exporting snow peas, a nontraditional export, in the late 1980s, it had a serious problem with pesticide residues that took several years to control. A program to pretest shipments in Guatemala to ensure they would pass FDA inspections finally resolved the problem.

⁴ *Cyclospora* is a protozoan parasite that causes cyclosporiasis, a potentially debilitating diarrhea that can last for three weeks or more. The disease is treatable and is only considered potentially life threatening to those with compromised immune systems. The hepatitis A virus causes liver disease. The bacterium *Salmonella* causes salmonellosis, which is characterized by diarrhea, fever, and abdominal cramps. Most people recover without treatment but it can cause death in some cases when the infection spreads beyond the intestines.

Box 5.1—Microbial Contamination and FDA’s Good Agricultural Practices (GAPs)

There are many sources of potential microbial contamination for produce and some regions will face more challenges than others. Some of the major sources at the grower and shipper level include: soil, water, green or inadequately composted manure, dust in the air, wild and domestic animals, human handling, and contaminated equipment (FDA, 2001e). Sources of water contamination include water used for irrigating, mixing with pesticides, washing and rinsing produce, and making ice to cool produce. Different food safety practices can mitigate the chances of contamination. Other factors unique to specific plants also affect the probability of contamination.

Good agricultural practices (GAP) principles provide growers with guidelines to reduce the potential for microbial contamination of their products. Guidelines cover growing, harvesting, sorting, packing, and storage operations. National-level guidelines on GAPs enhance the consistency and scientific basis of food safety programs developed by public and private institutions. Using GAPs reduces but does not eliminate all risk—an unobtainable goal with current technologies.

Growers and shippers are directed to evaluate their operations in terms of water quality; manure/municipal biosolids; worker hygiene; field, facility, and transport sanitation; and traceback capabilities. Traceback is the ability to track food from the consumer point of purchase back to the grower. Recommended practices are provided to mediate each risk. Since there are numerous potential ways to reduce risk, FDA encourages growers to pick the most cost-effective combination of practices. Therefore, two growers in different areas with different environmental conditions could both adhere to GAP principles but use different methods to do so.

GAP guidelines do not outline specific testing and monitoring regimes because scientific data is lacking for establishing more specific guidelines (FDA, 2001e). The GAP guidelines state “Water quality should be adequate for its intended use. Where water

quality is unknown or cannot be controlled, growers should use other good agricultural practices to minimize the risk of contamination.” The guidelines do not specify how to measure whether water quality is adequate; no one knows for sure and what is adequate varies by crop. For example, irrigation water for a crop that matures on the ground may need to be cleaner than water for an orchard crop.

Use of the GAP guidelines can be broken down into three stages. First, growers and shippers can use GAPs to evaluate their food safety system and assess needs. Some large firms with food safety staff may evaluate their own systems. Some smaller growers might hire a third-party audit firm to do an evaluation. FDA does not regulate third-party audit firms. In 2001, a FDA report estimated the cost of an evaluation at \$300-\$500 per farm (FDA, 2001e). An evaluation would include a review of the current food safety system and an assessment of what additional practices might be needed to reduce the chance of contamination, including the documentation necessary to assure continuous compliance with GAPs.

Once growers have a food safety system evaluation and needs assessment, they may decide to adopt new practices to reduce risks. The cost of implementation depends on the particular crop, the existing food safety system, and the environment in which the growers operate (e.g., some areas may have more water contamination problems to contend with than others). Some typical practices that a farmer might adopt could include: water testing; water treatment programs; development of a documentation system to corroborate practices and trace product; and provision of additional hygiene facilities for workers.

Growers may opt to have their food safety program audited periodically by third-party audit firms. Some retailers now require third-party audits to verify that growers and shippers are in compliance with GAPs. In 2001, FDA estimated the typical cost of an audit to be similar to the cost of an evaluation, about \$300-\$500 per farm (FDA, 2001e).

outbreaks. It is difficult to assess the exact incidence of foodborne outbreaks associated with produce and how it has changed over time. The Centers for Disease Control and Prevention (CDC) collect data on all reported foodborne outbreaks. The average annual number of foodborne illness outbreaks associated with fresh produce, both domestic and imported, more than doubled between 1973-87 and 1988-91, from 4 per year to 10 (Tauxe et al., 1997). The increasing trend appears to have continued through 1997 (Sivapalasingam, 2002). More recent data are not yet available.

What does this trend indicate? The data are incomplete so it is difficult to generalize about food safety outbreaks beyond saying the number reported has increased. Researchers assume that most sporadic cases and many outbreaks of foodborne diseases are unreported since a case cannot be reported unless individuals seek medical care. Many outbreaks are never definitively linked to a particular contaminated product or source. In the case of perishable fruit and vegetables, by the time the authorities begin to investigate, the physical evidence has usually been consumed or discarded. As a result, it is not possible to say anything authoritative about the incidence of contamination for various types of fruit and vegetables. It is also not possible to say whether imported produce is any more prone to food safety problems than is domestic produce (Zepp et al., 1998).

The data also include outbreaks associated with contamination at all levels. Produce can be contaminated at the grower or shipper level, at some intermediate level of the distribution system, or at the final point of service (retail store, foodservice establishment, or private residence, etc.). Data are limited and inconclusive regarding what percent of outbreaks are attributable to contamination at the grower or shipper level compared with other points along the distribution chain, or whether contamination at any one level is increasing.

Efforts are underway to further investigate the incidence of food safety problems in produce. As part of the Produce and Imported Food Safety Initiative, USDA's Agricultural Marketing Service (AMS) is implementing the Microbiological Data Program, a nonregulatory program that will provide baseline information on microbial contamination of produce. A select group of produce items, both domestic and imported, are being tested for pathogenic *E. coli* and *Salmonella* (AMS, 2001). There is industry concern, however, that since USDA is testing at terminal mar-

kets and chain store distribution centers, it will not be clear where any detected contamination occurred (*Produce News*, 2002). A problem might be mistakenly attributed to the farm level when it could have occurred somewhere else along the distribution chain. On the other hand, a finding of no contamination at the terminal market and chain store distribution center level would shift concern towards problems at the final point of service.

For the Produce and Imported Food Safety Initiative, FDA collected data on the incidence and extent of pathogen contamination (FDA, 2001a). Beginning in March 1999, FDA tested domestic and imported produce items for three microbial pathogens—*Salmonella*, *Shigella*, and *E. coli* O157:H7.^{5,6} *Salmonella* and *Shigella* were both found in imports and domestic products, but no *E. coli* O157:H7 was found in either. The focus of these studies was to identify problems resulting from failures to implement adequate GAPs and good manufacturing practices (GMPs).⁷ The testing program was not intended to determine whether imported or domestic produce is more prone to safety problems since the statistical properties of the samples did not allow broad conclusions about general food safety of produce or comparisons between countries.

Policymakers and researchers are concerned about why reported food safety outbreaks associated with produce are increasing. Better reporting due to improved outbreak investigations and better diagnostics have undoubtedly contributed to some of the increase (FDA, 2001e). Some scientists, however, do not believe that better reporting alone explains the increased level of outbreaks (Tauxe et al., 1997). It is difficult to sort out the competing factors.

⁵ The *Shigella* bacteria causes shigellosis, an infectious disease characterized by diarrhea, fever, and stomach cramps. People with severe cases can usually be treated with antibiotics. Those with milder cases will usually recover without antibiotics.

⁶ For the imported produce survey, FDA sampled broccoli, cantaloupe, celery, cilantro, culantro, loose-leaf lettuce, parsley, scallions, strawberries, and tomatoes from 21 countries. The crops were selected based on a combination of five factors that contributed to overall food safety risk: previous association with outbreaks, structural characteristics that might provide a particularly hospitable environment for bacteria, growing conditions, degree of processing, and importance in U.S. consumption (FDA, 2001a).

⁷ GMPs are FDA regulations for food processors. FDA recommends firms packing raw, intact fruit and vegetables use GMPs, but they are not required to do so. Firms packing fresh-cut products, like bagged salads, are required to use GMPs.

One explanation for increased foodborne illnesses is new and emerging pathogens. Several outbreaks in the 1990s were due to these pathogens, and scientists had to develop new practices to avoid contamination. The microbial pathogen *E. coli* O157:H7 was identified in 1982 and was initially associated with ground hamburger.⁸ In the early 1990s, *E. coli* O157:H7 was first associated with a number of produce items. The parasite *Cyclospora* was described definitively only in 1994 and has been linked to numerous outbreaks since. *Cyclospora* has only been associated with a few products—raspberries, basil, and lettuce—although many cases could not be traced to a particular product.

Another potential explanatory factor behind the rise in outbreaks attributed to produce is the change in U.S. consumption habits. U.S. per capita consumption of fresh fruit and vegetables (not including juices and other processed products) increased from 249 pounds in 1981 to 339 pounds in 2000, an increase of 36 percent. The types of food consumed have also changed. The typical grocery store carried 345 produce items in 1998, compared with 173 in 1987 (Calvin et al., 2001).

Retailers now routinely provide produce items that were once considered seasonal on a year-round basis. Most produce is highly perishable and cannot be stored to provide a year-round supply, so imports are important. However, even storable produce is sometimes imported; apple imports provide consumers with different varieties and qualities (e.g., fresh-harvest apples from Southern Hemisphere countries during the spring versus stored apples). In 2000, imports accounted for 19.5 percent of fresh fruit consumption (excluding bananas), up from 3.1 percent in 1975.⁹ Similarly, in 2000, imports accounted for 13.6 percent of fresh vegetable consumption (excluding fresh potatoes), up from 5.7 percent in 1975 (table 5.1).

Bananas top the list of per capita fruit consumption in the United States, with imports accounting for 99.6 percent of consumption. Likewise, 76.1 percent of

⁸ One of hundreds of strains of the *E. coli* bacterium, *E. coli* O157:H7 produces a powerful toxin that can cause severe illness. Infection often produces bloody diarrhea, but most people recover without antibiotics or other specific treatment. Some people, particularly children and the elderly, may develop hemolytic uremic syndrome, a life-threatening disease that causes kidney failure.

⁹ Data are not true consumption data from consumer surveys but rather disappearance data (production for the fresh market plus imports and minus exports equals disappearance—a proxy for consumption).

Table 5.1—Fresh fruit and vegetable consumption and imports

Item	Per capita consumption		Imported share of consumption	
	2000	1975	2000	1975
	— Pounds farm weight —		— Percent —	
Fruit:¹				
Bananas	28.4	17.6	99.6	99.9
Apples	17.4	19.5	7.2	2.2
Oranges	11.7	15.9	8.5	0.8
Grapes	7.3	3.6	44.1	5.9
Peaches	5.5	5.0	6.4	0.3
Grapefruit	5.1	8.4	3.0	0.6
Strawberries	5.0	1.8	5.8	8.9
Pears	3.2	2.7	20.6	3.5
Pineapples	3.2	1.0	76.1	48.0
Tangerines	2.8	2.6	25.7	9.5
Vegetables and melons:²				
Potatoes	47.2	52.6	5.7	1.2
All lettuce	32.0	23.5	0.7	0.0
Onions	18.3	10.5	9.3	4.0
Tomatoes	17.6	12.0	32.9	21.9
Watermelon	13.9	11.4	11.5	5.9
Cantaloupe	10.8	5.2	37.4	12.4
Carrots	10.4	6.4	5.5	4.4
Sweet corn	9.2	7.8	2.1	0.0
Cabbage	9.1	8.9	3.5	0.3
Bell peppers	7.0	2.5	19.6	12.6
Cucumbers	6.4	2.8	41.4	21.6
Broccoli	6.0	1.0	6.3	0.0

¹ For citrus, the year reflects the end of the harvest; for noncitrus, the beginning of the harvest.

² ERS traditionally reports melons with vegetables. Consumption is on a calendar-year basis.

Source: *Fruit and Tree Nut Yearbook*, and *Vegetable and Specialties Yearbook*, ERS, USDA.

pineapples, another tropical product, are imported. For a storable crop like apples, imports are 7.2 percent of consumption. For grapes, which are now available every month of the year, the import share increased from 5.9 percent in 1975 to 44.1 percent in 2000. For the vegetable and melon category, 37.4 percent of cantaloupe consumption was imported in 2000, up from 12.4 percent in 1975. Less than 1 percent of lettuce is imported because it can be produced year-round domestically. Tomatoes, bell peppers, and cucumbers have high import shares due largely to winter imports from Mexico and increasing greenhouse imports, particularly from Canada.

There is no reason, however, to assume that imports are more prone to food safety problems than domestic

produce. Many growers in foreign countries specialize in exports. For example, in the Mexican winter vegetable industry, growers are producing to comply with relevant U.S. government standards (pesticide residues, microbial contamination, etc.) as well as demands of their U.S. marketer and final buyers such as a particular retail chain. Growers are well aware of the food safety requirements. If prices are favorable, they may sell some of their production to the domestic Mexican market but produce grown in Mexico for the domestic market could not easily be sold into the U.S. market.

Much of the U.S. and foreign produce industry has developed a global focus. A network of business relationships tie domestic and foreign producers and encourage high standards of food safety (see box 5.2).

However, with improvements in communications, storage technology, and transportation, it is possible to acquire commodities from many new areas. In recent years, imports have arrived from many nontraditional suppliers. The Caribbean Basin Initiative and the Andean Trade Preference Act have eliminated tariffs on many agricultural items and encouraged imports from these areas. The share of total volume of fresh produce imports (excluding bananas) from three traditional suppliers—Mexico, Chile, and Canada—dropped from 81 percent in 1990 to 72 percent in 2000. Less traditional suppliers have increased their market share of imports. For example, in 1990 only 10 percent of asparagus imports came from Peru, compared with 47 percent in 2001. Similarly, Costa Rica and Guatemala accounted for 17 percent of cantaloupe imports in 1990 and 60 percent in 2001.

Another consumption trend that may affect outbreaks is the growing share of food eaten at foodservice establishments, potentially increasing the number of people handling produce before it is eaten (and the chance of contamination). In 2001, 47.4 percent of total food expenditures went to the foodservice sector, up from 33.4 percent in 1970 (ERS, 2002).

Three Examples of Foodborne Illness Outbreaks Associated With Imports

Three case studies examine recent food safety problems: (1) disease outbreaks due to *Cyclospora* contami-

nation of Guatemalan raspberries, which began in 1996, (2) the 1997 outbreak of hepatitis A associated with strawberries from Mexico, and (3) the 2000-2002 outbreaks due to *Salmonella* contamination associated with Mexican cantaloupe. By coincidence, all three cases deal with fruit but this does not imply that vegetables are not also associated with foodborne illnesses.

Raspberries and *Cyclospora*

In the spring and early summer of 1996, CDC and Health Canada received reports of more than 1,465 cases of foodborne illness due to *Cyclospora* in the United States and Canada (for more details on the raspberry case, see Calvin et al., 2002). There were no fatalities. This was a very large outbreak compared to others associated with fresh produce. On June 8, 1996, the Texas Department of Health issued a health warning that erroneously identified the source of the problem as California strawberries, then at peak production. On July 18, 1996, the CDC and the Ontario Ministry of Health issued a statement reporting that Guatemalan raspberries were the most likely source of the outbreaks. The California Strawberry Commission estimated that this false alarm led to \$16 million in lost revenue to growers in the central coast of California during the month of June (Mishen, 1996).

By the time raspberries were identified as the source of contamination, the Guatemalan raspberry spring season was over so no immediate regulatory action was taken. FDA and CDC sent a team of investigators to Guatemala later that year to observe growing conditions and to better understand the berry industry there. Because the disease was relatively new to scientists, no one knew which raspberries were contaminated, how they became contaminated, or how to solve the problem. The CDC concluded, after considering the many differences in various aspects of the distribution systems for the implicated raspberries, that simultaneous and persistent contamination on multiple farms was the most likely explanation for the outbreak (Herwaldt et al., 1997). Subsequent research, based on the events for which well-documented traceback data were available, indicated that the 1996 outbreak could have been accounted for by as few as six farms (Herwaldt et al., 1999). Traceback is the ability to track food from the consumer point of purchase back to the grower. FDA provided advice/technical assistance and suggested using GAPs (then under development), GMPs, and sanitation standard operating procedures.

Box 5.2—Ties That Bind the Domestic and Foreign Produce Industry

A firm importing produce into the United States to supply the offseason market will want a product that is equal in quality to their own to maintain their reputation. This takes planning. The pressure to coordinate year-round production, often in far-flung locations, and provide food safety assurances may favor both horizontal and vertical integration or coordination (Wilson et al., 1997; Hennessey, 1996). For example, a U.S. grower-shipper may decide to collaborate with a foreign grower-shipper to provide a year round supply with particular characteristics—horizontal integration or coordination. A U.S. shipper may decide to collaborate with a foreign grower for the same reason—vertical integration or coordination.

U.S. firms have many types of interests in foreign production to expand their season. For the U.S. firm, it is important that the foreign product be consistent with the quality their firm sells from domestic sources. For example, a U.S. firm may grow product on its own farms in a foreign country for sale in the U.S. market. A U.S. firm might also have a joint venture with a firm in a foreign country to produce a crop to be sold in the United States. In some cases, U.S. firms may merge with a foreign supplier. Many U.S. shippers and grower-shippers also market for foreign growers and charge a sales commission. Some U.S. grower cooperatives have foreign members who must meet domestic production standards

These suppliers must develop relationships with reliable foreign growers to provide these products. Suppliers may travel frequently to foreign production regions to cement the relationship with their growers. The suppliers may send agronomists to check on production and crop conditions. Some even have staff liv-

ing in foreign countries. The stakes are high when procuring product from another country. In any of these situations, if the product has food safety problems and cannot be sold, the U.S. supplier may not have adequate supplies for its customers, a serious problem in the competitive produce industry. On the other hand, selling a substandard product may damage the firm's reputation if a foodborne illness outbreak is traced back to the firm. The stakes are also high for the foreign producer too. Many foreign countries have very specialized produce industries geared almost exclusively towards exports. If products are not acceptable in the U.S. market they often have few alternative markets. For example, some of the products grown in Mexico for export to the U.S. market, such as bell peppers, cherry tomatoes, and eggplant, have virtually no alternative domestic market.

Large foreign suppliers are following the same trend in horizontal and vertical integration in reverse. For example, some large Mexican and Chilean winter suppliers are expanding into production or joint ventures in the United States and other countries to provide a year-round supply for their U.S. buyers. Foreign growers have also vertically integrated by acquiring marketing operations in the United States. This provides foreign growers with the ability to better market fruit and vegetables since they directly control the quality of their production. For example, many of the shippers located in Nogales, Arizona, where winter vegetables from Mexico enter the United States, are really just the marketing arms of large Mexican growers. In the 1996/97 season, 63 percent of the tomatoes in Nogales were sold by these vertically integrated, Mexican-owned firms (Calvin and Barrios, 1998).

A grower organization, the Guatemalan Berry Commission (GBC), developed a system to characterize farms according to risk and allowed only certain farms to export. However, the plan had no enforcement mechanism for the 1997 spring season and another outbreak of foodborne illness (with no fatalities) in the United States and Canada was again traced to Guatemalan raspberries. Either the new practices were not completely implemented, were ineffective, or were not directed at the true source of contamination (Herwaldt et al., 1999). After consulting with FDA, the GBC voluntarily stopped raspberry exports to the United States

on May 30, 1997. Guatemala estimated that stopping exports in the middle of the spring season resulted in a loss of \$10 million in income (Powell, 1998).

After a second season with *Cyclospora* contamination problems, both the GBC and the government of Guatemala realized that more stringent controls and enforcement were required. In November 1997, the Guatemalan government created a commission to lead the effort to improve food safety. This gave the GBC's certification process enforcement power that was critical to making any export plan manageable.

In December 1997, FDA, not yet convinced that Guatemala had adequately addressed the *Cyclospora* contamination problem, issued an import alert for Guatemala for the following spring season, putting all shipments from the country under detention without physical examination (DWPE) and denying imports entry into the United States. Denying all imports of raspberries based on country of origin rather than rejecting products from a specific shipper with problems was an unusual response, and one used only after all other means of resolving the problem were exhausted. Generally, FDA collects random samples at the border, preventing entry of products that fail inspections. FDA can also detain a product without physical examination if the shipper has failed previous FDA port inspections or if FDA has other information indicating that the product might violate standards. The product may remain in DWPE status until the shipper proves that the product meets FDA's standards.

Denying imports without physical evidence was very rare in 1997, and in this case the import alert was based only on epidemiological evidence about past outbreaks and FDA observations on current production practices. Not until 2000 did FDA actually observe *Cyclospora* on a Guatemalan raspberry (Ho et al., 2002). Since 1997, FDA has become less reluctant to deny imports on epidemiological evidence alone.

FDA, Health Canada, the Canadian Food Inspection Agency, and Guatemalan officials consulted to consider improved intervention strategies for raspberry production. Beginning in the spring 1999 season, the United States allowed entry of raspberries produced under the Model Plan of Excellence (MPE), a joint program of the GBC and the government of Guatemala. Farmers are only allowed to join the MPE program and export by complying with a detailed program of food safety practices and successfully passing Guatemalan government inspections and FDA audits. Food safety practices include the use of filters for water and better worker hygiene facilities. The program also requires a code applied to each clamshell of raspberries, which allows traceback to an individual grower. Traceback and traceforward capability is critical in the event of a food safety problem. These tools can be used to revoke the export authority of any firms associated with a food safety problem in order to maintain the integrity of the MPE. In some cases, traceback can be used to eliminate Guatemalan rasp-

berries as a potential source of contamination. In spring 1999, there were several outbreaks in the United States and Canada due to *Cyclospora* but the GBC could show, using its traceback and traceforward capabilities, that Guatemalan raspberries were not served at the events associated with the outbreaks. In 2000, there were two outbreaks associated with *Cyclospora* contamination of raspberries traced to one Guatemalan farm that was consequently removed from the MPE program. There have been no further outbreaks associated with Guatemalan raspberries since 2000. In 2002, only three raspberry growers remained in the MPE program. In 1996, before the contamination problem began, the number of growers was estimated to be 85.

The MPE program is a process standard. GAPs, for example, recommend that water quality be adequate for its intended use, but the MPE program requires farmers to use a nominal 1 micron filter as a prefilter to remove particulate matter and an absolute 0.45 micron filter for water used on plants and for employee hygiene. When a food safety problem becomes intractable, a process standard may be necessary rather than relying on the more flexible GAPs. Some firms might have been able to produce a safe product without the expensive filters, so a process standard may introduce inefficiency. However, the MPE process standard may have resolved the food safety problem faster, reducing economic losses, than if the industry had relied on voluntary GAPs.

The problem with raspberries affected other products. U.S. demand for Guatemalan blackberries also declined; blackberries were never cited as a definitive cause of any foodborne illnesses in the United States, although they were in Canada. In addition to possible food safety concerns, blackberries faced decreased demand because retailers prefer to buy a range of berry products all from one buyer if possible. When Guatemala could provide only blackberries, many buyers purchased berries from other regions that could provide the desired mix of berries. The blackberry industry has, however, fared much better than the raspberry industry; in 2001, U.S. imports of Guatemalan raspberries were 16 percent of 1996 levels and blackberries were 55 percent of their 1996 level. Guatemala has a voluntary food safety program for the much larger blackberry industry but it is much less rigorous than the MPE.

When confronted with the food safety problems in Guatemala, many berry shippers made alternative plans. One Guatemalan shipper closed all his domestic

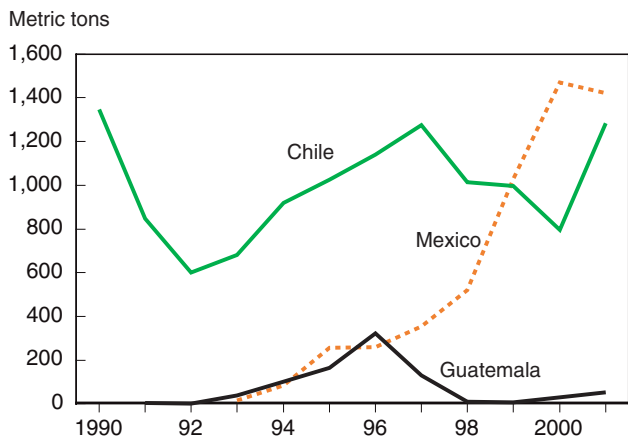
operations and began production in Mexico. A large Chilean firm that ships to the U.S. and Europe had raspberry operations in Guatemala but after the first outbreak this firm stopped shipping raspberries from Guatemala and began to develop production in Mexico. This change of strategy might have occurred even without the *Cyclospora* problems; it is cheaper to transport raspberries from Mexico by truck than from Guatemala by airfreight.

While Guatemala worked to increase food safety standards, other competitors, particularly Mexico, made inroads into its spring and fall market niches in the U.S. market (fig. 5.1). Prior to the 1996 outbreaks, the size and growth of Guatemalan and Mexican exports to the United States were very similar. With outbreaks in 1996 and 1997, many U.S. buyers decided to purchase raspberries elsewhere. Some buyers still feel that there is no reason to take a risk when there are alternate sources of raspberries. Others are reassured by the MPE, arguably the strictest industrywide program for raspberry production in the hemisphere.

In addition to the changes in Guatemala, the outbreaks led to improved private food safety programs for raspberry producers in Chile, Mexico, and the United States (although none of these countries were associated with *Cyclospora* contamination of raspberries). After the *Cyclospora* problem had such an adverse impact on the California strawberry industry, the California Strawberry Commission (CSC) developed a food safety program. California raspberry shippers (and their growers) also use this plan since all raspberry shippers also market strawberries.

Figure 5.1

U.S. imports of raspberries, 1990-2001



Source: U.S. Department of Commerce.

Strawberries and Hepatitis A

In March 1997, more than 200 schoolchildren and teachers in Michigan contracted hepatitis A. Cases were reported in other States as well (Hutin et al., 1999). It was quickly determined that the source of the contamination was frozen strawberries processed by a firm in California. The processor had used fresh strawberries shipped to the United States in April 1996, a year earlier, from Baja California, Mexico. Most of the Mexican berries had been sold in the fresh market and some were sold to the processor (FAS, 1997). FDA was able to determine that California-grown strawberries were not the source of contamination. However, FDA could not determine whether the Mexican-growers fruit was contaminated in Mexico at the farm level or at the California processor. The product was not contaminated in Michigan.

General concerns about the safety of fresh strawberries affected demand for berries from all sources. The monthly price received by growers fell 40 percent from March to April in 1997, compared with an average decline of 16 percent for the years 1990-1996 and 1998-2000. Initial estimates from the CSC put losses at \$15 million with later estimates at \$40 million, but both estimates are subject to debate (Richards and Patterson, 1999). As some of the California growers had joint ventures in Mexico, they shared in the financial losses there too.

The 1996 outbreak associated with *Cyclospora*-contaminated raspberries, when California strawberries were initially and incorrectly implicated, increased the strawberry industry's awareness of their vulnerability to food safety problems. Following that outbreak, the CSC began developing the voluntary Quality Assurance Food Safety Program to help producers improve their food safety standards and mitigate microbial contamination. The CSC worked with FDA and the California Department of Health Services to develop the program. This was one of the earliest good agricultural practices programs for the produce industry that focused on mitigating microbial contamination. An industrywide food safety program is expensive and the CSC has spent about \$250,000 to date.

California standards for production practices and documentation were already fairly rigorous, but the CSC's Quality Assurance Food Safety Program strengthened both. Traceback is a critical part of the voluntary program. If there is a problem, the industry wants to be

able to say the product is not from California or trace the product back to the field and isolate the problem farm from the rest of the industry. Growers use a variety of traceback systems. The best systems include information on shipper, date, field, and picker on each box.¹⁰ It is not enough to just have safe products; growers must be prepared to quickly demonstrate their food safety program in the case of an outbreak. The Quality Assurance Food Safety Program encourages farmers to always have all their documents regarding food safety ready in the case of emergency. This includes documents regarding water, soil, and any fruit testing; pesticide and fertilizer use; and records of hygiene practices.

This program was introduced in November 1996 and was in effect, although still in its infancy, when the strawberry problem occurred in 1997. Although the contaminated product was frozen strawberries, consumer confidence in fresh strawberries was also shaken. In response to a second year of media scrutiny, the CSC was prepared to deflect unwanted attention from their industry. The CSC announced that fresh California strawberries were not responsible for the outbreak and that because growers were using a sophisticated food safety program they were unlikely to ever be responsible for such an outbreak. Researchers estimated the impact of positive and negative publicity in this case. Prices responded more strongly to bad news than good news, so it is very important to prevent or stop negative publicity as soon as possible (Richards and Patterson, 1999).¹¹ Before the outbreak of hepatitis A associated with strawberries, the growers in Mexico were members of the California Strawberry Commission. After the outbreak, the Commission decided to limit membership to California producers to maintain the California focus and a consistent message in its marketing program. However, because the Baja California and California strawberry industries are so integrated, with growers in Mexico marketing through California shippers, the Mexican producers still benefited from the CSC's food safety research.

¹⁰ In the case of strawberries, information on the picker was fairly easy for many shippers to incorporate into their traceback programs. Because the strawberry industry uses an hourly wage as well as a piece-rate payment, the industry already had to be able to tie product to individual pickers.

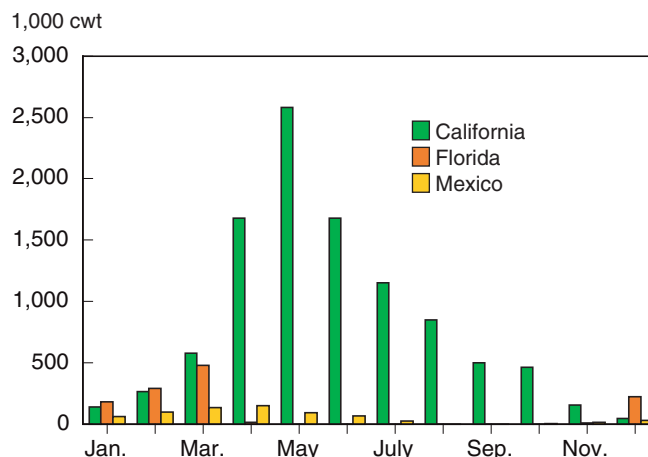
¹¹ Two other aspects of the outbreak kept the news in the public eye. The processor illegally sold the frozen berries as U.S.-grown berries to the National School Lunch Program, which requires domestic product (Richards and Patterson, 1999). Also, many schoolchildren were immunized against hepatitis A as a precautionary measure when there was concern that some of the contaminated product might have been served in Los Angeles area schools.

Although it was never proven that the contamination occurred in Mexico, the outbreak had a serious impact on the Baja California, Mexico industry. The United States imports very small amounts of fresh strawberries—just 6 percent of total U.S. consumption in 2001—and almost all of that is from Baja California, Mexico. The Baja California season runs from January to July, with the highest production typically in April. Baja California production augments the low winter supply in the United States. Figure 5.2 shows the importance of Mexican strawberries during the winter for firms offering a year-round supply.

The publicity surrounding the hepatitis A outbreak had an immediate effect on fresh strawberry shippers from Baja California. Figure 5.3 shows the precipitous decline in fresh strawberry shipments from Mexico in April 1997, compared with 1996. Due to the collapse of market demand in the United States, the primary market for Baja California producers, U.S. shippers told their Mexican growers to stop harvesting, and about 200 hectares of strawberries in Baja California were left unharvested (out of 563 planted hectares).

In response to the outbreak, the Baja California strawberry growers and their local grower organization established more stringent food safety standards (FAS, 1998). Since most of their production is exported, the growers needed to ensure their product would be accepted in the United States. Growers started using third-party audits immediately for strawberries as well as other produce items. Many of the large U.S. third-party audit firms have operations abroad in important growing areas. Some growers

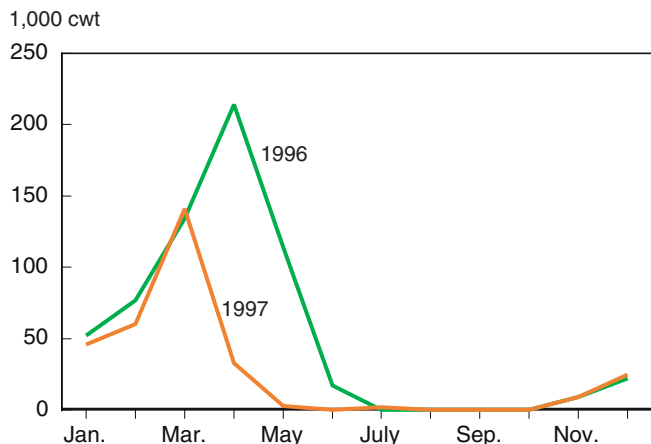
Figure 5.2
U.S. monthly strawberry shipments, 2001



Source: Agricultural Marketing Service, USDA.

Figure 5.3

Strawberry shipments from Mexico, 1996-1997



Source: Agricultural Marketing Service, USDA.

adopted the CSC’s food safety program. In an integrated industry, new practices in the United States are quickly adopted in Baja California.

FDA officials went to the California processor and the Mexican strawberry fields to inspect operations but results regarding the origin of the contamination were inconclusive. FDA provided training on GAP recommendations that were just being developed. These recommendations provided guidelines similar to those of the CSC program. The Mexican state-level department of agriculture was instrumental in disseminating information on FDA’s GAP recommendations to growers. Since that time, they have also hosted FDA and the California Department of Food and Agriculture, among others, for classes on food safety (Avendaño, 2002). At the time of the outbreak, there was no effective way to test for the presence of hepatitis A on strawberries so there was no increased microbial surveillance specifically targeted at this pathogen. FDA was also involved with the recall of frozen strawberries and processed products made with the berries. In the case of produce consumed in fresh form, there is rarely any product to recall by the time an outbreak is detected and the source is identified.

Although fresh strawberry imports from Mexico in 1997 were only 47 percent of 1996 levels, imports in 1998 increased to 86 percent of the earlier level. In 1999, U.S. imports of fresh strawberries from Mexico were at record levels. This outbreak had only a short-run impact on fresh trade.¹² Apparently U.S. shippers were confident that their Mexican strawberry growers had taken adequate precautions.

Cantaloupe and *Salmonella*

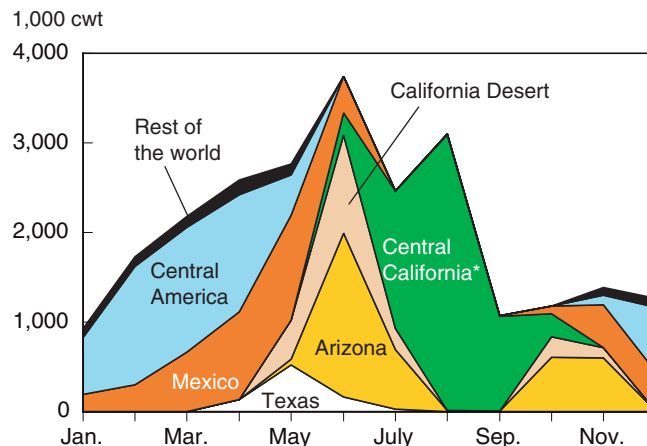
In 2000, 2001, and 2002 there were outbreaks of *Salmonella* associated with Mexican cantaloupe. Mexico exports cantaloupe from various regions during its long export season; in each case, contaminated cantaloupe came only from one region in the south. While Mexico only supplied 7.2 percent of total U.S. consumption in 2001, Mexico and Central America are the major suppliers during the winter season (fig. 5.4 shows suppliers in 1999, the last year of trade without *Salmonella* contamination problems).

In 2000, cantaloupe from southern Mexico were implicated in a *Salmonella poona* outbreak. Forty-seven people became sick in March and April and by late May cantaloupe was implicated (Anderson et al., 2002). The outbreak occurred during the spring when Mexico ships a large volume of cantaloupe to the U.S. market. By the time the outbreak was traced to cantaloupe, the Mexican season was coming to a close. U.S. producers then bore the brunt of consumer backlash against cantaloupe. The outbreak was traced to a particular shipper in Arizona selling cantaloupe from southern Mexico. FDA issued an import alert for this shipper and one farm. In the fall, FDA visited the farm in southern Mexico. Although scientists are more familiar with *Salmonella* than emerging pathogens like *Cyclospora*, they cannot always determine exactly how

¹² U.S. imports of frozen strawberries from Mexico were higher in 1997 than in the previous year. Frozen strawberries come from central Mexico and were apparently not affected by concerns about food safety problems in Baja California.

Figure 5.4

U.S. cantaloupe supply, 1999



*Central California shipments are estimated.

Source: Agricultural Marketing Service, USDA.

the contamination occurred and how to definitively resolve the problem. The primary host for *Salmonella* is animals, followed by humans. A firm shipping product contaminated with *Salmonella* is most likely failing to follow GAPs and GMPs. FDA prepared an adverse findings report, which identified farm activities that were inconsistent with GAPs and GMPs; FDA does not tell a farmer how to fix the problem. When the distributor provided documentation demonstrating corrective actions taken to respond to FDA's adverse findings, the import alert was lifted and the firm and farm resumed exporting to the U.S. market.

In late spring 2001, two additional outbreaks of *Salmonella* attributed to cantaloupe occurred (first *Salmonella poona* and then *Salmonella anatum*). Fifty people were sickened and two died from *Salmonella poona* (Anderson et al., 2002; FDA, 2001c). Fewer people were sickened in the *Salmonella anatum* outbreak. Although *Salmonella* can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems, healthy people who become infected generally experience less severe medical problems. Based on the traceback investigation, FDA determined that the contaminated cantaloupe in 2001 came from the same farm in Mexico and shipper in Arizona that were implicated in the 2000 outbreak. The firm is a large shipper of winter melons from Mexico and has been in the business for 30-40 years (*The Packer*, 2001). Either implementation of the new practices was inadequate or the changes failed to address the problem. Again, by the time cantaloupe from Mexico were determined to be the culprit, most of the Mexican shipping season was over. FDA announced that anyone who had any cantaloupe from this company should remove it from sale, and the company issued a recall of its cantaloupe. Growers from northern Mexico were still selling small volumes to the United States. Some shippers in Arizona told their Mexican growers to sell to the Mexican market. On May 25, 2001, FDA issued an import alert for the distributor and grower that is still in effect in early 2003. The firm cannot ship cantaloupe to the United States but it can still ship honeydew melons.

In May 2002, an outbreak of *Salmonella poona* in the United States and Canada was associated with Mexican cantaloupe shipped through McAllen, Texas. Fifty-eight cases were identified (Anderson et al., 2002). The importing firm issued a voluntary recall and FDA issued an import alert (FDA, 2002a). This was the third season of outbreaks traced to southern

Mexico. The Mexican government is investigating the source of contamination.

U.S. cantaloupe imports from Mexico in the 2001-2002 season were 64 percent of the previous season's volume (fig. 5.5). However, one large multinational firm's decision to move operations to Central America accounts for at least some of the decline. Other factors behind declining imports from Mexico include production problems and increasing input costs. Honeydew imports in 2001-2002 were 97 percent of the previous season's volume. Unlike the case in Guatemala where problems with raspberries affected demand for blackberries, commercial buyers do not seem to be particularly worried about honeydew melons from Mexico.¹³

Repeated outbreaks within an industry prompt several concerns. First, the industry fears that when people get sick, investigators may immediately, and incorrectly, focus on the product with a history of trouble. Second, the produce industry is concerned that FDA might issue a consumer warning about eating the contaminated produce.¹⁴ Third, growers are concerned that if a problem looks like it affects more than a few growers, the FDA might decide to initiate an import alert against all producers from a particularly country, as in the case of Guatemalan raspberries. Fourth, there is concern that an ongoing problem could hurt the reputation of other products from the same region. Fifth, FDA introduced a mandatory food safety program for fruit and vegetable juices after three outbreaks. FDA always has the option of making food safety programs mandatory—something most growers would like to avoid.

The California cantaloupe industry's efforts to promote food safety predate the 2000-2002 *Salmonella* outbreaks associated with Mexican cantaloupe. Over the years, cantaloupe has been associated with several other foodborne disease outbreaks. Outbreaks of *Salmonella* in the

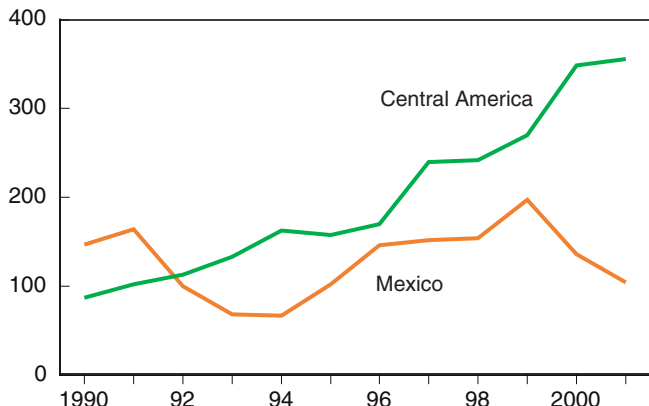
¹³ Although all field-grown melons mature on the ground and are therefore exposed to potentially contaminated soil and irrigation water, cantaloupe appear to be particularly susceptible to microbial contamination, perhaps because of the rough webbing on the rind, which may harbor pathogens (FDA, 2001a). Smooth-skinned honeydew melons, which are often grown in similar areas, appear to be less prone to contamination problems.

¹⁴ Beginning in 1995, there were numerous outbreaks traced to sprouts that the industry could not seem to resolve. In 1998, FDA warned high-risk groups to avoid eating raw alfalfa sprouts. Then in 1999, FDA broadened the warning to include all consumers, not just those at high risk, and all types of raw sprouts (FDA, 1999). This warning was repeated in 2002 and expanded to include lightly cooked mung bean sprouts (FDA, 2002c).

Figure 5.5

U.S. imports of cantaloupe from Mexico and Central America

1,000 metric tons



Source: U.S. Department of Commerce.

United States in 1990, 1991, and 1997, and in Canada in 1991 and 1998 were traced to cantaloupe (FDA, 2001d). In 1991, the news about contaminated cantaloupe emerged in August, when half of the large Central Valley crop in California is shipped (fig. 5.4). The U.S. cantaloupe industry initiated a food safety program called the “Melon Safety Plan” (Tauxe, 1997). Once the crisis was over, however, the program ran out of money and sputtered to a stop.

Since 1998, the California Melon Research Board, which represents all California melon producers, except watermelon growers, has spent more than \$300,000 on funding melon food safety research at the University of California at Davis. Growers who remember the economic chaos of the 1991 outbreak and are concerned about the potential impact of any new food safety problems fund the research. This group of California growers, with the largest cantaloupe production in the United States, views this investment in food safety as critical for the reputation of their industry. This research focuses on California cantaloupe and while the general principles of this research will be widely applicable, the specifics will not. California melons are mostly field packed and forced-air cooled. In other parts of the United States, Mexico, and Central America, shed packing and cooling with cold water or ice are more common and these practices pose different food safety challenges.

Beginning in 2000, the California Cantaloupe Advisory Board (a marketing order for California cantaloupe grown north of Bakersfield) began requiring additional traceback information on cantaloupe boxes

as part of their State marketing order (this program was voluntary in 1999). This was not a very difficult process. California cantaloupe is packed in the field and the Board had already contracted with the California Department of Food and Agriculture to inspect cantaloupe during harvest for quality control and apply an inspection sticker to every box (growers pay the Board a per-box fee for this service). Cantaloupe from this area cannot be sold without the sticker identifying the county and shipper. The new program requires information on the packing date, field, and packing crew, which allows a grower to trace the problem right back to a particular part of a field. Some growers had already been providing this additional information. Adding this additional traceback information to the box was neither particularly costly nor complicated. It did take some administrative changes, however.

To be able to require traceback, the members of the Board had to propose a change to their marketing order and vote on it. Their original marketing order covered grades and quality standards. The new marketing order specifically approves “such grade and quality standards of cantaloupes as necessary, including the marking or certification of cantaloupes or their shipping containers to expedite and implement industry practices related to food safety” (California Department of Food and Agriculture, 2000). If another outbreak were to occur, this program would allow the industry to immediately pinpoint the source of the problem or deny that the problem is due to California cantaloupe, depending on the situation. This may be the only mandatory program for produce in the United States that requires such detailed traceback information on each box.

The Mexican cantaloupe industry is also concerned. In FDA’s first round of microbial testing of produce, both imported (1999-2000) and domestic (2001-2002) shipments of cantaloupe tested positive for *Salmonella*. The FDA followup survey (beginning in January 2001) on imported cantaloupe showed no contaminated samples from Mexico. CDC contends that the interpretation of the 2001 results are limited by the small size—only 29 samples (Anderson et al., 2002). Mexican industry insiders feel that the initial results from the FDA served as a wake-up call to growers; an indication that normal operations would not be sufficient and that the cantaloupe industry would have to be seen as proactive on the food safety issue to maintain its reputation. This may be particu-

larly important when cantaloupe from Central America are also available during much of the Mexican season. Results from the 2002 sampling program are not yet publicly available.

In 2001, the Mexican government agency in charge of food safety, Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA), began developing a food safety program for cantaloupe. The program is based on planting permits, production programs requiring GAPs and GMPs for growers and packinghouses, and monthly melon testing. The program also includes more sophisticated traceback capability. As in other cases, it is imperative to identify any grower or packer that harms the integrity of a food safety program. All exports must have an international phytosanitary permit, which will only be issued if compliance with GAPs and GMPs is certified (*The Packer*, 2002c). FDA and SENASICA were discussing this program in early summer of 2002. Parts of this system were in place on a voluntary basis in some states in fall 2002. Also in 2002, FDA and SENASICA began preparing to conduct joint training for government inspectors and farmers.

U.S. cantaloupe growers lobbied FDA to take a more aggressive role in this evolving case (this was apparently not the case in the raspberry outbreaks). On October 28, 2002, FDA issued an import alert against all cantaloupe imports from Mexico (FDA, 2002d). Although the outbreaks had been traced just to two States in southern Mexico (Michoacan and Guerrero), FDA justified the countrywide import alert because of FDA samples showing *Salmonella* contamination in cantaloupe from other States (Sonora, Jalisco, Colima, Coahuila, Mexico, and Tamaulipas). Also, FDA was concerned that with a regional approach, melons from restricted regions could be commingled with melons from a nonrestricted area. On November 4, 2002, Canada issued a similar import alert for all Mexican cantaloupe (CFIA, 2002).¹⁵

Mexican growers have complained about the timing of the decision—just as growers in Sonora were ready to begin harvesting cantaloupe for the U.S. market. They also complained that the penalties FDA is imposing

are higher than those for U.S. cantaloupe producers with similar food safety problems. While FDA samples showed *Salmonella* contamination in shipments from several regions of Mexico, samples from the U.S. in 2001 also showed contamination, but the U.S. growers are not faced with similar restrictions (FPAA, 2002). Also, for Mexican growers to be removed from the countrywide import alert, they will have to demonstrate higher food safety standards than U.S. growers. An individual Mexican firm can petition FDA to remove their firm from the import alert by providing documentation of their food safety program. According to the import alert announcement “after reviewing these submissions, FDA, either solely or in conjunction with the relevant Mexican regulatory authority may conduct a limited number of onsite inspections of the growing/processing areas to audit the validity of the information submitted to FDA. FDA intends to give first priority to firms or growers who have their operations inspected by a third-party audit firm that has expertise in agricultural and transportation processes.” A third-party audit showing compliance with GAPs will not necessarily be enough to be removed from the import alert list. In contrast, U.S. cantaloupe growers are not required to use GAPs, although many comply voluntarily.

November 2002 saw developments on both sides of the border. On November 8, Mexico presented a formal complaint to the World Trade Organization’s Sanitary and Phytosanitary Committee claiming that the U.S. import alert against all Mexican cantaloupe was not consistent with U.S. trade commitments with respect to discrimination, protectionism, and unnecessarily trade restricting actions (SAGARPA, 2002). On November 13, the Mexican government published legislation that gave the government legal authority to require all cantaloupe growers to comply with the new food safety program. On November 20, importers associated with the 2000 and 2001 outbreaks were indicted in the United States on Federal charges of “trying to impede and defeat lawful government functions of the U.S. Customs Service and the U.S. Food and Drug Administration” in their traceback efforts (*The Packer*, 2002d). The importers entered a plea of not guilty and the trial, initially scheduled for January 2003, has been delayed. On November 27, 2002, FDA authorized imports from two farms from the northern Mexican state of Sonora (*The Packer*, 2002e). This paper only covers events through November 2002 in a case that will continue to evolve.

¹⁵ In the raspberry case, between 1998 and 2000, either the United States or Canada had an import alert but never in the same year. Since *Cyclospora* was an emerging pathogen, it was not clear what actions were adequate to resolve the problem. This inconsistency in policy raised concerns in Guatemala about the scientific basis of trade policy.

Summary of Responses to Food Safety Problems

Private Response

In a food safety outbreak, the grower's first line of defense is to adopt GAPs if they are not already in place.¹⁶ Some growers develop their own food safety programs that are even more stringent than FDA's GAP guidelines. However, it is often difficult to determine how contamination occurred and what practices are adequate to resolve the problem. In Guatemala the problems took several seasons to resolve and the exact means of contamination was never determined. It is not clear how long it will take to solve the problem in Mexico since neither the extent of the problem nor the source of contamination have yet been identified.

In the past, an individual grower could adopt a better food safety program when faced with a food safety problem, but it was difficult to signal to buyers that the firm's product was safer than that of others in the industry. In the raspberry case, the two market leaders—large U.S. and Chilean firms—adopted new food safety programs for all their growers in different countries. These firms are so large that the cost of improved practices and additional testing was likely small compared with the losses associated with a potential food safety problem and damage to their reputation. If consumers and large-scale buyers recognize the brand name, then these firms may be able to maintain consumer confidence even if other firms' reputations suffer from a food safety problem.

The growth in the use of third-party audits for GAPs has provided growers with a new tool to indicate that appropriate practices are in place. An audit can reduce asymmetric information between the grower and shipper and between the shipper and commercial buyers. In the late 1990s, with GAPs in place, third-party auditors

¹⁶ Of course, some firms already had sophisticated food safety practices in place, even before the more recent concern with food safety. Many of the largest firms have their own food safety programs with trained scientists overseeing production and packing operations. This is particularly important for the new fresh-cut products like bagged salads which often have consumer-recognized brands. Investment in food safety protects the brand name. Branding is becoming more common in produce; in 1997, 19 percent of retail produce sales were branded products, compared with only 7 percent in 1987 (Kaufman et al., 2000).

began to verify food safety programs for field operations as being in compliance with these guidelines. While FDA developed GAPs, the private sector has developed the third-party auditing industry for microbial contamination.¹⁷ There is no government oversight of third-party audit firms—an issue that concerns many in the produce industry (*The Packer*, 2002a). Standards may vary between auditing firms and between retailers requiring use of audits. Growers and shippers are concerned that this raises their costs if they need to have different audits for different buyers.

Another concern regarding third-party audits for microbial food safety is that this focus is relatively new for produce. The third-party audit industry has its roots in pesticide residue testing and auditing of indoor HACCP programs. Examining produce for pesticide residues is much easier than looking for microbial contamination. Although adherence to GAP guidelines and successful third-party audits of food safety programs do not guarantee food safety, FDA is concerned that some outbreaks have been traced back to firms that have successfully completed third-party audits.¹⁸ An audit can verify that growers are using certain food safety practices that should help reduce microbial contamination but it is much harder to observe the potential for contamination. For example, GAP guidelines say that water must be adequate for its intended use. An auditor may take water samples in an attempt to provide a more comprehensive assessment of risk. However, water samples can be problematic since water contamination is not necessarily a constant presence. A sample of surface water that tests negative for microbial organisms on one day indicates nothing

¹⁷ In 2001, USDA's AMS began a pilot program offering third-party audits for produce in several States, the Fresh Produce Audit Verification Program (AMS, 2002). The AMS audits are similar to private audits. The AMS program does not seek to influence the third-party audit industry, just to provide another source of the same service. The program is run through the State departments of agriculture. AMS has inspectors at shipping-point locations and has experience working with growers. This program grew out of a request from New Jersey growers. Currently, the program is offered in New Jersey, California, and Oregon. It is just starting in Washington and Florida. The cost of an AMS audit is similar to those offered by the private sector. The typical audit takes 5-6 hours. In California, an audit costs \$65 per hour plus \$31 per hour in travel costs (*The Packer*, 2002b).

¹⁸ This concern has become more obvious in the import alert for Mexican cantaloupe, which states that FDA will conduct their own investigations and not rely solely on third-party audits. This is similar to FDA conducting audits of Guatemalan raspberry farms in the early stages of the MPE program.

about the chances of contamination on another day. Tests of water from wells that are protected from surface contamination are more helpful; for example, a yearly sample from such a well might be sufficient to determine the overall water quality.

Growers have another reason to adopt GAPs and use third-party audits. In 1999, Safeway, the third largest U.S. food retailer, expanded their food safety program to require all their suppliers of certain commodities to verify that they follow government food safety standards and specifications in production and packing. Some other retailers have followed suit. To qualify as a Safeway supplier, a grower must have an independent third-party auditor verify that they are using GAPs for production and GMPs for packinghouses. Requiring verification of use of GAPs and GMPs was a new idea and met with initial opposition. Domestic and imported produce sold by Safeway must meet the same standards. Research covering a select group of U.S. fruit and vegetable shippers indicates that in 1999, almost half of those studied provided third-party audits for GAPs or GMPs for at least one of their buyers. While shippers were not always happy about complying with this request, most indicated that they would implement verification programs in response to changing buyer preferences (Calvin et al., 2001).

In each of the case studies, shippers tried to distance themselves from those associated with a food safety problem. Shippers can reduce their risk by requiring growers to provide third-party audits or by dropping growers with less sophisticated food safety programs or more challenging environments. The problems in Guatemala may have helped the small but growing industry in Mexico since shippers could satisfy most of their needs with Mexican raspberries. Mexico cantaloupe growers may face a similar situation in the future if U.S. buyers decide to reduce their risks by switching to Central American cantaloupe.

Grower Organization Response

Grower organizations have also been important forces for resolving food safety problems. Beginning in the mid-1990s, the fresh produce industry became aware of the potential cost of food safety problems related to contamination at the farm level. Many trace this heightened awareness to the well-publicized 1996 outbreak of *E. coli* O157:H7 that was traced to mesclun (lettuce mix) grown and packed on one small farm in

California. This was the first reported multistate outbreak of *E. coli* O157:H7 associated with lettuce (Hilborn et al., 1999). It was also one of the earliest cases clearly identifying microbial contamination at the farm level.

Concerned about potential government regulation, the Western Grower's Association, which represents the California and Arizona produce industry (including almost all U.S. lettuce production), and the International Fresh-cut Produce Association, took the initiative and developed their own set of guidelines for fresh produce food safety. Similarly the CSC developed its own set of guidelines following the raspberry contamination problem in 1996. FDA's GAP guidelines published in late 1998 built, in part, on these earlier industry efforts.

One grower organization has been active in providing guidance to the third-party audit industry. The United Fresh Fruit and Vegetable Association has developed a training program on food safety auditing. Growers were concerned that some auditors experienced only in indoor audits were unfamiliar with the produce industry and outdoor settings where some factors cannot be controlled. This program also serves a need for continuing education for growers interested in evaluating their own food safety programs.

Grower organizations have become more concerned about the reputation of their crops for food safety. A very large and important firm may be able to maintain its reputation despite the actions of others in the industry, but most firms must rely on the overall reputation of the industry. Retail buyers may know that a particular firm has never been associated with an outbreak, has a strong food safety program, and has successful third-party audits for adherence to GAP principles, but consumers generally do not have that great a knowledge of the industry. News reports of an outbreak associated with a particular grower may affect consumer perceptions about all growers of that product in that same area or anywhere else.

A grower organization's effort to build a reputation for food safety is a public good. At least in the short run, everyone benefits from the reputation for safety even if they are not investing in improved food safety. In each of the three cases studied, grower organizations have focused on developing systems to trace products from final selling point back to the grower, which encourages grower responsibility and reduces the free-rider

problem.^{19,20} In the case of an outbreak, a grower organization that encourages traceback can prove to the public that their product is not responsible for the problem. Or, where the industry is responsible for the outbreak, the responsible grower or growers can be identified and damage can be limited.

In the raspberry case, the Guatemalan food safety program with its traceback and traceforward capabilities is mandatory. With the California Strawberry Commission, the Quality Assurance Food Safety Program is voluntary but the Commission is confident that all shippers use some sort of traceback, although the degree of sophistication varies. The Baja California strawberry growers appear to follow the California Strawberry Commission's program closely. In the case of cantaloupe, the California Cantaloupe Advisory Board's traceback program is mandatory. Mexico's new cantaloupe food safety program with enhanced traceback is also mandatory.

This level of traceback capability may not be representative of other industries who have not yet faced food safety problems, even though traceback capability is an integral part of GAPs. The difficulty of implementing a traceback program may vary by crop because of particular harvesting or marketing practices. For example, products that are packed in the field can easily be labeled with the origin of the product. If products are harvested and then packed in a central facility, a little more care is required to maintain traceability. Crops like tomatoes present a particular traceability challenge. They are often harvested, packed, and then sent to repackers where tomatoes from several producers may be commingled before being resorted by maturity.

Government Response

FDA's most important contributions to improving food safety for produce is the development of guidelines for

¹⁹ Even before recent food safety problems and emphasis on using GAPs, some firms voluntarily adopted traceback programs as a good business practice.

²⁰ The Federal Government does not currently require traceback nor monitor voluntary activities (Golan et al., 2002). However, the newly enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002 will eventually require some traceability capability (FDA, 2002). Although farmers are exempt, shippers and most other firms in the distribution channel will be required to be able to identify where any product came from and where it went to ("one up, one down"). FDA must publish their regulations for establishing this system by December 12, 2003.

food safety practices. The value of GAPs will increase as science provides more answers regarding how to reduce risk of microbial contamination.

Because it is so difficult to identify microbial contamination on produce, FDA cannot rely on random testing at the border to detect contaminated produce. FDA will do inspections when there is reason to think there might be a problem. Because of the problems with cantaloupe in recent years, FDA conducts microbial testing on imported and domestic cantaloupe. Instead of focusing on testing, FDA has concentrated much of its efforts on education in foreign countries. All efforts to solve food safety problems abroad reduce the burden on the consuming public and on the FDA and CDC, which investigate outbreaks. In 1997, FDA spent 6,274 hours investigating the *Cyclospora*-contaminated raspberries (U.S. GAO, 1999).

When invited by a foreign government, FDA will visit individual farms associated with contamination problems and identify practices that are not consistent with GAPs. Findings compiled from these visits are used to identify trends for future training and guidance development. FDA, in association with the University of Maryland, teaches food safety practices in the United States and abroad through the Joint Institute of Food Safety and Applied Nutrition. This program has provided classes on GAPs. In addition, FDA provides training for conducting farm investigations. In 2002, FDA conducted several training courses in Mexico on how to do farm investigations for produce.

When an outbreak is associated with imported produce, FDA must determine whether the problem can be easily solved or whether the individual firm or country should not be allowed to ship to the United States until the problem is fixed. Traditionally, FDA relies on laboratory identification of pathogens on a product before making decisions on withdrawing a product from the market or banning its import. This is a problem for fresh produce, which is rarely available for analysis when an outbreak develops. Over time, FDA has become more comfortable with making decisions based on epidemiological evidence alone. The *Cyclospora* case in Guatemala was the first big produce case that relied solely on epidemiology. The Mexican *Salmonella* case demonstrates again the reliance on epidemiology.

The role of FDA varies depending on the case. For Guatemalan raspberries, FDA eventually banned all imports because an individual farm could not be iden-

tified and the problem seemed pervasive. FDA and CDC sent researchers to Guatemala to investigate the industry and provide assistance in developing a production system to minimize the potential of microbial contamination. FDA's role in the Mexican strawberry case appears to have been limited at the farm level, particularly since no one could determine where the contamination occurred. In this case, however, the strawberries were processed so FDA was involved in the recall of the processed product. With a fresh product, there is often no product to recall. In the Mexican cantaloupe case, FDA first issued import alerts for three firms selling cantaloupe associated with *Salmonella* outbreaks. In late 2002, FDA banned all cantaloupe imports from Mexico. FDA is evaluating petitions from individual Mexico growers for exemption from the ban.

State organizations, such as the California Department of Food and Agriculture, are also involved in food safety outreach programs to producers in other countries. Again, the motivation is self-interest since contamination problems traced to imports can have such negative impacts on U.S. producers.

As the case studies demonstrate, in most cases foreign governments have tried to resolve food safety problems, although perhaps not as aggressively as desired by the United States in the early stages. In Guatemala, the government became involved in the GBC's efforts to develop a workable and enforceable food safety plan. In the strawberry case, the industry in Baja California acted almost as a part of the U.S. industry and benefited in an indirect way from food safety initiatives of the CSC. Mexican government activities appear to have been limited to the state level in that case. In November 2002, the Mexican government put into place a food safety program to try to resolve the cantaloupe problem.

Conclusions

Food safety and produce trade are clearly compatible; the vast majority of imports are never associated with food safety outbreaks. Producers in the United States and foreign countries, grower organizations, governments, and commercial buyers are actively involved in improving food safety.

Producers are self-motivated to provide safe produce because of the financial consequences of an outbreak traced back to their operation. Of course, there are always some cases where people will not invest suffi-

ciently in food safety practices because they think their product is safe or they deliberately cut corners. As traceability improves, however, the probability that responsibility for contaminated food will fall on those farmers with inadequate food safety programs will increase.

Grower organizations are motivated because of the public good nature of a product reputation. Since an outbreak anywhere can have a negative impact on consumers' perceptions of the product, grower organizations must do something to try to reassure the public that their product is safe and distinguish themselves from other groups of growers associated with a problem.

Fears of economic and reputation losses if a contaminated produce item is traced to their firm motivate retailers and other commercial buyers to demand high food safety standards. Buyers want to know about a grower's food safety plan. Some demand third-party verification of compliance with GAPs and GMPs.

In the United States, FDA encourages farmers to follow guidelines to reduce microbial contamination in produce. It does have the power to impose mandatory food safety programs if necessary. With respect to trade, FDA restricts imports from individual firms or all producers in a region or country when food safety problems cannot be resolved. FDA has been active in promoting improved food safety abroad. In both Mexico and Guatemala, microbial food safety programs have traditionally been voluntary. Government programs became mandatory for the particular products after food safety problems resulted in U.S. import alerts.

There is no reason to think that this trend toward more sophisticated food safety programs is any more difficult for foreign growers to cope with than for domestic growers. However, increased concerns about microbial food safety programs pose particular challenges for smaller farmers in both the United States and foreign countries. When there are food safety problems, the costs of production increase for everyone producing for the U.S. market. New fixed costs, such as purchasing a water filtration system, would be particularly problematic for small producers spreading the cost of the new investment over smaller volume of output. Also, smaller farmers (or geographically dispersed farmers) might not be able to support the grower organizations that have been so important in resolving food safety problems.

The case studies show that failure to resolve food safety problems quickly can have serious impacts on an indus-

try and trade. A major policy challenge is to determine when government intervention may be required to resolve a problem. Science is not as definitive as desired when trying to make decisions about trade and food safety. While some practices clearly increase the probability of microbial contamination, it is often difficult for FDA and others to identify the source of contamination and the new practices that would yield safer food. There is a chance that too aggressive a stance would unnecessarily restrict international trade when using GAPs might resolve the problem in the next season. In the hepatitis A outbreak linked to strawberries, if the contamination occurred in Mexico, use of GAPs alone may have been sufficient to solve the problem (or it may be a sporadic problem that might pop up again in the future). Restricting trade can be economically devastating for an industry, as in the Guatemalan raspberry case. However, the raspberry and cantaloupe cases show that it can take several years to resolve a problem and in both cases the foreign governments intervened. In these cases a more moderate response may be inadequate, leading to more outbreaks and economic losses in affected industries.

In each case, damage was not limited to the producers of the contaminated product. Anyone producing a product for the U.S. market, including U.S. growers, may be caught in the consumer backlash against a product and will probably have to adopt more stringent food safety programs. Given the widespread impacts of food safety outbreaks, there may be opportunities for grower organizations in different countries to organize joint efforts to resolve problems. Organizations would have to weigh the negative fallout of a food safety problem originating with their competitors against the potential gain if their competitors' sales were restricted. The costs and benefits would vary by industry.

The case studies show the actions of growers, grower groups, and governments caught up in foodborne illness outbreaks. Future research should investigate what other sectors of the produce industry, which have not yet faced the economic disruption of a foodborne illness outbreak, are doing to prepare for the possibility.

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