Chapter 1

Introduction and Overview

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Background

Increased international food trade means that countries share the responsibility for food safety, which pertains all along the food supply chain from producers to consumers. With increased international food trade, this supply chain transcends international borders. Consumers benefit from worldwide trade through lower prices, year-round supplies, and a greater quality and variety of food. However, globalization of the food supply could introduce new food safety risks, revive previously controlled risks, and spread contaminated food wider. For food producers, food safety issues can raise production costs, influence reputation, and close off international markets.

Trade in international markets may introduce new costs for addressing and managing food safety hazards. Most internationally traded food poses no human health risks, with food safety incidents rare considering the total volume of trade. Trade disputes over food safety, however, can be persistent, and may require public intervention/investment and private costs to overcome. This report highlights how food safety disputes and challenges arise and are resolved.

Although food safety standards are frequently viewed as technical barriers to trade, improvements in food safety and expanded international trade are likely compatible and even mutually reinforcing. Domestic and international firms share and respond to the same incentives to provide safer food. Reputation and sales can be enhanced for those exporting firms and industries making noticeably safer products, whereas firms implicated in a food safety crisis may suffer a wide range of business losses. From our research here, we believe that, over time, food safety should continue to improve worldwide with the spread of private and public food safety control efforts, increased scientific understanding about food safety, and improved dialogue between countries.

Food safety risks are defined here as they pertain to human health, covering well-established and perceived impacts from agents and sources including: (1) microbial pathogens (i.e., illness-causing bacteria, viruses, parasites, fungi, and their toxins); (2) residues from pesticides, food additives, livestock drugs, and growth hormones; (3) environmental toxins such as heavy metals (e.g., lead and mercury); (4) persistent organic pollutants (e.g., dioxin); (5) unconventional agents such as prions associated with bovine spongiform encephalopathy (BSE) or "mad cow disease" in cattle; (6) zoonotic diseases that can be transmitted through food from animals to humans (e.g., tuberculosis); and (7) foods produced or processed with practices perceived to involve risks, such as irradiation. Scientists generally agree that food safety risks are low relative to many human health risks such as cancer and heart disease. Among food safety hazards, human health risks are highest from foodborne pathogens such as *Campylobacter* and *Salmonella*, each of which causes well over a million illnesses annually in the United States (Mead et al., 1999). These are also common pathogens worldwide.

Food safety and trade issues related to it are becoming more pronounced. There has been an increased scientific awareness of the public health risks from unsafe food, including both acute and long-term health consequences (Lindsay, 1997). Many foodborne pathogens and diseases, such as new pathogenic strains of *E. coli*, are emerging as technological improvements enable their detection (Käferstein et al., 1997). Also troubling is accumulating evidence that some pathogens are becoming resistant to certain antibiotics (GAO, 1999; Tauxe, 1997). Public health authorities are growing more engaged with food safety as improvements in information and reporting systems accompany greater concern about food safety in general (Käferstein et al., 1997).

The traditional foodborne outbreak scenario is changing (Tauxe, 1997). In the past, outbreaks were mostly

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acute and highly local and resulted from a high level of contamination. Now, we see relatively more outbreaks from low level contamination of widely distributed commercial food products affecting many counties, States, and nations. This development has been attributed to changes in food production and distribution and to the growth of international trade.

The U.S. food system is changing at all levels—consumption, production, and trade. These changes alter the nature and incidence of food safety risks. In the past few decades, consumption of poultry, fish, fruits, and vegetables has increased (Regmi, 2001), as has consumption of prepared foods and foods consumed away from home (Lin et al., 1999). Meanwhile, the demand for better food safety has tended to increase with growing consumer affluence and awareness of food safety issues (Hooker and Caswell, 1999). Food production has changed notably, leading to a different set of food safety risks for the food industry to manage. For example, U.S. aquaculture production increased by over 50 percent between 1990 and 2000 (NMFS, 2002) and the aquaculture share of total world production has also increased (FAO, 2000). Farm-raised fish pose a different set of food safety challenges than does wild-caught seafood. Farm-raised fish are subject to contamination from residues by production inputs (e.g., vaccines, feed additives, and antibiotics), whereas wild-caught seafood are more likely subject to contamination from, say, histamine (FDA, 2001).

Shifts in food consumption have led to some of these changes in food production, while other changes are driven by advances in technology and by comparative advantages of nations. Shifts in food consumption coincide with increased trade and changes in the composition of world agricultural trade (Regmi, 2001). Not only are trade volumes increasing—especially of fresh, minimally processed, or high-value foods—but countries like the United States are looking to imports for a wider variety of safe food year-round.

There is no scientific evidence that food imported into the United States, as a whole, poses greater food safety risks than domestically produced food (Zepp et al., 1998). Concern remains, however, for products such as seafood because more countries are exporting to the United States and some of these countries have poor internal control systems and/or are in tropical areas where toxin and bacteria hazards are intrinsically higher (Ahmed, 1991). In general, importing countries have limited ability to enforce their standards outside their borders and may view exporters' standards as inadequate or unreliable (Lichtenberg, 2003). Establishing the equivalence of another country's regulatory system is difficult (see chapter 3). Although risks from imported food sources are similar to the kind and extent of risks from domestic sources, the United States has less food safety oversight over countries from which we import, which are increasingly from developing countries.

In general, less developed countries are adapting to higher standards of food safety oversight as they enter new markets, and technical assistance helps with this. Often, higher standards apply only to production for export markets (see chapter 5). Both public and private sectors are helping to safeguard imported food. For example, private importers may set safety standards for imports over and above those set by the U.S. Government. However, reducing a residue tolerance, for example, does not necessarily provide additional protection from disease or injury. Governments in exporting countries may work with their industries to ensure food safety as well.

Although over a dozen Federal agencies share jurisdiction over food safety (e.g., education, enforcement, inspection, monitoring, outbreak management, research, and surveillance), four have major regulatory roles: the Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Commerce's National Marine Fisheries Service (NMFS) (IOM, 1998).[2] These four agencies actively monitor imports and, in some cases, survey the safety of production abroad. In general, FDA oversees almost all import inspections, which include testing for pesticide residues or sanitary violations. Meat and poultry products fall under FSIS jurisdiction, and this agency carries out audits of foreign plants to ensure that sanitation meets U.S. standards. FSIS also re-inspects imports of these products using statistical sampling techniques to verify that exporting countries' inspection systems are working. FSIS and FDA share responsibility for egg product imports (IOM, 1998). For seafood, NMFS conducts a grading program and a voluntary inspection of fishing vessels, seafood products, and processing plants; FDA has regulatory responsibility for seafood safety, including imports (IOM, 1998). FSIS requires that exporting

[2] For FSIS, see *www.fsis.usda.gov*, for FDA, see *www.fda.gov*, for EPA, see *www.epa.gov*, and for NMFS, see *www.nmfs.noaa.gov*

countries have food safety systems equivalent to those in the U.S., while FDA lacks such authority, relying mostly on port-of-entry sampling to determine if imports meet U.S. standards (GAO, 1998).

With heightened awareness of food safety concerns and the rapidly changing food system, food safety standards are becoming more stringent and responsive to new hazards (see chapter 3). Countries that trade internationally may have different desired levels of food safety and food safety regimes, as well as different costs of complying with regulations. These differences may lead to trade conflicts or reductions in trade (see chapter 2). These differences may, on the other hand, lead to increased dialogue between countries and cause some to change or even improve their food safety systems.

Who Manages and Ensures Food Safety?

Food safety, both domestically and internationally, is managed and ensured by both private and public sector efforts (Caswell and Henson, 1997).

Private Sector

The private sector, both here and abroad, has strong incentives to prevent food safety crises and to mitigate their impact if they arise. Firms implicated in a crisis may suffer from reputation lost, stock prices reduced, plants closed for cleanup or permanently shut down, food poisoning lawsuits filed, premiums raised for product liability insurance, and demand for product reduced enough to threaten entire markets or industries (Buzby et al., 2001). For example, the Guatemalan raspberry industry shrank from 85 producers to 3 once caught in the spotlight of repeated *Cyclospora* outbreaks from contaminated raspberries (see chapter 5).

Many sectors have great potential for growth in world markets and so have added incentives to produce safer food (e.g., see chapter 4 on the growth of the red meat sector). As safety and quality attributes are increasingly demanded by consumers, the private sector responds.[3] For example, the seafood sector exhibits increased market segmentation, with wealthier countries favoring higher valued, safer products while less wealthy countries favor lower valued products with fewer food safety assurances (Wessells, 2002). In general, the private sector pioneers food safety advances. Firms such as Nestle, in fact, have developed food safety assurance standards beyond mandated ones (USDEC, 2001).[4] Importers often target their food safety efforts to sell to large supermarket chains with particular food standards (e.g., regarding produce).

For branded products, private-sector diligence may help firms improve their international competitiveness when their products are perceived to be noticeably safer. Private approaches fostering food safety include self regulation, vertical integration, third-party certification, and common approaches to risk identification, assessment, and management such as Hazard Analysis and Critical Control Point (HACCP) systems and voluntary guidelines or Good Agricultural Practices (GAPs). Vertical integration is growing in the United States and is characterized by a single firm controlling the flow of a commodity across two or more stages of production (Martinez and Reed, 1996). It can better guarantee the safety and quality of a firm's inputs and enhance the ability to trace product ingredients or processes back through the food production and marketing chain. Traceback capability is critical in the event of a food safety problem; it can help identify the source of the contamination. Tracing such incidents forward can eliminate other firms or products as potential sources of contamination (see chapter 5).[5]

Third-party certification provides assurances to consumers that the information supplied by firms is correct (Golan et al., 2000) (e.g., the International Organization for Standardization has its ISO 9000 series or "EN 29000" in Europe). HACCP essentially identifies, monitors, and controls hazards at critical points in food production and processing. Many producer groups have instituted quality assurance programs, and firms often use a mix of approaches.

[3] Although the Food and Agriculture Organization of the United Nations considers food safety to be one attribute of food quality, the U.S. Food Industry considers food safety and quality as separate attributes. Therefore, we follow the latter usage in this report.

[4] Of course, the amount of market share that firms can capture from increased food safety efforts will depend on how well consumers can distinguish the safer product, how willing they are to pay for the safer product, and how well firms communicate that their products are safer to consumers.

[5] Note traceback is different than traceabilty. Traceability is established when information about a particular attribute of a food product is systematically recorded from creation through marketing (Golan et al., 2002).

Public Sector

Although the private sector has strong incentives to produce safe food, market signals to producers are imperfect. Consumers often cannot discern the safety of their food before buying it, and so their preference for safer food may not be reflected in the price they are willing to pay. Also, market transactions do not include all of the social costs of food safety (e.g., medical costs, lost work time) (Buzby and Roberts, 1997). Additionally, high transaction and information costs, combined with the structure of the legal system, limit the effectiveness of litigation for compensating ill consumers and providing firms with signals to produce safer food (Buzby et al., 2001). Therefore, in addition to private sector approaches, government regulation is necessary to ensure food safety.

New approaches to food safety regulation emerged in industrialized countries during the 1990s following advances in science, changes in markets, and increased awareness of food safety risks. There are seven main trends for food safety regulation in industrialized nations (see chapter 3). Regulatory agencies are increasingly:

- Organized into one agency that can focus on food safety,
- Using risk analysis to design regulation,
- Stressing a farm-to-table approach in addressing food safety hazards,
- Adopting the HACCP system as a basis for new regulation of microbial pathogens in food,
- Adopting more stringent standards for many food safety hazards,
- Adding new and more extensive regulation to handle newly identified hazards, and
- Improving market performance in food safety through provision of information.

These trends cut across commodities (see chapters 4, 5, 6, and 7). However, each food sector may also face unique issues, such as BSE in cattle and bovine products, histamine poisoning in seafood, and mycotoxin (toxic byproduct of mold infestations) risks in grains.

Different food safety standards and regulations naturally evolve around the world, even when countries have similar levels of economic development. For example, standards may differ because countries disagree about science—countries may have different scientific standards or they may interpret the same science differently. Food safety contamination can vary greatly among countries because of differences in available technology (e.g., refrigeration), plant and livestock host factors (e.g., herds exhibit varying infection rates, endemic diseases), food production practices (e.g., use of veterinary drugs), cultural differences (e.g., routine consumption of raw seafood), and geographic or climatic differences (e.g., colder climates may kill some pathogens) (Buzby and Roberts, 1999). These differences among countries may affect the relative risks or imports of food from different countries.

When the U.S. sets standards that affect imports or negotiates access to other markets with different standards, it does so under the rules set out by the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures, which was established under the World Trade Organization in 1995. The SPS Agreement was a result of the 1986-93 Uruguay Round of Multilateral Trade Negotiations. This Agreement addresses food safety regulations and provides a framework for determining the legitimacy of regulations that restrict trade and for resolving potential trade conflicts. Under the SPS Agreement, WTO members recognize several principles, including:

- *Transparency*: Member nations are required to publish their regulations and provide a mechanism for answering questions from trading partners.
- *Equivalence*: Member nations must accept that SPS measures of another country are equivalent if they result in the same level of health protection.
- *Science-based measures*: SPS measures must be based upon risk assessments and must be chosen so as to minimize distortions to trade.[6]
- *Harmonization*: Member nations recognize the desirability of common SPS measures. Three international organizations are recognized as sources of internationally agreed-upon standards: the Codex Alimentarius Commission (Codex) for human health measures, the International Office of Epizootics (OIE) for animal and human health measures, and the International Plant Protection Convention (IPPC) for plant health measures.

[6] Risk assessments identify the sources and incidence of risks, and identify possible control strategies.

The SPS Agreement also establishes dispute resolution mechanisms. Because of improved transparency and the international SPS framework established for food safety, many disputes are diffused or resolved before reaching a formal dispute process. Several chapters in this report refer to the SPS Agreement, because it has played a role in the negotiation of trade disputes or potential disputes over food safety standards. For example, the emergence of BSE has created many difficulties for trade of live cattle and bovine products, and international organizations have helped prompt new standards to control BSE in the beef supply.

One area of controversy is the difference in food safety standards that exists among countries (e.g., mycotoxin risk assessments and standards, see chapter 6). Codex has facilitated the discussion of internationally acceptable standards, and the SPS Agreement has eased negotiations among countries concerned about new standards proposed by the European Union (EU) and by others. Food safety issues examined in this report for other commodities, such as produce, seafood, and poultry, have been addressed either through private efforts to meet standards or through bilateral negotiations over acceptable standards and systems of oversight.

In essence, the private and public sectors have responded to consumer demand for quality and safety by developing and implementing common approaches for quality and safety control, management, and assurance (Regmi, 2001), often working in partnership. The extent of public versus private responsibility varies among commodities and food products. Public and private approaches are often intertwined with each other and with multilateral coordination mechanisms (e.g., Codex and HACCP). For example, the public sector mandates HACCP for some foods, while the private sector voluntarily implements it for other foods. In another example, the fruit and vegetable sector is using third-party certification to reduce microbial and other hazards, and this certification is based on GAPs provided by FDA.

How Do Food Safety Disputes in Trade Arise?

The dynamic nature of food trade, the emergence of new hazards, and remaining differences in regulatory approaches and capacity can still spur disputes over differing food safety standards. In particular, food safety disputes in trade may arise from the following (see chapter 3):

- The appearance of new hazards and/or increased trade volumes from new sources can lead to food safety incidents or disputes in trade (see chapters 4, 5, and 8 for examples);
- Rising standards and rapidly changing food safety regulations in industrialized countries can create challenges for developing countries (see chapters 5, 6, and 7 for examples);
- If new or more stringent standards are process standards, then it is more difficult to determine whether an equivalent safety outcome has been achieved (see chapters 4 and 7 for examples);
- Strong differences remain with respect to consumer risk preferences, consumer perceptions, and the role of non-science issues in regulatory decisionmaking (see chapters 3 and 4).

The causes of food safety and international trade disputes are complex and likely to persist for some time.

Recently, several new food safety hazards have disrupted trade. BSE, for one, emerged in the mid-1990s and instigated new regulations, some of which have proven contentious among trading partners (chapters 3 and 4). And the Belgian dioxin crisis temporarily suspended the trade of wide range of products (e.g., pork, cheese, and poultry) in many countries (chapter 8).

What Food Safety-Related Trade Disputes and Challenges Arise in U.S. Commodity Sectors?

Health risks from internationally traded agricultural products outweigh risks from domestically produced products in at least one important respect—trade can spread pathogens, pests, and diseases into countries traditionally free of these hazards. In essence, animal, plant, and human health concerns with domestic agricultural products tend to stem from endemic pathogens, pests, and diseases, and the responses to these hazards are often established and ongoing. Hazards introduced through international trade may pose a whole new set of problems unfamiliar to the importing country. These problems may threaten trade and the economic health of the importing and exporting country. BSE, for example,

has affected a number of U.S. domestic industries even though there has never been a BSE case identified in the United States (chapter 4).

Food safety challenges are different across commodity and food types because of the nature of the products. First, it matters **whether the product is highly perishable**. The potential for faster decomposition means a shorter shelf life, greater food handling challenges, and fewer leftovers to test in the event of an outbreak. Raw foods tend to pose higher risks than cooked or processed foods and may be more likely to pose risks of cross contamination.[7] Animal products such as meat, poultry, seafood, dairy products, and eggs are the foods most likely to cause outbreaks of human illness in the United States (CAST, 1994, p. 32).[8] In recent years, the variety of foods associated with foodborne illness (e.g., salami, lettuce, bean sprouts, and raspberries) has increased (Tauxe, 1997), perhaps with improvements in detection and traceback. In particular, foodborne outbreak investigations are tracing a greater proportion of outbreaks to fresh produce (Tauxe, 1997). Less perishable foods such as grains tend to pose fewer acute food safety challenges (e.g., mycotoxins) (chapter 6).

Second, the **nature of the human health risks** associated with food matters. Do risks lead to illnesses that are acute or chronic, of low or high severity, and/or low or high incidence? The nature of risks determines how the risk is regulated and controlled, and its associated costs. For example, most food safety hazards from seafood, meat, and poultry are from the immediate health risks of ingesting foods contaminated with pathogens and their toxins, so regulation and testing tends to focus on reducing these kinds of contamination. On the other hand, human health risks from contaminated grain products generally stem from increased cancer risk due to long-term exposure to mycotoxins, so surveillance and prevention measures are aimed at these hazards. Food safety concerns from produce involve both the immediate health risks from pathogens and the chronic risks from long-term exposure to pesticide residues, and so testing is for both types of hazards.

Third, **whether the food safety issue is linked with productivity** in the commodity sector also matters. Meat and poultry are singular commodities in that their human and animal health issues are often linked. Some pathogens such as *Salmonella* and *E. coli* O157:H7 exist naturally in the gastrointestinal tracts of animals and birds (Wells et al., 1998). Some pathogens can impair the health of the animal, and contaminate meat and poultry during slaughter if the gastrointestinal tract is punctured or if the hides, feathers, and hoofs are contaminated when animals enter the slaughterhouse (IFT, 2002; Feinman, 1979). Animals fed mycotoxin-contaminated grain can become ill, which can lower animal productivity (weight gain, milk or egg production) (CAST, 2003). Animal byproducts must be destroyed if mycotoxin residue levels exceed standards (CAST, 2003). Mycotoxin levels are higher when crops are under stress or stored in improper conditions, so well managed crops would suffer less contamination and reduce waste. This improves the incentives for food safety diligence (CAST, 2003).

Fourth, differences in challenges across commodity sectors also depend on the **extent of vertical coordination and joint cooperation** among stakeholders in the sector. Well-developed mechanisms for coordination enhance the ability of a commodity sector to share costs and incentives arising from food safety improvements. Such mechanisms can also facilitate traceback and recalls if outbreaks occur. For example, grower organizations in produce have spearheaded traceback systems to protect the reputation of their particular crops (chapter 5). Without a rapid and effective system for traceback, sectors may face serious financial consequences if their products are erroneously implicated with a food safety crisis. For example, the California Strawberry Commission estimated that growers in the central coast of California lost $16 million in revenue during June 1996 when their products were falsely implicated with the *Cyclospora* outbreak later attributed to Guatemalan raspberries (Mishen, 1996).

Although food safety issues, challenges, and approaches differ among sectors, food safety incidents can compromise markets, market share, and business or product reputation across the board. All commodity sectors are concerned with protecting their product's reputation for safety in both domestic and international

[7] Although processing and refrigeration can kill or slow growth of some hazards in perishable foods, they do not result in zero risk. Some pathogens such as *Listeria* can grow and even multiply under refrigerated conditions, and some toxins and mycotoxins can remain harmful after cooking or processing.

[8] The extent of product co-mingling may also be important. For example, the nature of ground beef is such that one hamburger may contain meat from many cows and any existing contamination can be spread throughout a batch of hamburger, making thorough cooking even more important (chapter 4).

markets (see chapters 4 and 5). Furthermore, producers in all commodity sectors prefer to have regulations and standards applied in the same way to imports and domestic production, so that they can compete on an equal basis to provide safe food (see chapter 4 for an example of differential application of standards).

Trade Frictions Over Food Safety Persistent but Surmountable

Food safety concerns and new food safety regulations in industrialized nations have led to trade frictions. Though all countries value food safety, the best means of ensuring it and the extent of control necessary is debatable—and is debated. For example, the United States and the EU have disagreed over both risk standards and methods of risk management (e.g., the role of scientific and economic analysis; level of product standards; risk equivalence of different process standards) (chapter 3). Such trade frictions can be persistent. For example, mycotoxin contamination is recognized as a risk that is difficult or impossible to control, and under the precautionary principle, some countries may set new standards on certain mycotoxins despite unclear scientific evidence about health risks (chapter 6).

Ultimately, facilitating trade without compromising consumer protection is an inherently challenging task (chapter 6). Any coherency between trade goals and food safety goals will likely incur private costs and/or public intervention and investment. International institutions are working toward harmonizing trade and food safety goals and the private sector is also contributing, particularly where market incentives are strong. When a food safety crisis arises, both governments and the private sector react quickly to minimize human illnesses and financial losses. With the *Cyclospora* outbreak attributed to Guatemalan raspberries in 1996, FDA, Health Canada, the Canadian Food Inspection Agency, and Guatemalan officials joined forces, while the Guatemalan Berry Commission developed a system to characterize farms according to food safety risks (chapter 5).

There has been remarkably little disruption to trade for food safety reasons, despite large increases in the volume, value, and variety of food trade. Global food and agricultural trade has increased from $138 billion in 1975 to $436 billion in 2001. For the United States at least, there is no evidence that food safety risks are correlated with trade volume.

Food safety can enhance trade as more prosperous consumers worldwide demand certain attributes, like safety. Both market share and value could grow for producers who can manage and certify quality and safety. Trade provides consumers with a year-round supply of a wider variety of food. If a food safety crisis does occur, international markets and crisis-free exporters offer a source of flexibility in satisfying demand.

Because the government and private sector have limited resources to devote to food safety, it is important to target them effectively. More research is needed to support priority setting. FDA product sampling is already targeted to products with higher risks to human health. But how to monitor and set standards for foods produced in different ways under different regulatory systems? Research might explore what kind of standards (e.g., process or product) provide for easier monitoring and assurance of food safety in trade and explore the relative cost of these standards.

Food sectors quickly respond and adjust food safety practices after food safety incidents (e.g., the private sector response to *Cyclospora* outbreaks). Meanwhile, consumers tend to adapt and regain trust in the food supply when new private/public oversight efforts are announced (or simply with the passage of time).

The complexity of food safety issues in trade means that disputes and difficulties will continue to arise. Nevertheless, the many similarities in regulatory approaches among industrialized nations may enable greater agreement about higher standards. As industrialized countries with major markets adopt new regulations, there is incentive for other countries to follow suit (Vogel, 1995). Furthermore, government can help the private sector allay food safety concerns, by providing guidelines for good agricultural practices (see chapter 5). Private certification of compliance with these guidelines can facilitate trade, even when standards and requirements differ among countries.

Food trade will continue to expand with growth in demand, increased market access, and reductions in technical barriers. Food safety enhancement is essential to consumer welfare and product reputation. Both U.S. consumers and producers have an interest in seeing improved food safety and expanded food trade. This report highlights the issues that must be managed if this is to happen.

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