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Food Safety Policy and Economics

A Review of the Literature

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Food Safety Policy and Economics: A Review of the Literature

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Abstract

This paper provides an overview of developments in food safety policy in major industrial countries and of economic analysis of this policy. It describes the elements of a risk-based, farm-to-fork food safety system as it is emerging in OECD countries guided by discussions through Codex Alimentarius and traces its roots in the development of risk management policy in the United States. The goal of this paper is to provide a nontechnical introduction to food safety policy and economics for students, economists and others interested in food safety policy, but new to the field.

Key Words: food safety, risk management, comparative law, health economics, cost-benefit analysis

JEL Classification Numbers: D18, F13, F19, I18, K23, K33, Q18

Contents

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Sandra Hoffmann*

Introduction

Modern food safety policy came into being at the turn of the twentieth century in response to scandals in the meat packing and food processing industries (Sinclair 1906). A second generation of policy is emerging now, also driven by scandals and crises of trust, including the early 1990s' *E. coli* O157:H7 outbreak in the United States and the BSE scandal of the late 1990s in the UK. Behind the current crises lie economic and technological transformations in both food and the food supply system. Institutions are rushing to catch up with the implications these changes have for public health risks.

The first generation of food safety law was characterized by command and control forms of safety regulation. Policy was nationally focused and relied on early twentieth-century industrial management practices such as continuous line inspection, visual product inspection, and detailed specification of approved hygiene practices. At the heart of this second generation of food safety policy is an emerging global consensus on the need for a preventive, public health-focused policy that fosters integrated management of foodborne hazards from farm-to-fork. This consensus calls for use of modern science-based risk management instruments that enhances efficiency by more accurately targeting public actions and by allowing firms flexibility in how they achieve public health goals rather than relying on narrowly prescriptive command and control policies. While the broad vision for this second generation of policy is clear, much of the detail has yet to be worked out. Economists have a significant role to play in this process.

The purpose of this chapter is to orient economists new to this issue. The first part of this chapter provides an overview of the scope of current food safety problems and the food safety policy reforms being adopted to address them around the world. Current efforts to modernize food safety policy are being shaped by several larger trends: globalization, use of risk analysis and cost-benefit analysis in public administration, and total quality management regimes in industry. The second part of this chapter briefly examines two major roles that public economics

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can play in food safety policy: better informing policy makers about the social benefits and costs of their decisions and strengthening risk assessment.

Trends in Food Safety Challenges

Illness from foodborne pathogens is a significant global health concern (Rocourt et al. 2003; WHO 2002). Population level incidence estimates, however, are uncertain due to underreporting and difficulty in attributing illness to food consumption. In the U.S. the Centers for Disease Control estimate that contaminated foodborne pathogens cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths among a population of 273 million each year (Mead et al. 1999). The World Health Organization believes incidence rates in OECD countries are similar (Rocourt et al. 2003). In developing countries, where it is more difficult to separate water and foodborne illness, approximately 2.2 million people die from these causes (Rocourt et al. 2003; WHO 2002). Such a level of illness and mortality drains productivity, imposing an in-kind of tax on human energy (FAO/WHO 1984).

Chemical hazards remain a concern. In 1996, the United States passed the first major pesticide legislation reform in thirty years, requiring evaluation of cumulative impact of low-dose exposure to multiple chemicals on adult and child health and that standards be set to protect children (NRC 1993; Hamilton and Crossley 2004). The new European chemical regulatory law, REACH (Registration, Evaluation, Authorisation and Restriction of Chemical Substances), addresses similar concerns (European Council 2006). The last three decades have also seen significant scientific transformation (Kinsey 2001). New technologies, such as genetically modified foods and, more recently, nanotechnologies, often raise public concern and calls for new regulation. Consumer attitudes toward new technologies have differed considerably across countries, leading to differences in laws and the threat of trade disputes (Brom 2004).

Globalization has brought many benefits to consumers, including more varied and nutritious food supplies throughout the year, but it has also complicated management of both infectious and noninfectious foodborne hazards. In developing countries, globalization has helped increase incomes. Globalization has also fostered industrialization and urbanization, which can strain capacity for adequate sanitation and safe food handling (Kaferstein et al. 1997; WHO 2002). It can also lead to more rapid spread of foodborne disease. Poor sanitation in developing countries can result in contamination of food exports to developed countries, as happened in the 1996 *Cyclosporiasis* outbreak in the United States associated with Guatemalan raspberries (Katz et al. 1999; Calvin et al. 2003). But trade may also spread foodborne pathogens

between developed countries, as in the spread of BSE from Britain to Japan in 2001, or from developed to developing countries (McCluskey et al. 2005).

With globalized markets, weak institutional capacity in one country can influence health globally. Emerging economies, such as China, are industrializing and urbanizing as rapidly as those of Europe and North America in the nineteenth century and are encountering the same kinds of problems documented by Upton Sinclair and other muckraking journalists at the turn of the last century. Recent experience with economic adulteration of pet food, milk, and toothpaste from China demonstrates the need for the institutional capacity of industry and governments in emerging economies to grow with their productive capacity (Gale and Hu 2009; Roth et al. 2008).

Current disease levels reflect past and as well as current investments in controlling foodborne hazards. A failure to maintain these controls can lead to a reemergence of problems thought to have been addressed. In 1999, Belgian animal feed was unintentionally contaminated with dioxin in polychlorinated biphenyls (PCBs) and distributed to approximately 2,500 farms. In the winter of 2008–2009, neglect of a leaky roof, led to more than 700 people being sickened by *Salmonella* infected peanut products in the U.S. (U.S. CDC 2009b). These incidents remind us that failure in private management and public enforcement are always possible (Covaci et al. 2008).They also remind us that without continued control, problems that are now largely contained, like *Trichinosis* in U.S. pork, can reemerge.

Public Sector Response

The 1990s and 2000s saw major efforts to modernize food safety law in many countries and regions. These efforts drew on wider trends in public administration and industrial management and involved an increasing role for international institutions in global governance.

Science-Based Public Decision Analysis

Food safety policy has a long history of using risk analysis to guide public decisions. A study by U.S. Food and Drug Administration (FDA) toxicologists in the mid-1950s introduced safety factors to establish acceptable daily intake of food additives on the basis of acute toxicity, an approach still applied today (Lehman and Fitzhugh 1954).

By the early 1980s, risk analysis in the United States was being relied on more widely to justify regulatory action, not only in food safety, but also in national environmental policy, consumer product safety, and occupational safety law. The U.S. Administrative Procedures Act

requires that all federal regulatory action have a rational basis in fact. A 1980 U.S. Supreme Court case, *Industrial Union Department v. American Petroleum Institute,* 448 U.S. 607 (the Benzene case), was particularly significant in requiring agencies to conduct scientific assessment of risk when developing health and environmental standards.

In 1981, Congress directed the FDA to contract a National Academies study on the merits of an independent institution to conduct risk assessments for all federal agencies as a means of protecting the scientific integrity of risk assessment (NRC 1983). The report characterized risk analysis as a three part process involving risk assessment, management, and communication. Ultimately, the report did not recommend an independent risk assessment agency, but did argue that the scientific process of risk assessment be protected from the more political process of risk management. The report did not break new ground. Instead, it consolidated and clarified the structure of existing risk governance practices in federal agencies. Its influence has extended far beyond the United States.

In the United States, the 1980s also saw the first formal requirement that cost-benefit analysis be conducted to evaluate major health and safety regulations (Executive Order 12866 1993; Smith 1984). This was viewed in part as a means for the Office of the President to gain greater control over the agendas of Departments and Agencies (Andrews 2006). In reaction, the U.S. Environmental Protection Agency (EPA) administrator looked to risk analysis as a way to keep regulatory oversight focused on "science-based, outcome-focused analysis" (Andrews 2006). In particular, EPA looked to comparative risk ranking to help set and justify the Agency's agenda (EPA 1987 (Unfinished Business)). The rather qualitative approach to risk-ranking relied on by EPA did not live up to the hopes placed in it (Finkel and Golding 1994, Davies 1996). Today food safety agencies in the United States and elsewhere are drawing on this experience in using much more quantitative risk ranking processes to prioritize inspection and to inform broader agency priority setting (NRC 2009; FAO 2009; U.S. FDA 2006). Even more quantitative risk ranking has one critical limitation. It generally does not take into account the relative effectiveness, cost or non-health benefits of reducing risk (Nelson and Krupnick 2005). These factors are critical to efficient use of public resources.

In the EU and its member states, the precautionary principle has played a central role in debates over risk management policy. The precautionary principle provides norms for risk management in situations where decisionmakers have reasonable grounds for concern about risk to health or the environment, but there remains substantial scientific uncertainty. Under the precautionary principle, a decisionmaker has the option to act to protect health or the environment while seeking more complete scientific information. Article 7 of the EU's General

Food Law gives risk managers the option of acting under the precautionary principle when confronted by conditions where they have reasonable concern about safety, but significant scientific uncertainty. These actions must still conform to norms of non-discrimination and proportionality and are provisional until more adequate scientific information is available. The SPS agreement adopts a rather weak form of the precautionary principle by allowing nations to regulate on the basis of available scientific information when there is "insufficient" scientific information. The regulatory action must be provisional pending better information, applied in a way that is non-discriminatory and reviewed within a reasonable period of time. Substantial time has been spent in Codex meetings over the past few years debating the proposals containing precautionary principles (Nortin 2010). The Codex Working Principles for Risk Analysis note that precaution is "an inherent element of risk analysis" and that risk assessment and risk management should reflect scientific uncertainty about the hazards of concern, but they do not directly invoke the precautionary principle (Codex 2003).

Risk-Based Process Management in Industry

In the late 1950s, NASA asked a major U.S. food processing firm to adapt failure control systems used in rocket development to develop food products that met the reliability needs of manned space flight. The result was a process called hazard analysis and critical control point (HACCP) systems (Huelebak and Schlosser 2002).

HACCP provides a systematic way to identify, assess, and control points in a food production system where foodborne hazards are most likely to enter. Because firms are free to choose how best to control these critical points, HACCP is promoted as providing the flexibility to use more cost-effective technology and to adapt to changing conditions.HACCP found fairly quick acceptance among national governments and international institutions (Unnevehr and Jensen 1999). In 1993, the Codex Alimentarius Commission (Codex) included HACCP guidelines in its *Recommended International Code of Practice*. Throughout the 1990s, U.S. food safety agencies began a shift to HACCP as their basic regulatory approach to controlling microbial hazards (U.S.D.A. 1996; U.S. FDA 1995, U.S. FDA 2001).

International Institutions and Food Safety: The WTO and the Sanitary and Phytosanitary Agreement

Broader government commitments to greater economic integration have had and will continue to have significant impact on food safety policy. The General Agreement on Trade and Tariffs (GATT), negotiated in the wake of World War II, has and continues to provide the central

legal structure for international trade. Its goal is to liberalize trade through successive rounds of negotiation guided by the principals of equal treatment for trading partners, transformation of nontariff barriers to tariffs, and negotiation to reduce tariffs over time (GATT 1947, Art. 1). GATT recognizes limited exceptions to its general requirements. One of the most important is the exception for actions required to protect health (GATT 1947, Art. XX).

The Uruguay Round of trade negotiations (1986–1994) created a permanent institutional home for the GATT within the World Trade Organization (WTO). It also resulted in adoption of the Sanitary and Phytosanitary (SPS) Agreement (Alemanno 2007, Fortin 2009). This agreement provides a basis for distinguishing legitimate from protectionist use of safety and phytosanitary laws and encouraging their legitimate use (WHO 1997). The SPS Agreement seeks to provide greater certainty about when national sanitary and phytosanitary laws comply with GATT and to reduce their impact on trade by promoting harmonized laws (SPS Agreement, Art. 2[1]).

Like other GATT provisions, the SPS Agreement is enforced by international dispute resolution processes and, if necessary, trade sanctions levied by injured countries against offending ones. The agreement recognizes that compliance may make it more difficult for developing countries to be involved in international trade and encourages wealthier members to provide or fund technical assistance to help poorer countries develop food safety systems that comply with the SPS Agreement and to provide time extensions to poorer countries for compliance with SPS obligations (SPS Agreement, Arts. 9 and 10[3]).

The Evolving Role of Codex Alimentarius

Under the SPS agreement, standards consistent with those agreed to by the Codex Alimentarius Commission are presumed to be in compliance with GATT. Nations adopting other standards need to support their scientific legitimacy through risk analysis.

The Codex Alimentarius Commission was established in 1963 by the United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO) to provide a forum for international technical collaboration on the development of food safety and quality standards (Josling, Roberts and Orden 2003). Membership in Codex is open to nations that are members or associate members of the WHO and FAO, but other countries may participate as observers (CAC 2008). Some 175 countries, representing 98 percent of the world's population, currently participate (van der Meulen and van der Velde 2008).

The Codex Commission works through a system of technical subject matter and regional subcommittees. These committees work to prepare and revise draft standards through a formal

procedure of iterative review by the commission and member governments. Decisions on rules are reached by consensus as often as possible (CAC 2008).

Much of Codex's effort has gone into producing model standards. These include commodity standards aimed at preventing consumer fraud, quantitative standards for food additives, and quantitative tolerances for contaminants such as pesticides and veterinary drugs. The commission has also developed a set of recommended practices referred to as codes of practice or guidelines. These include guidelines for HACCP systems and an international food hygiene code (CAC 1997, CAC 1999). Codex has adopted more than 200 standards, close to 50 hygiene and technological codes, some 60 guidelines, more than 1,000 food additives and contaminants evaluations, and more than 3,200 maximum residue limits for pesticides and veterinary drugs.

Since 1995, Codex has also developed guidelines for microbial risk assessment, biotechnology risk assessment, microbial risk management, and validation of safety control measures as well as principles for traceability and risk analysis. Borrowing from the U.S. National Academy of Sciences' 1983 "Red Book", it outlines a four step process for microbial risk assessment: hazard identification, exposure assessment, hazard characterization, and risk characterization (CAC 1999). Codex discussions have contributed significantly to the spread and development of the relatively new field of predictive microbiology. Codex principles on risk analysis also incorporate the 1983 NAS recommendation that risk assessment and risk management be separated to protect the scientific integrity of the risk assessment and avoid conflict of interest (CAC 2007).

EU Reform

From 1958 to the mid-1990s, the focus of European food law was to reduce barriers to creating an integrated internal market for foods (van der Meulen and van der Velde 2008; Alemanno 2006). Uncertainty about product content, not food safety was viewed as the major barrier to a single food market. The BSE crisis and other foodborne illness crises of the mid- to late 1990s changed this perspective (van der Meulen and van der Velde 2008). The nature of BSE—a fatal, neurodegenerative disease related to scrapie in sheep—and the way that crisis was handled had a significant impact on subsequent legislative reform.

At the time it was identified, the British government maintained that BSE, like scrapie, was not transmissible to other species (Prusiner 1991). By the late 1980s, transmission among cattle was traced to the presence of animal offal and bone meal in cattle feed. Britain banned this

practice in1988 and the EU banned importation of beef offal from Britain. Scientific evidence began to mount that BSE was being transmitted to humans (Krapohl 2008). Britain continued to maintain that this was not the case until March 1996 (van der Meulen and van der Velde 2008). The European Commission (EC) banned export of cattle and cattle products from the UK several days later.

A 1996 EU Committee of Inquiry found that the structure of EU food safety governance that allowed domination of decisions by a single member state, politicization of science, and lack of transparency contributed to the inability of the EU to respond to the crisis quickly (European Parliament 1997). Subsequent European food safety crises contributed to pressure for immediate action (van der Meulen and van der Velde 2008; Holland and Pope 2004). Recommendations for structural change followed quickly in the form of a Green Paper in April 1997 and a White Paper on food safety in January 2000 (EC 1997, EC 2000).

The White Paper laid out a roadmap for EU legislative reform guided by five central principles: clearly defined food safety responsibilities for all actors; traceability of food, feeds, and food ingredients to their sources; risk analysis as the framework for science-based policy; transparency and separation of scientific analysis from risk management; and use of the precautionary principle to guide risk management (Halkier and Holm 2006). To reduce the role of economic interests in food safety policy decisions, responsibility for risk assessment and scientific advice would lie with a new European Food (Safety) Authority and responsibility for risk management would lie with the European Commission. A set of 84 legislative and policy initiatives was outlined. The goal was to make European food law more coherent and comprehensive and to strengthen enforcement and make it more consistent across countries (van der Meulen and van der Velde 2008).

In the years that followed, most of the recommended legislation has been enacted. In January 2002, the EU General Food Law (GFL) came into force.[1] Legislation modernizing pesticide tolerances, food labeling, food and additive regulation, and novel foods is now being drafted (van der Meulen and van der Velde 2008).

[1] Under the EC Treaty, "a regulation shall have general application. It shall be binding in its entirety and directly applicable to all Member States" (Article 249 European Community Treaty). In contrast, "A directive shall be binding, as to the result to be achieve, upon each member state to which it is addressed, but shall leave to the national authorities the choice of form and methods."

The GFL lays out basic principles intended to guide European food safety legislation. The system is a three-legged stool resting on an integrated farm-to-fork system of food safety responsibilities and enforcement, a modern system of monitoring and communication that allows rapid action in the case that problems arise, and protection of the integrity of scientific analysis on which policy decisions rely. The goal is to ensure "a high level of protection of human health and consumers' interest in relation to food" (EU General Food Law, Arts. 1, 5, and 9).

A core element of the new law is the ability to trace foods and share information. A centralized tracking system follows the movement of livestock from origin to slaughter (U.S. GAO 2008). Another has been established to disseminate information about serious threats to health from food or feed to all EU member states and to notify all other European ports of entry of shipments of food refused entry at any EU port (U.S. GAO 2008). Member states are responsible for disease surveillance and outbreak response within their country, for informing the European Centre for Disease Prevention and Control of outbreaks that may affect other member states and for cooperating with other member states and EU level offices in responding to multi-member country outbreaks. The public is to have access to information on the product, the nature of the risk, and the control measures taken (Holland and Pope 2004).

The final major component is a structure to ensure that scientific analysis of food safety policy is protected from political influence. Food law is to be based on risk analysis (EU General Food Law, Art. 6). The GFL creates the European Food Safety Agency (EFSA) as an independent entity responsible for providing scientific advice, risk assessment, and technical support for policy and requires member states to maintain a separation between risk assessment and management. The European Commission, European Parliament, and European Council have responsibility for risk management decisions at the EU level.

Several studies have examined the European food safety policy reform movement of the 1990s from the perspectives of law, political science, public administration, and sociology, but few from an economic perspective (Halkier and Holm 2006; Ansell and Vogel 2006; Alemanno 2006; Vos and Wendler 2006). The most fundamental change in the E.U. system has been recognition of the central role that food safety and consumer protection play in integration of the European food market and with this adoption of risk analysis as a structure to shape and bring transparency to conflicts between the goals of integration and maintenance of diverse food cultures and other local and national values (Alemanno 2006). The EFSA has responsibility for conducting scientific assessment of new food safety policy, but national competent authorities do as well. While both the EC and national authorities are required to take account of EFSA scientific assessment, they are not bound by it. While many food safety issues are now addressed

by EU-wide regulation, not all are and in the absence of EU-wide regulation, food is deemed safe and marketable across the EU if it meets the national safety requirements. As Alemanno points out "a claim by a domestic food authority that a certain good is safe or unsafe is likely to involve not only an assertion about science, but also about the willingness of this country to bear or not bear the level of risk considered acceptable in order to continue or reject a certain local tradition" (Alemanno 2006: 254). Of course, national decisions may also be driven by a desire to protect local economic interests. In the case of conflicting scientific opinion, it will be up to the European Court to determine the balance between local, national and Europe-wide interests. It remains to be seen what balance is ultimately worked out between national and EU concerns.

National Responses

National governments of many OECD nations have undertaken major food safety legislative reform since the 1990s (Halkier and Holm 2006; Ansell and Vogel 2006). Within the EU, individual countries have passed laws to come into conformance with the GFL and to respond to the BSE crisis (Table 1) (Vos and Wendler 2006). Table 1 summarizes some of the national efforts to modernize food safety law by EU member states. Legislative and administrative reforms in Australia, Canada, and New Zealand (Table 2) have been driven largely by a desire to enhance the efficiency of public administration by eliminating overlapping authorities, focusing resources on high risk areas, and reducing inconsistencies in enforcement (U.S. GAO 2008). Although each country has its own motivation for modernization of food safety law, the presence of international forums and the driver of harmonization goals under the GATT result in actions in one country influencing those in others.

Table 1. Elements of National Food Safety Policy in Europe

Denmark	▪ farm-to-fork risk management system ▪ risk classification of food establishments are the basis for inspections ▪ risk management conducted by Ministry of Food, Agriculture, and Fisheries ▪ risk assessments conducted by Technical University of Denmark
Ireland	▪ oversight responsibility lies with Food Safety Authority ▪ risk assessments, profiles, scientific advice with FSA committee of experts ▪ food safety rules for import/export of animal products enforced by Department of Agriculture and Food ▪ requirements in food establishments and on imports enforced by Health and Safety Executive
Sweden	▪ import controls and rules governing meat packers and food processors under National Food Administration ▪ production overseen by National Fisheries Board and Board of Agriculture ▪ marketing and small producers overseen by municipalities ▪ risk assessment and management conducted by different NFA departments ▪ outside scientific advisors play significant role in NFA ▪ studying idea of single agency rather than tripartite responsibilities
UK	▪ farm-to-table food safety authority lies with Food Standards Agency ▪ GFL food and feed law implemented by FSA ▪ emphasis on public health and consumers ▪ risk management lies with an agency ▪ risk assessment with agency committees

Sources: UK House of Commons 1999; HM Treasury 2003; Slorach 2008; interview with Derrick Jones, chief economist FSA, 2009

Table 2. Elements of National Reforms outside the European Union

Joint Australian./ New Zealand Reforms	▪ joint food standard system under Food Safety Australia/New Zealand ▪ farm-to-table food safety regulation ▪ risk assessment and management separated ▪ food standards code, technical analysis, and developing standards administered by FSANZ ▪ final authority over standards and balance in objectives of public health, efficient food provision, and minimal regulatory burden in hands of Food Regulation Ministerial Council
Canada	▪ food safety responsibilities under Canadian Food Inspection Agency ▪ disease surveillance under Public Health Agency, participates in outbreak response ▪ food safety standards set by Health Canada ▪ enforcing standards, inspections, and quarantine under CFIA ▪ effectiveness of CFIA enforcement evaluated by Health Canada ▪ import inspection under Border Services Agency ▪ no mandatory traceability of food generally ▪ focus moving toward preventive measures, risk-based inspection, product traceability
Japan	▪ risk-based import control ▪ most imports inspected randomly ▪ all lots of high-risk imports inspected ▪ priorities for monitoring imports revised annually ▪ random inspections free ▪ importers pay for enhanced inspections and violation
New Zealand	▪ food safety administration not isolated from promotion of agriculture ▪ risk-based approach to inspection of imports ▪ moving toward importer verification and away from border inspection

Sources: FSANZ 2009; NZFSA 2008; Slorach 2008; WHO/FAO 2006; CAC 2007; FAO 2007a, FAO 2007b; Government of Canada 2009; U.S. GAO 2008

U.S. Reform Efforts

In many respects, the United States ushered in the current generation of food safety policy reform. Both the Food and Drug Administration and the U.S. Department of Agriculture (USDA) began reorienting their food processing rules around HACCP in the early 1990s. In general, industry and consumer groups have supported HACCP, though both consumer groups and the GAO have insisted on the need to tie HACCP to performance standards (Holland and Pope 2004). But in the past several years, the U.S. has lagged, struggling to find the political will to rationalize a fragmented and sometimes under-funded system of multi-agency control. Despite this, U.S. administrative agencies have implement reforms very similar to those embodied in Codex principles and the EU's General Food Law. This is in part because of the active role they have played in Codex and SPS negotiations.

HACCP was one of the first of many steps the United States took toward more risk-based food safety management. Throughout the 1990s and the following decade, substantial technical and policy expertise in food safety was directed at adapting risk analysis methods and

frameworks to microbiological hazards in foods. Much of the scientific effort focused on developing microbiological risk assessment ((IoM 2002; USDA FSIS 1998; WHO/FAO 2002, 2004). In the United States, responsibility for risk assessment and risk management is generally within a single agency, but assigned to different work groups or offices to help ensure that risk assessment endpoints are appropriate for risk management purposes. In recent years, both the FDA and USDA have been using risk profiling to focus inspection resources and increase their effectiveness (USDA FSIS 2008; U.S. FDA 2007). In addition, FDA has been looking toward more risk-based approaches to managing import safety. The United States has also invested in improvements in disease monitoring with an eye to risk-based targeting—most importantly FoodNet, a nationwide active surveillance system, and PulseNet, which uses genetic finger printing in tracing the source of outbreaks as well as efforts to develop more reliable methods to attribute foodborne illness to foods or sources of contamination (U.S. CDC 2009a, U.S. CDC 2009c).

Given the central role U.S. scientists and technical experts have played in developing FAO/WHO guidance, coupled with the integration of Codex guidelines into the SPS agreement, it is likely that the United States will continue to move toward adopting international norms, whether through statutory or administrative law or government-facilitated industry action, such as marketing orders. The United States clearly sees international cooperation on food safety as not only a way to protect its trade interests, but also as essential to protecting the safety of its food supply. For example, the United States, Australia, New Zealand, and Canada are all actively involved in international consultation on technical and policy aspects of food safety both through Codex and through multilateral forums (U.S. FDA 2009d; NZFSA 2007).

The United States is beginning to move toward a farm-to-fork approach to food safety, but on a more case-by-case basis than in Europe, and often in response to highly visible failures to assure food safety. For example, outbreaks of shiga-toxin *E. coli* in leafy greens in 2006, which resulted in three deaths and 200 illnesses, are pushing produce growers and regulators to develop better control systems (Hitti 2007). Draft FDA guidance on produce safety takes a supply-chain approach, but is voluntary (U.S. FDA 2009a, U.S. FDA 2009b, U.S. FDA 2009c). The United States bans feeding offal to cattle, regulates pesticide use on farms, and nonmedical use of antibiotics in livestock production (Hoffmann forthcoming). Yet on the whole, farmers, particularly smaller farmers, have resisted on-farm regulation. In the past, conventional wisdom has been that because each state has two senators, providing rural, agricultural states with votes disproportional to their population, it is unlikely that a regulatory approach to the farm portion of farm-to-table food safety policy will be adopted. And that a more likely scenario is that specific

food safety incidents will create enough market pressure that self-policing by farm groups, through mechanisms like marketing orders, will gain strength. But in July 2009, the President's Working Group on Food Safety announced that FDA would work to impose regulatory standards for safe produce production (U.S. Office of President 2009).

One of the basic structural problems in U.S. food safety regulation is that responsibility is fragmented across as many as fifteen agencies (U.S. GAO 2009). Primary responsibilities rest with four: USDA (meat, poultry, and processed egg products), EPA (setting pesticide tolerances), Commerce (seafood), and FDA (all other foods including food additives and economic adulteration) (U.S. GAO 2005). The U.S. Centers for Disease Control, together with state public health authorities, are responsible for disease surveillance. Local public health authorities and state offices of public health are jointly responsible for regulating food hygiene in local food service and retail establishments, assisted by FDA model food hygiene codes. Similar fragmentation drove food safety reform in the European Union and its member states, particularly the United Kingdom. Despite a recent string of foodborne illness outbreaks and highly publicized failures of import controls, the political will to consolidate seems to be lacking in the U.S. In part, difficulties with the formation of the Department of Homeland Security raised questions about the effectiveness of such consolidation (Hall 2004). Current legislative proposals focus on the more limited goal of strengthening FDA food safety authority (U.S. Congress 2009a, U.S. Congress 2009b).

Economic Analysis of Food Safety Policy

Economists play multiple roles in informing food safety policy. Most commonly, they are called on to assess the costs and benefits of proposed policies. Most OECD countries now require some form of economic analysis of major policies. Ideally, economists also play a role in the design of policy innovations. They also have the capacity to play a greater role in improving the accuracy of risk assessment. Economic research that increases our understanding of how food safety risks are generated in food production, processing, marketing and preparation, and how industrial structure influences these processes, can support this work. Research into consumer perceptions of and attitudes toward risk, their willingness to pay to reduce risks, and the economic burden of foodborne disease supports it as well.

Theoretical Foundations

Choice of products in a market is generally a choice among bundles of nonseparable attributes (Lancaster 1971). Safety is only one of many attributes of food, and consumer

preferences for safety are typically modeled using a multiattribute utility function that recognizes possible trade-offs among attributes. In such a model, a product is modeled as a set of attributes, for example, ground beef as a bundle of fat content, freshness, price, and safety.

On the supply side, food can be modeled as a quality-differentiated product in which safety is only one of several attributes produced (Chambers 1988). Safety, like its counterparts, has a shadow-price. The degree to which the cost of producing safety is separable from the cost of producing other product attributes is an empirical question, but as a general rule, suppliers must invest resources to produce safety. Antle (2001) provides an excellent overview of theoretical literature on both supply and demand applicable to food safety economics.

Supply and demand analysis is complicated by the fact that safety attributes are not usually directly observable by consumers, and often are either not observable to suppliers or observable by them only at a cost. Even where information relevant to product safety is available to one firm in the supply chain, there is a cost associated with communicating that information to downstream firms and consumers. Labeling and other information approaches to food safety policy are an attempt to deal with the resulting information asymmetries between consumers and suppliers. Traceability requirements, like those in the EU, are designed to address information asymmetry in the supply chain, increasing the speed of response to safety failures and helps strengthen market and liability incentives for precaution (Pouliot and Sumner 2008). Firms may also invest in obscuring information about product quality and safety by using colorants, additives, and processes that preserve attributes, such as meat color, that consumers look to as signals of safety.

Benefits Assessment

Reduction in consumer health risks is usually the primary benefit of food safety policies. Willingness to pay for health and mortality risk reduction is generally viewed as the most complete and correct welfare theoretic measure of these benefits, but as a practical matter, cost of illness is more widely used in regulatory analysis (for a brief discussion, see Antle 2001: 1096–97). Harrington and Portney (1987) show that willingness to pay can be decomposed into the cost of medical treatment, lost productivity, and a change in consumer utility. Because cost-of-illness estimates generally include only the cost of treatment and lost productivity, they are usually a lower bound on the benefits of preventing morbidity. Berger and colleagues (1987) show that cost of illness measures may not be a lower bound on willingness to pay for actions that reduce the probability of both morbidity and mortality. Many foodborne pathogens result in both illnesses and deaths. Kenkel (1994) demonstrates how cost-of-illness measures can

significantly bias cost-benefit estimates. Chapter 37 of this handbook provides a more detailed examination of the economics literature on benefits estimation. Kuchler and Golan (1999) provide a critical review of alternative methods of valuing health risks and their use in food safety policy. The proceedings of a 2001 U.S. Economic Research Service conference include a comprehensive discussion of the issues involved in choice of valuation metric from a U.S. regulatory perspective (Kuchler 2001).

The public health literature often uses health adjusted life year (HALY) measures as an alternative to either cost of illness or willingness to pay. These measures are widely accepted in Europe and used in the World Health Organization's Global Burden of Disease estimates (WHO 2008). Their use in U.S. regulatory analysis was recently permitted by OMB under the Bush administration (U.S. OMB 2003). HALYs are indices of the impact of illness on physical well-being and function. They were developed to provide a common metric for the severity of health outcomes in evaluating the cost-effectiveness of alternative medical treatments. To be used in cost-benefit analysis, HALYs must be monetized. This has been controversial because HALY measures are not consistent with the utility theoretic foundations of welfare economics (Hammitt 2002, Hammitt 2003; see also Krupnick 2004; Dickie and List 2006). A recent U.S. National Research Council report recommended against monetizing HALYs (IOM 2006).

HALYs measure discomfort associated with each year of life, they do not measure consumer preferences over reduction in risks of future health states. This leads to HALY measures placing greater weight on reducing chronic disease than to reducing mortality, particularly mortality in the elderly. In an empirical assessment of U.S. diesel fuel regulation, Hubbel (2006) shows that this conceptual difference between HALY and WTP metrics can change the outcome of regulatory analysis, particularly for policies involving more chronic disease than mortality. This could be of significance for food safety analysis comparing the benefits of interventions to reduce pathogens such as *Campylobacter,* which are associated with significant chronic morbidity and pathogens like *Toxoplasma gondii*, which has a higher mortality rate. It would be of even greater importance in comparing the relative merits of reducing expose to chemical residues and pathogens.

Empirical research estimating the benefits of food safety policy has used multiple methods including hedonic estimates of demand for safety from market data, stated preference surveys, and experimental auctions (see, e.g., Marks et al. 2003; Shogren et al. 1999). Van Ravenswaay (1995), Antle (2001), and Golan et al. (2005) provide reviews of the empirical literature, focusing on the U.S. Many areas of applied economics is increasingly looking to meta-analysis, is a method of using statistical analysis to look at systematic patterns across related

studies, to derive valuation estimates for use in policy analysis (Nelson and Kennedy 2009; Bergstrom and Taylor 2006). Florax et al. (2005) conducted a meta-analyses of research on willingness to pay reduce health risks from pesticide exposure through food and other pathways. Lusk et al. (2005) conducted a meta-analysis consumer willingness to pay to avoid genetically modified foods. A recent U.S. study looks at the sensitivity of willingness to pay for avoiding foodborne illness to duration and severity of illness (Hammitt and Haniger 2007). These reviews all have a U.S. focus. European valuation studies have been published related to BSE (Latouche et al. 1998), GM foods in Italy (Boccaletti and Moro 2000), organic foods in Denmark (Weir et al. 2002), and *Salmonella* in chicken (Sundström and Andersson 2009). Mørkbak et al. (2008) provide a comprehensive review of stated preference studies of meat safety and quality.

Cost Assessment

Governments of most OECD countries provide guidance on conducting regulatory cost analysis (see, e.g., U.S. EPA 2000 or HM Treasury 2003). While there is some variation, these generally follow basic principles of applied welfare economics. U.S. EPA guidelines decompose total social cost of regulation into three components: direct compliance costs, indirect costs to consumers and producers, and the social costs of market adjustment. Direct costs of compliance might include fixed costs, such as the capital costs of additional equipment and employee training or variable costs such as changes in production procedures and input quality. Indirect costs are social welfare losses that can occur if compliance costs are large enough lead to increased consumer prices and changes in the consumer/producer surplus. Finally, social adjustment costs might arise if regulatory standards result in firm closure or relocation. For example, banning the use of harmful pesticides might lead to regional shifts in agricultural production, disruptions in production, and unemployment.

Unnevehr and Jensen (2005) use the EPA guidance framework to structure a review U.S. empirical literature on the cost of compliance with regulation of pesticide and microbial hazards in food. The broad lessons they draw from this literature illustrate some of the kinds of policy insights that can be drawn from cost assessment. First, the distribution of costs of compliance is likely to be more important than the impact on consumer prices. Most studies found little impact on the cost of food because there are so many alternative sources of supply. But because supply can shift to different size or vintage of plants, different regions or even different countries, social adjustment costs in terms of changes in employment or income may be significant. Second, studies did find meaningful long-term incentive impacts on investment in new technology, plant, equipment and human capital. Unnevehr and Jensen emphasize the importance of these types of

incentives on the nature of productivity growth in the food sector. Third, studies support the theoretical position that incentive-based measures generally provide the most cost-effective means of achieving public health goals. And fourth, that a "risk-based systems approach" can provide a better way of understanding costs through the entire supply chain.

Antle (2001) builds on Chambers' (1989) model of quality-differentiated production to develop a theoretical foundation for empirical estimation of the direct costs of complying with food safety policy. Two fundamental modeling issues arise: first, whether in representing production of the safety attributes of food output can be fully separated from input demand (input-output separability); and second, whether it is possible represent production of safety and other attributes through separate production functions with separate inputs (non-jointness of input use). Antle (2001) notes that usually neither will be possible in the case of food safety production. He argues that, in part because of this, analysis of the cost of food safety policy typically uses a non-separable, joint cost function rather than the primal problem of profit maximization subject to a non-separable, non-joint production function.

Unnevehr and Jensen (2005) and Antle (2001) emphasize the degree to which both theoretical modeling and empirical analysis of the costs imposed by food safety policy vary by type of policy and industrial structure. Antle (2001) presents alternative theoretical models for process controls, inspection, input and product testing, labeling and traceability. Unnevehr and Jensen (2005) focus on differences between pesticide regulation and regulation of microbial hazards. Both papers emphasize the importance of dynamic as well as static analysis and of focusing on the impact of food safety policy on industrial structure. And both also note the difficulty of empirically distinguishing between technological and managerial innovation made in response to market incentives and government policy.

Many empirical methods are used to estimate costs of compliance. Antle (2001) emphasizes the extent to which either firm-level cost accounting (U.S. FDA 1994; USDA FSIS 1995; Cato and Lima dos Santos 1999; Colatore and Caswell 1999) or firm-level economic-engineering modeling of production processes have been used (see Duewer and Nelson 1991; Jensen and Unnevehr 1999; Narrod et al. 1999). Because these are detailed, usually firm-specific approaches, they are usually used to develop a model of representative plant. Antle (2001) maintains, however, that because they are costly, the number of plants modeled is usually small, as a result, firm heterogeneity is usually not captured, and studies using this firm level approach may therefore be unrepresentative at the industry level. He argues that although econometric models of costs at either the plant or industry level do not provide the process detail of

accounting or economic-engineering models, they do provide a better basis for estimating behavioral response of plants and market segments to regulation.

Ultimately, the results of such empirical studies are used in broader analysis of the social cost of regulation. The scope of this analysis may vary from partial equilibrium analysis of the impacts on a limited market sector where the impact of regulation on prices or average costs are small (see, e.g., Roosen and Hennessy 2001; Lichtenberg et al. 1988) to general equilibrium analysis for policies expected to have broad economy-wide effects due to significant changes in product, input prices or plant closure (see, e.g., Golan et al. 2005). More frequently, impacts will spread beyond the directly affected market, but will not be economy wide. In these cases, multi-market analysis will usually be used (see, e.g., Unnevehr et al. 1998; Onal et al. 2000).

Integrating Economics and Risk Assessment

Risk analysis is intended to provide decisionmakers with a clear, fact-based understanding of how actions affect physical risks. It helps decisionmakers reach better decisions by providing a workable model of how real-world systems are likely to respond to proposed policy changes. This is an inherently interdisciplinary task. In practice, risk analysis has often only been interdisciplinary in limited ways. Disciplinary divides and institutional structures have created barriers to fully interdisciplinary risk analysis. The separation of risk assessment from risk management characterized by the U.S. NRC Red Book and embodied in the EU's GFL and Codex guidance makes matters worse. Economics is conventionally viewed as part of risk management, and therefore isolated from risk assessment modeling. Yet, as Williams and Thompson (2004), argue economic analysis needs protection from political influence as much as other areas of scientific analysis.

Past discussions about the interaction between economic analysis and risk assessment have primarily focused on the difficulties the separation creates in valuing policy benefits. These discussions frequently look at how lack of communication between risk assessors and risk managers has resulted in risk assessment providing outcome measures that were difficult to use in economic analysis of policy impacts (Dockins et al. 2004). There has been much less discussion about how separation of economic analysis from risk assessment weakens risk assessment.

Risks are generated by human interaction with the biological and physical world. Yet risk assessment typically focuses on modeling only the biological and physical sides of this risk generation process. Hoffmann (forthcoming*b*) discusses ways in which broader use of fully

integrated modeling of physical, biological and socio/economic systems could enhance the accuracy and relevance of risk assessment.

Sometimes the behavioral factors that affect risk are directly related to the policy. For example, if the policy affects the price of the food through which people are being exposed, people are likely to substitute away from this food to other foods. This will reduce the risk being focused on, but may increase other risks. More often, the behavioral factors influencing risk will be unrelated to the policy under consideration. For example, labor market trends may lead to greater consumption of food outside the home, changing patterns of exposure to foodborne pathogens and toxins. Similarly, shifts in the relative costs of production across industry sectors may lead to change in the distribution of return on investment in safety, resulting in a shift in risk industry sector.

The kind of integrated bio/physical-economic modeling that may help improve risk assessment of food safety policy is already being done many areas of natural resource and environmental policy. For example, there is a long history of use of bio-economic modeling in fisheries management as well as in forestry, integrated pest management, and wildlife management. Fairly simple models of both fish populations and fish markets have provided highly useful predictions of alternative fisheries policy. Sanchirico and Wilen (2007) review recent efforts to integrate models of the spatial ecology of marine subpopulations and models of human predation. The key to these efforts is their attempt to capture the salient characteristics of both population dynamics and human economic activity in a single optimization model.

Integrated physical-economic modeling has also played a critical role in assessing climate change policy (Energy Modeling Forum 2009). These large simulation models are usually made up of linked mathematical submodels of physical, biological and economic systems with explicit mathematical linkages between the submodels, much as a multi-regional Computable General Equilibrium model will have economy-wide models of individual regions linked by trade, financial and labor flows. Some climate models, for example, the U.S.Department of Energy's MiniCam model, have done a great deal to create a truly integrated bio/physical/economic model (Sands et al. 2002; McCraken et al. 1999).

Because modeling always involves judgments about which linkages are important and which simplifications matter and which do not, it will take time to develop sound judgments on how to best conduct integrated modeling in the food safety arena. The art of integrated assessment is for all involved to understand each others' models well enough to be able to identify and model critical interactions. Efforts to conduct such analysis are beginning on this

work and are likely to grow with the increased emphasis on farm-to-table, integrated risk management (Havelaar et al. 2006).

Conclusion

Food production and marketing is undergoing a level of change and innovation around the world that is reminiscent of the shift experienced at turn of the last century. Markets are more vertically integrated, more concentrated and more global than at any time in the past. Advances in communication and shipping have facilitated these and other changes. Consumers are demanding and getting new products, ready-to-eat produce and summer produce in the winter. Novel technologies lower price, increase supply and promise other benefits. But many of these changes also pose new challenges to maintaining the safety of the food supply. Globalized supply chains transport foodborne hazards as well as food. It also means that each countries investment in public institutions has reach far beyond its own borders.

It is clear that conventional approaches to food safety policy that have been in place since the turn of the last century are not adequate to meet these new food safety challenges. This chapter has reviewed a rather coherent set of policy reforms that are being adopted worldwide to modernize food safety policy. It is recognized that in a world of globalized markets, global coordination of these efforts is a necessity, not only to avoid trade disputes, but also to assure the safety of the food supply. A broad consensus of the vision for this new structure for food safety policy is emerging, in part, through international negotiations over the Sanitary and Phytosanitary Agreement and international technical consultations sponsored by the WHO/FAO Codex Alimentarius Commission. The vision is for a preventive system that manages foodborne hazard from farm to fork. This system relies on risk management practices developed in the public sector to guide environmental and health and safety policy and in the private sector to reduce risk of failure in process engineering. As a broad concept, there is also recognition that the food system has grown complex and extensive enough that safety can no longer be managed solely through reliance on command and control regulation and government inspection. There is also a desire to rely more heavily on performance standards and other approaches that allow firms flexibility in how they achieve public health goals.

These efforts are still in the early stages of development. Economics has many contributions to make because of the complexity of the management problem and the systems. To the extent that there is commitment to integrating management farm-to-fork, economists are in a unique position to study and model the supply chain relationships. Economists are in a position to provide needed insight into the design of incentive mechanisms and non-

governmental safety assurance instruments. Economists also play have a central role to play in modeling risk, costs and benefits of public programs. But as in many areas of health and safety policy where sciences and engineering dominate policy debates, it will be a challenge for economists to make certain that their insights are heard and their relevance understood. Interdisciplinary research and modeling is central this effort.

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