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Food Safety and Risk Governance in Globalized Markets

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Abstract

Today a new generation of food safety policy is emerging in OECD countries and international public health forums. The United States has actively contributed to the thinking and scientific research underlying this new generation of policy. A consensus has emerged among nations about the basic components of an effective food safety system based on modern science and management practices. In shorthand, the vision is of a farm-to-fork, risk-based, scientifically supported safety control system. This system is built on several decades of experience with risk management in national governments, particularly in U.S. environmental and occupational and consumer safety policy. This paper 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.

Key Words: food safety, risk management, policy reform, comparative law

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

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Sandra Hoffmann and William Harder*

Introduction¹

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.² Behind these scandals lay dramatic changes in the economic structure of food production and distribution. Rapid technological change was transforming life into something now recognizable as a modern urban-industrial society. Food production was shifting away from home and local production and processing toward more industrial processing and regional or even national marketing. As just one example, in the United States, long-distance rail systems and the refrigerated railcar made possible the rise of a national meat-packing industry, with primary production on the Great Plains and slaughter and processing in rail centers such as Kansas City and Chicago. Institutions that had emerged to manage risks in an economy of local production and distribution were incapable of providing socially acceptable protection in this more nationally integrated economy. Institutional innovation was needed to manage the resulting changes in health risks. In 1906, the U.S. Congress passed both the Meat Inspection Act of 1906 (Chapter 3913, 34 Stat. 674) and the Pure Food and Drug Act. In amended form, this legislation continues to serve as the basis for U.S. food safety law.

A second generation of major food safety policy reform is emerging now. These reforms are also being driven by scandals and crises of trust—the Jack in the Box *E. coli* outbreak in the United States that sickened more than 600 and killed four children in January 1993, the bovine spongiform encephalopathy (BSE) crises in Britain and Europe, dioxin in Belgian feed, and

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¹ We thank Richard Williams (George Mason University) for sharing insights from his experience with food safety risk analysis and economics at the U.S. Food and Drug Administration.

² For a historical perspective on economic and social situations leading to food safety legislation in the United States in 1906, see generally Upton Sinclair, *The Jungle* (Doubleday, Jabber & Company 1906).

melamine in Chinese food exports.³ As they did a century ago, economic and technological transformations in both food and the food supply system lie behind these crises. The past three decades have seen heightened concentration in both food production and marketing, as well as globalization of food supply chains. These changes have been enabled by revolutions in information and transportation technology. Rapid advances in life and materials sciences are giving rise to novel products and practices whose safety remains, at least in many consumers' eyes, unproven. As they did at the turn of the last century, institutions are rushing to catch up with the implications these changes have for public health risks.

At the heart of this second generation of food safety reform is an emerging global consensus on the need for a risk-based, scientifically supported, integrated farm-to-fork policy. Economists, food scientists, and public health analysts have significant contributions to make in fleshing out what such a policy entails. Current food safety policy debates are shaped by the intersection of several larger trends: economic globalization, rationalization of public administration by use of decision and risk analysis, and spread of total quality management regimes in manufacturing sectors.

This paper presents an overview of current food safety problems and the global risk governance structure that is emerging to manage them. Section 1 focuses on food safety as a public health and economic issue. Section 2 describes the development of risk analysis as a regulatory paradigm in the United States and Europe. Section 3 discusses globalization and the place of a risk analysis paradigm in the emerging global framework for second-generation policy. Section 4 examines regional and national food safety reforms in response to national and regional crises and how these are being shaped by this global framework. I also look at the ways in which food safety crises are affecting the way risk analysis practices are being institutionalized into governance structures.

³ Elise Golan, Tanya Roberts, Elisabete Salay, Julie Caswell, Michael Ollinger, and Danna Moore, Food Safety Innovation in the United States: Evidence from the Meat Industry, Agricultural Economic Report No. AER-831 at 10 (2004); British Broadcasting System, BSE and CJD: Crisis Chronology (visited Aug. 17, 2009) <http://news.bbc.co.uk/1/hi/english/static/in_depth/health/2000/bse/default.stm>; Ahmed El Amin, Belgium, Netherlands Meat Sectors Face Dioxin Crisis (2006) (visited Aug. 17, 2009) <<http://www.foodproductiondaily.com/Quality-Safety/Belgium-Netherlands-meat-sectors-face-dioxin-crisis>>; *Melamine Found in More Chinese-Made Food Products*, NY Times, Sept. 26, 2008 (visited Aug. 17, 2009) <<http://www.nytimes.com/2008/09/26/world/asia/26iht-milk.4.16516560.html>>.

An old adage in U.S. law practice is that “bad facts make bad law.” Risk analysis provides the central intellectual framework for food safety policy reform going on around the world. The BSE crisis in the United Kingdom and Europe was a horrific shock to confidence in UK and European food safety authorities. Major government investigations in the United Kingdom and on the Continent highlighted the role that conflicts of interest between scientific analysis and agricultural interests played in prolonging the crisis and deepening its health impact. One result has been that subsequent legal reforms have institutionalized a rigid separation of scientific analysis (risk assessment) from managerial decisionmaking (risk management). In the process, economics and social sciences, which are commonly viewed as solely part of risk management rather than scientific analysis, may also be isolated from scientific assessment of risk. Food safety risks are created by human activities affecting biological and physical processes. Economics and other behavioral sciences provide a scientific basis for studying the influence of this behavior on health risks. If rigid separation of risk assessment from risk management results in isolation of economics and other behavioral science analysis from risk assessment, the cost *may* be less accurate risk assessment. This could weaken the factual basis on which second-generation food safety policy is based. This is an issue not only for Europe, but also for the United States and all other countries. Global governance structures in food safety are based on internationally negotiated consensus about best practices. To the extent that the European institutionalization of a rigid separation between risk assessment and risk analysis prevents integration of biological, physical, *and* economic and behavioral science analysis in risk assessment, this separation could easily become global “best practice.”

1. Recent Food Safety Trends

Food safety, particularly infectious foodborne illness, is a significant and increasing global health concern.⁴ Population-level incidence is quite uncertain because of underreporting, but it has been estimated that in the United States, foodborne illness causes approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths annually.⁵ The impact is

⁴ See generally J. Rocourt, G. Moy, K. Vierk, and J. Schlundt, *The Present State of Foodborne Disease in OECD Countries* (2003); UN World Health Organization (WHO), *Global Strategy for Food Safety* (2002).

⁵ P.S. Mead, L. Slutsker, V. Dietz, L.F. McCaig, J.S. Bresee, C. Shapiro, P.M. Griffin, and R.V. Tauxe, *Food-Related Illness and Death in the United States*, 5 *Emerging Infect. Dis.* 607–25 (1999). In 1999, the U.S. population was approximately 273 million according to the U.S. Bureau of Census <<http://www.census.gov/popest/archives/1990s/popclockest.txt>>.

undoubtedly higher in developing countries, where it is more difficult to distinguish foodborne from waterborne illness than it is in industrialized countries.⁶ Each year, approximately 2.2 million people in developing countries die from food- and waterborne infectious disease.⁷ In addition to the direct suffering involved, such a level of illness and mortality drains productivity, imposing a kind of tax on human energy.⁸

Over the last two to three decades, foodborne infectious disease has emerged as the primary health concern driving food safety policy.⁹ Epidemiological data from many countries around the world showed substantial increases in the rate of foodborne infectious diseases from the 1970s into the 1990s.¹⁰ Although this period did see substantial investment and improvements in disease surveillance, public health scientists agree that there has been a real increase in the incidence of foodborne illness.¹¹ In addition, scientists are recognizing that foodborne illness may be more serious than previously thought. New pathogen hazards, such as BSE and shiga toxin-producing *E. coli*, with serious health consequences have recently emerged. And medical science is learning that foodborne infections previously thought of as simply causing acute diarrhea are responsible for chronic diseases, such as reactive arthritis and kidney and heart disease.¹²

This recent focus on foodborne infectious disease also reflects a widely held view among food scientists and public health officials that chemical hazards have been reasonably well

⁶ See generally F.K. Käferstein, Y. Motarjemi, and D.W. Bettcher, *Foodborne Disease Control: A Transnational Challenge*, 3(4) *Emerging Infect. Dis.* 503–10 (1997).

⁷ *Id.*

⁸ See generally UN Food and Agriculture Organization (FAO)/World Health Organization (WHO), *The Role of Food Safety in Health and Development*, Report of the Joint FAO/WHO Expert Committee on Food Safety, WHO Technical Rep. Service 705 (1984).

⁹ See generally WHO, *supra* note 4.

¹⁰ See *id.*, and see also Käferstein et al., *supra* note 6. Rocourt et al., *supra* note 4, identified eight new conditions and practices since the 1970s that contributed to this increase.

¹¹ See Rocourt et al., *supra* note 4 at 11.

¹² See generally Robert Tauxe, *Emerging Foodborne Diseases: An Evolving Public Health Challenge*, 3 *Emerging Infect. Dis.* 425 (1997); J.M. Rangel, P.H. Sparling, C. Crowe, P.M. Griffin and D.L. Swerdlow, *Epidemiology of Escherichia coli O157:H7 outbreaks, United States, 1982–2002*, 11 *Emerging Infect. Dis.* 603–9 (2005).

¹² Tauxe, *supra* note 11; Rangel, et al. *supra* note 11; J.J. McCluskey, K.M.Grimsrud, H.Ouchi, and T.I. Wahl, *Bovine Spongiform Encephalopathy in Japan: Consumers' Food Safety Perceptions and Willingness to Pay for Tested Beef*, 49 *Australian J. Agr. Resource Econ.* 197–209 (2005).

controlled.¹³ Chemical residue and food additive standards are seen as being set with substantial margins of safety on the best available scientific models.¹⁴ Compliance with chemical residue standards, at least in Organisation for Economic Co-operation and Development (OECD) countries, is believed to be reasonably high. Although detecting disease from low-level chronic chemical exposure is difficult, epidemiological evidence of significant problems has been at best scant.¹⁵

Yet chemical hazards remain a concern for both consumers and food safety experts. Continuing consumer concern about pesticide residues has resulted in the development of organic standards and the growth of organic food as a market sector.¹⁶ Public health concerns have focused on the effects of cumulative exposure and impacts on sensitive populations. In 1996, the United States passed the first major pesticide legislation reform in 20 years, requiring that the cumulative impact of low-dose exposure to multiple chemicals on adult and child health be evaluated and that standards be set to protect children.¹⁷ The last three decades have also seen scientific transformation, first in the life sciences and more recently in materials sciences.¹⁸ New technologies—including the development of genetically modified plants and animals, the use of growth-enhancing hormones, and the emergence of nanotechnology—have required evaluation for risk and modification of regulations. Consumer attitudes toward new technologies differ significantly across countries, creating the potential for trade disputes.¹⁹

¹³ Rocourt et al., *supra* note 4.

¹⁴ See generally W.H. van Eck, *International Standards: The International Harmonization of Pesticide Residue Standards for Food and Drinking Water*, in *Pesticide Residues in Food and Drinking Water: Human Exposure and Risks* (D. Hamilton and S. Crossley eds., 2004).

¹⁵ See generally L. Davies, M. O'Connor, and S. Logan, *Chronic Intake*, in *Pesticide Residues in Food and Drinking Water: Human Exposure and Risks* (D. Hamilton and S. Crossley eds., 2004).

¹⁶ See generally Carolyn Dimitri and Catherine Greene, *Recent Growth Patterns in the U.S. Organic Foods Market*, U.S. Department of Agriculture, Economic Research Service, Market and Trade Economics Division and Resource Economics Division, Agriculture Information Bulletin No. 777 (2002).

¹⁷ Food Quality Protection Act of 1996, Pub. L. No. 104–70 (1996). See generally National Research Council, *Pesticides in the Diets of Infants and Children* (1993).

¹⁸ J.D. Kinsey, *The New Food Economy: Consumers, Farms, Pharms, and Science*, 83(5) *Amer. J. Agr. Econ.* 1113–30 (2001).

¹⁹ See generally United Nations, *International Trade in GMOs and GM Products: National and Multi-lateral Legal Frameworks*, Policy Issues in International Trade and Commodities Study Series No. 29 (2005); F. Brom, *WTO, Public Reason, and Food Public Reasoning in the “Trade Conflict” on GM-Food*, 7(4) *Ethical Theory and Moral Practice* 417–31 (2004). See also David Byrne, *The Regulation of Food Safety and the Use of Traceability/Tracing in the EU and USA: Convergence or Divergence?* at 3–4, Address at the Food Safety Conference, Washington, DC (March 19, 2004) (visited Oct. 1, 2009)

Globalization has complicated management of both infectious and noninfectious foodborne hazards. In many developing countries, it has helped raise incomes but also has fostered rapid urbanization, straining sanitation and water systems needed for safe food handling.²⁰ Rapid urbanization is also accompanied by a shift from home to commercial food production and processing, leading to a heightened need for training in new food hygiene management practices. Emerging economies, such as China's, are moving through periods of rapid industrialization and urbanization similar to those that Europe and North America experienced in the nineteenth century. And with this the world is seeing the reemergence of problems, such as intentional adulteration of products for economic gain, referred to as economic adulteration, at a level that is more reminiscent of the 1800s than the 2000s. Recent problems with economic adulteration of food exports from China demonstrate how increased global trade coupled with weak national food safety institutions and the difficulty of observing or detecting safety attributes of food create incentives for consumer fraud.²¹ The institutional capacity of industry and governments in emerging economies needs to grow with their productive capacity. Such countries should be able to benefit from 100 years' experience with risk management in modern industrial production.

In developed countries, globalization has meant more globalized food supplies. For example, in the United States, fresh fruit imports increased from 9 percent of consumption in 1985 to 23 percent in 2001, and vegetable imports grew from 8 percent to 17 percent.²² Without care, imported foods can also effectively result in the importation of another country's sanitation problem, as in the 1996 outbreak of cyclosporiasis in the United States from Guatemalan raspberries and the 2008 outbreak of salmonella in the United States from Mexican jalapeño peppers.²³ Consumers in developed countries tend to point a finger at imports from developing countries. But the international impact of food safety does not flow only from developing

<http://ec.europa.eu/dgs/health_consumer/library/speeches/speech168_en.pdf>.

²⁰ Käferstein, *supra* note 6. See also WHO, *supra* note 4.

²¹ On melamine in Chinese milk, see generally F. Gale, and D. Hu, Supply Chain Issues in China's Milk Adulteration Incident, Intn'l Assoc. of Agr. Econ. 2009 Conference, Beijing, China (2009); on Chinese melamine in pet food, see generally A. V. Roth, A. A. Tsay, M.E. Pullman, and J.V. Gray, *Unraveling the Food Supply Chain: Strategic Insights from China and the 2007 Recalls*, 44(1) J. of Supply Chain Management 22–39 (2008).

²² See generally A. Jerardo, *Import Share of U.S. Food Consumption Stable at 11 Percent*, USDA, Economic Research Service FAU-79-01 (2003)

²³ See, e.g., Linda Calvin, Luis Flores, and William Foster, *Case Study Guatemalan Raspberries and Cyclospora*, 10(7) 2020 Vision Briefs, Intn'l Food Pol. Res. Institute, Washington, DC (2003).

countries. For example, the spread of BSE to Japan and other Asian countries can be traced to British beef and cattle-feed exports in the 1990s.²⁴

It is important to recognize that current disease levels reflect past and current investments in controlling foodborne hazards. In 1999, Belgian animal feed was accidentally contaminated with dioxin in polychlorinated biphenyls (PCBs) and distributed to approximately 2,500 farms. In the winter of 2008–2009, salmonella from a peanut processor in Georgia sickened more than 700 people in 46 states.²⁵ The problem stemmed from a leaking roof and poor hygiene conditions that were not addressed despite public inspectors' being aware of the problem. These incidents remind us that failure in private management and public enforcement is always possible, even in countries considered to have strong food safety practices and institutional safeguards.²⁶ They also remind us that without continued control, old problems, like tuberculosis, can reemerge.

2. Foundations for Food Safety Policy Reform around the Globe

The 1990s and 2000s saw three major innovations in food safety policy: expansion of the role of multinational institutions; emergence of an international consensus around the basic components of a modern structure for food safety policy; and national-level reform of food safety law. These innovations embody broader policy agendas with roots going back almost half a century that coalesced in the face of the food safety crises that have arisen since the early 1990s. These agendas include the introduction of scientific management practices into public administration, particularly since the 1960s; adoption of total quality management as a conceptual framework for process engineering in the United States and Europe, again particularly since the 1960s; and a continued commitment to global integration of markets since World War II.

²⁴ See McClusky et al., *supra* note 12.

²⁵ U.S. Centers for Disease Control, Investigation Update: Outbreak of *Salmonella* Typhimurium Infections, 2008–2009 (visited Aug. 17, 2009) <<http://www.cdc.gov/salmonella/typhimurium/update.html>>.

²⁶ See generally A., Covaci, S. Voorspoels, P. Schepens, P. Jorens, R. Blust, and H. Neels, *The Belgian PCB/Dioxin Crisis—8 Years Later: An Overview*, 25 *Env't Toxicology and Pharmacology* 164–70 (2008).

Science-Based Public Decision Analysis

In both the private and public sectors, the post–World War II period has been characterized by a drive for greater rationalization in decisionmaking, particularly risk management and decisionmaking under uncertainty.²⁷ Food safety management and policy have at times led and at times benefited from this drive.

Food safety policy is among the oldest areas of modern consumer safety law and has a long history of using risk analysis to guide public decisions. Much as we are seeing a revolution in life sciences today, the 1940s and 1950s were a period of revolutionary development in applied chemistry. One area of application was food additives. Lehman and Fitzhugh suggested the use of safety factors to establish acceptable daily intake of food additives on the basis of acute toxicity.²⁸ This safety factor approach to risk assessment is still used in modern food codes today.²⁹ Lehman and Fitzhugh’s model includes a safety threshold below which chemicals are assumed to have no effect. Controversy about whether such a threshold exists for carcinogens led to a 1958 amendment to the Food, Drugs, and Cosmetic Act of 1938, the Delaney Clause. This legislation effectively prohibited sale in the United States of foods found to contain any detectable level of a pesticide shown to be carcinogenic.³⁰ As the analytical ability to detect residues increased, arguments about the appropriateness of the Delaney Clause’s nonthreshold model grew. In 1973, the U.S. Food and Drug Administration (FDA) abandoned the nonthreshold dose-response model for carcinogens.³¹

In 1981, controversy over FDA’s abandonment of the use of the nonthreshold model led the U.S. Congress to direct FDA to contract a study by the National Academy of Sciences (NAS) on the merit of creating an independent institution to conduct risk assessments for all federal

²⁷ Two threads have emerged as particularly central to policy: rationalized risk management as a paradigm for public governance of health, safety, and environmental hazards; and processing engineering controls systems to food processing. From an economics perspective, both fit into the legacy of von Neumann and Morgenstern in the rich literature on expected utility theory and rationalizing decision making under uncertainty. John von Neumann and Oskar Morgenstern, *Theory of Games and Economic Behavior* (1944).

²⁸ See A.J. Lehman and O.G. Fitzhugh, *100-fold Margin of Safety*, 18 *Assoc. Food Drug Off. U.S.Q. Bull.* 33–35 (1954), the seminal scientific paper behind the FDA’s 100-fold margin of safety for chemical residues in food.

²⁹ Codex General Standard for Food Additives (GSFA, Codex STAN 192-1995) (1995).

³⁰ Food Additive Amendments of 1958, § 409 (1958) (Pub.L. 85-929 21), U.S.C.346a.

³¹ See generally Robert J. Scheuplein, *Risk Assessment and Food Safety: A Scientist’s and Regulator’s View*, 42 *Food Drug Cosm. L.J.* 237–50 (1987).

agencies.³² The study, known as the “Red Book,” summarized and clarified the structure of risk governance practices being developed by U.S. federal agencies as they worked to use scientific developments to implement their statutory mandates. It described risk analysis as a three-part process for governing risk: risk assessment, risk management, and risk communication.³³ The committee recommended functionally separating risk assessment from risk management as a means of protecting the integrity of the scientific analysis, but did not suggest creation of an independent risk assessment institution. It is difficult to overstate the influence of the NAS “Red Book.” It has stimulated discussion about the role of risk analysis in governance of consumer and environmental risk in Europe as well as in the United States.³⁴ Both U.S. agencies and governments around the world still look to it as the basic framework for risk regulation. As will be seen, it has had direct influence on the shape of international food safety policy and national policy worldwide.

Andrews argues that during the 1980s, when the White House sought to exert control over the agendas of U.S. health and safety agencies through Office of Management and Budget (OMB) oversight, risk analysis gave regulatory agencies, particularly EPA, a way to shift OMB’s cost–benefit analysis toward science-based, outcome-focused analysis.³⁵ In the 1980s and 1990s, EPA experimented with comparative risk ranking projects to help inform agency priority

³² National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (1983).

³³ Risk assessment is the scientific evaluation of the level of risk faced by a population of concern. It typically involves assessment, dose–response, and risk characterization. Risk management is regulation or policy decisionmaking. Risk communication focuses on communicating results not only to the public, but also among policy circles. USDA, Food Safety Inspection Service, Fact Sheet: Risk Analysis (visited Aug. 29, 2009) <http://www.fsis.usda.gov/factsheets/Risk_Analysis/index.asp>.

³⁴ See Dreyer et al. (2006) at 1.1. See also Carnegie Commission on Science, Technology and Government, *Risk and the Environment: Improving Regulatory Decision Making* (1993). For an insightful comparison of risk regulatory systems in the United States and Europe, see Jonathan B. Wiener, *Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems*, 13 *Duke Journal of Comparative & International Law* 207–62.

³⁵ For a history of the emergence of risk analysis in U.S. federal government, see R.N.L. Andrews, *Managing the Environment, Managing Ourselves: A History of American Environmental Policy* (1999); R.N.L. Andrews, *Risk-Based Decision Making: Policy, Science, and Politics in Environmental Policy in the Twenty-first Century* 215–38, (Norman Vig and Michael Kraft eds., 6th ed. 2006).

setting.³⁶ OMB and the General Accounting Office (GAO) encouraged other agencies to use comparative risk assessment coupled with a goal of risk reduction to set budget priorities.³⁷ In the end, EPA concluded that available risk information was simply too coarse for budgeting purposes and the Agency's priorities too constrained by legislative mandate.³⁸ The idea of risk-based priority setting is beginning to find new application in food safety inspection policy.³⁹

Comparative risk ranking to inform priority setting has more critical limitations, however. In particular, it ignores the relative cost-effectiveness of alternative control options, as well as how citizens feel about different risks, about reducing one risk relative to another, and about reducing health risks relative to other outcomes they want to achieve. A parallel set of public administration reforms, beginning in the 1960s, sought to address these issues through the introduction of modern financial management practices from the private sector into public administration. All OECD countries have shared in the development of these practices.⁴⁰ The United States saw an acceleration of their use following Robert McNamara's institution of systems analysis, such as the Planning, Programming, and Budgeting System (PPBS), as a means of rationalizing U.S. Department of Defense strategic planning efforts in the 1960s. The legacy of McNamara's efforts continue in OMB requirements for cost-benefit analysis of major rules, use of regulatory impact assessments, and performance-based budgeting under the Government

³⁶ See, e.g., Adam M. Finkel and Dominic Golding, *Worst Things First? The Debate over Risk-Based National Environmental Priorities* (1994); J. Clarence Davies, *Comparing Environmental Risks: Tools for Setting Government Priorities* (1996); U.S. Env'tl Protection Agency, *Unfinished Business: A Comparative Analysis of Environmental Priorities* (1987); U.S. Env'tl Protection Agency, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* (1990).

³⁷ The General Accounting Office was renamed the Government Accountability Office in 2001. 21 Env't Rep. (BNA) No. 41 at 1796 (Feb. 8, 1991). See generally Sandra Hoffmann, *Getting to Risk-Based Food Safety Regulatory Management: Lessons from Federal Environmental Policy*, in *Toward Safer Food: Perspectives on Risk and Priority Setting* (Sandra Hoffmann and Michael Taylor eds., 2005).

³⁸ *Id.* at 10.

³⁹ See GAO, *infra* note 131.

⁴⁰ See Hoffmann, *supra* note 38.

Performance Results Act of 1993.⁴¹ Other OECD countries have required similar decision analysis in public decisionmaking.⁴²

Risk-Based Industrial Process Management

First-generation food safety policy relied heavily on line inspection to ensure product quality. Line inspection reflects industrial quality management practices of the early 1900s. In the United States, the Meat Inspection Act of 1906 required continuous visual inspection of meat slaughter and processing lines.⁴³ This was an effective means of enforcing hygiene practices and detecting visible signs of diseases such as trichinosis or tuberculosis. But 100 years later, it remains law even though current safety problems, primarily microbiological and chemical, cannot be detected through visual line inspection.⁴⁴

Even by the 1930s, manufacturers were replacing line inspection with more analytical quality control methods such as statistical batch sampling to improve the efficiency of inspection.⁴⁵ During World War II, the U.S. military began developing analytical management processes, such as failure mode and criticality analysis, to assess the reliability of equipment and procedures and to prevent failures.⁴⁶ After the war, NASA further developed these processes to prevent costly failures in rocket programs, where failures in small batches could fail a mission. In its various forms, failure and criticality analysis is part of the broader postwar movement in industrial engineering toward reliance on total quality control systems.⁴⁷ In the late 1950s,

⁴¹ Regulatory Planning and Review, Executive Order 12866 of September 30, 1993, as amended by E.O. 13258 of February 26, 2002, and E.O. 13422 of January 18, 2007; Government Performance Results Act, 103 P.L. 62; 107 Stat. 285 (1993).

⁴² See, e.g., Her Majesty's Treasury, *The Green Book: Appraisal and Evaluation in Central Government* (Treasury Guidance, London, TSO); Government of Canada, Cabinet Directive on Streamlining Regulation (April 1, 2007) (visited Sept. 30, 2009) <<http://www.regulation.gc.ca/directive/directive01-eng.asp>>.

⁴³ Meat Inspection Act of 1906, Chap. 3913, 34 Stat. 674 (1906).

⁴⁴ See, e.g., Gov't. Acct. Off., *Meat Safety: Inspectors' Ability to Detect Harmful Bacteria Is Limited*, T-RCED-94-228 (May 24, 1994). Based on personal observation of food safety reform debates over the past decade and discussions with senior food safety officials, there appear to be multiple reasons why line inspection has not been abandoned. Among them are resistance from a well-established inspectors union and a lack of certainty about what would happen if the continuous inspection requirement were removed.

⁴⁵ Walter A. Shewhart, *Economic Control of Quality of Manufactured Product* (1931).

⁴⁶ U.S. Army, *Procedure for Performing a Failure Mode Effect and Criticality Analysis*, November 9, 1949, United States Military Procedure, MIL-P-1629 (1949).

⁴⁷ See generally Junji Noguchi, *The Legacy of W. Edwards Deming*, 28(12) *Quality Progress* 35–38 (October 1995).

NASA asked Pillsbury, a major U.S. food-processing firm, to adapt these techniques for use in developing food products that met the very high safety reliability needs of manned space flight. This resulted in a process for food application called Hazard Analysis and Critical Control Point (HACCP) systems.⁴⁸

HACCP provides a systematic way to identify foodborne hazards, assess their criticality, and control weak points where they are most likely to enter a food production system. It begins with a hazard analysis that develops a detailed description of the food, its physical and biological properties, and its intended use and consumers, as well as a verified flow diagram of the process and inputs used to produce and distribute the food.⁴⁹ HACCP has been promoted as providing firms with the flexibility to adapt to changing conditions because its standard is whether a functional control system is in place and the system under control, rather than that particular controls must be adopted, as was typical under conventional hygiene regulations. From a financial perspective, this also provides firms with the flexibility to respond to changing relative prices and control hazards more cost-effectively.

Like other forms of failure and criticality analysis, HACCP gained wide adherence in industry and public health circles as an effective way to prevent system failure. This has been particularly true in the area of controlling microbiological hazards. HACCP found fairly quick acceptance among national governments and international institutions.⁵⁰ In 1993, the Codex Alimentarius Commission (Codex) included HACCP guidelines in its Recommended International Code of Practice. Shortly thereafter, U.S. food safety agencies began shifting to mandated use of HACCP as the basic regulatory approach to controlling microbial hazards.⁵¹

HACCP has met with more mixed response from industry and consumers. For large firms, HACCP fits fairly naturally with other industrial engineering management practices. HACCP requires relatively sophisticated administration and management and therefore can create a barrier to participation of smaller firms in the food industry. In the United States, federal

⁴⁸ See generally Karen Huelebak and Wayne Schlosser, *Hazard Analysis and Critical Control Point (HACCP) History and Conceptual Overview*, 22(3) *Risk Analysis* 547–52 (2002).

⁴⁹ National Advisory Committee on Microbiological Criteria for Foods, *Hazard Analysis and Critical Control Point Principles and Guideline*, 61(9) *J. of Food Protection* 1246–59 (Sept. 30, 1997).

⁵⁰ See Hoffmann, *supra* note 38 at 12–13.

⁵¹ *Id.*

agencies have responded with technical assistance programs to small firms.⁵² U.S. consumer groups have generally supported HACCP but insist that without enforceable performance standards, it provides no way to hold industry accountable for producing safe food. The scientific community is actively engaged in research to develop such standards.⁵³

Economic Globalization and the Rise of International Food Safety Governance

Broader government commitments to greater economic integration, both globally and regionally, have had, and will continue to have, significant impact on food safety policy. The General Agreement on Trades and Tariffs (GATT), negotiated in the wake of World War II, remains the central framework for international trade. Since 1947, the goal of GATT has been to liberalize trade through successive rounds of negotiation guided by the principles of equal treatment for trading partners, transforming nontariff barriers to tariffs, and negotiating reduced tariffs over time.⁵⁴ GATT recognizes limited exceptions to its general requirements. One of the most important is the exception for actions required to protect health, under which parties to the agreement may adopt laws “necessary to protect human, animal or plant health” as long as they are “not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.”⁵⁵

The Uruguay Round of negotiations (1986–1994) created a permanent institutional home for GATT within the World Trade Organization (WTO). An updated version of the 1947 agreement remains the core of the new GATT 1994. More critical for food safety, the Sanitary and Phytosanitary (SPS) Agreement was negotiated during the Uruguay Round to provide a basis for distinguishing legitimate from protectionist use of safety and phytosanitary laws and to

⁵²USDA Food Safety Inspection Service and National Advisory Committee on Microbiological Criteria for Foods, Draft FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants (Aug. 26, 1999) (visited Sept. 7, 2009) <<http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OA/haccp/hidguide.htm>>.

⁵³ Comments of Michael F. Jacobson, Ph.D., executive director, Center for Science in the Public Interest, Commissioner’s Consumer Roundtable, Washington, DC (Dec. 13, 2000) (visited Aug. 29, 2009) <http://www.goodnutrition.org/reports/mjcomments_cfsan.html>; National Research Council, *Scientific Criteria to Ensure Safe Food* (2003); Codex, Principles for the Establishment and Application of Microbiological Criteria for Foods, CAC/GL 21-1997 (1997).

⁵⁴ General Agreement on Trade and Tariffs (GATT 1947), art. I.

⁵⁵ General Agreement on Trade and Tariffs (GATT 1947), art. XX.

encourage their legitimate use.⁵⁶ The agreement, effective as of 1994, is one of roughly 60 the WTO countries have ratified.⁵⁷

Reiterating commitment to the health exception to GATT, 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.⁵⁸ Member states agree “to ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health”⁵⁹ and that measures are “based on scientific principles” and supported by “*sufficient scientific evidence*.”⁶⁰ Measures may not “arbitrarily or unjustifiably discriminate between members” under “identical or similar conditions”⁶¹ and may not be more trade-restrictive than needed to achieve the member state’s “acceptable risk” level.⁶²

WTO members agree to base their national measures on international standards where they exist.⁶³ National rules that conform to international standards are viewed as complying with the SPS and GATT agreements.⁶⁴ Members are free to set a higher level of protection than could be achieved based on international norms or adopt national norms where no international ones exist as long as they provide scientific justification or find it appropriate based on a risk

⁵⁶ WHO/FSF/FOS/ 97.8 Rev. 1. WHO, Food Safety and Globalization of Trade in Food 1997. This is not dissimilar to the role played by risk assessment and regulatory impact assessment in development of U.S. law. The Agreement on Technical Barriers to Trade (TBT), also adopted in the Uruguay Round, governs all other technical requirements and standards, including labeling, not covered by the SPS Agreement (WHO/FSF 1997).

⁵⁷ See generally P. van den Boshe, *The Law and Policy of the World Trade Organization: Text, Cases and Materials* (2005); Peter Gallagher, *The 1st Ten Years of the WTO, 1995–2005*, at 4 (2005); Diahanna Lynch Post, *Food Fights: Who Shapes International Food Safety Standards and Who Uses Them* (2005), which provides an empirical assessment of influence by groups of nations within Codex deliberations; Tim Josling, Donna Roberts, and David Orden, *Food Regulation and Trade: Toward a Safe and Open Global System* (2004); Bernd van der Meulen and Menno van der Velde, *European Food Law Handbook*, chap. 16 (2008). This last work is a well-organized English-language hornbook on European food law. It assumes no prior understanding of European Union law and is a very accessible entry point into this area of law for those new to law or to EU law. It is also complete enough to serve as a good reference book for those with substantial knowledge of the area.

⁵⁸ Agreement on Sanitary and Phytosanitary Standards art. 2(1) (1995).

⁵⁹ Agreement on Sanitary and Phytosanitary Standards art. 3(1) (1995).

⁶⁰ Agreement on Sanitary and Phytosanitary Standards art. 2(2) (1995).

⁶¹ Agreement on Sanitary and Phytosanitary Standards art. 2(3) (1995).

⁶² Agreement on Sanitary and Phytosanitary Standards art. 2(6) and Annex A(5) (1995).

⁶³ Agreement on Sanitary and Phytosanitary Standards art. 3(1) (1995).

⁶⁴ Agreement on Sanitary and Phytosanitary Standards art. 3(2) (1995).

assessment consistent with SPS guidelines. Annex A of the SPS Agreement defines international standards, guidelines, and recommendations for food safety as those established by Codex. Under the SPS Agreement, members agree to follow risk assessment principles adopted by relevant international organizations.⁶⁵ These assessments must take available scientific evidence into account. They may also consider economic factors, including “potential damage in terms of loss of product or sales in the event of the entry, establishment, or spread of a pest or disease; the cost of control or eradication in the territory of importing members; the relative cost-effectiveness of alternative approaches.”⁶⁶

Like other GATT provisions, the SPS Agreement is enforced by international dispute resolution and, if necessary, trade sanctions levied by injured countries against offending ones. A country may refuse entry of products that do not meet the standards faced by its own industry as long as those standards are consistent with GATT. Members also agree to accept the food safety rules of other nations as equivalent to their own if the exporting country demonstrates that its rules can achieve the same level of protection as the importing member’s rules.

The SPS Agreement is intended to make it easier for all countries to participate in international trade by creating greater certainty about when food safety rules comply with GATT and promoting harmonization of rules. The agreement, however, recognizes that compliance with its rules may make it more difficult for developing countries to be involved in international trade. It encourages wealthier members to provide or fund technical assistance⁶⁷ 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.⁶⁸

The Evolving Role of Codex Alimentarius

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.⁶⁹ It was created with two primary goals: protecting human health and promoting fair

⁶⁵ Agreement on Sanitary and Phytosanitary Standards art. 5(1) (1995).

⁶⁶ Agreement on Sanitary and Phytosanitary Standards art. 5(3) (1995).

⁶⁷ Agreement on Sanitary and Phytosanitary Standards art. 9 (1995).

⁶⁸ Agreement on Sanitary and Phytosanitary Standards art. 10(3) (1995).

⁶⁹ See Post, *supra* note 58 at 42.

trade practices.⁷⁰ It pursues both by providing a forum for deliberation on model standards and principles and guidelines that provide guidance to national governments. The incorporation of Codex norms into the SPS Agreement is likely to give them greater weight in future national regulatory and legislative development.⁷¹ Although they are not binding on nations, they do become the standard against which national laws are measured.

Membership in Codex is open to nations that are members or associate members of the WHO and FAO.⁷² Other countries may participate as observers.⁷³ Some 175 countries, representing 98 percent of the world's population, currently participate.⁷⁴ International nongovernmental organizations and other individuals and organizations also may participate as observers.⁷⁵

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.⁷⁶ Codex rules are committed to decision by consensus, with majority vote as a last resort.⁷⁷

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

⁷⁰ Art. 1(a), Statutes of the Codex Alimentarius Commission, in WHO/FAO, 2008 Codex Alimentarius Procedural Manual at 4 (2008).

⁷¹ Post, *supra* note 58, provides a rigorous empirical examination of the influence of Codex standards on national law to date, looking at the adoption of Codex standards by developed and developing countries.

⁷² WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. I (2008).

⁷³ WHO/FAO, 2008 Codex Alimentarius Procedural Manual arts. 2–4 (2008).

⁷⁴ *See generally* van der Meulen and van der Velde, *supra* note 58.

⁷⁵ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. II (2008).

⁷⁶ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. III (2008).

⁷⁷ *Id.* Final decisions on adoption of standards, principles, and guidelines are made by the commission. Some standards may be relevant only to particular regions or a smaller set of nations. In such cases, only these member states may vote.

hygiene code.⁷⁸ Codex has adopted “over 200 standards, close to 50 hygiene and technological codes, some 60 guidelines, over 1000 food additives and contaminants evaluations and over 3200 maximum residue limits for pesticides and veterinary drugs.”⁷⁹

Beginning in the mid-1990s, Codex began to look to risk analysis as a basic framework for developing standards and guidance.⁸⁰ The influence of the NAS 1983 “Red Book” is evident. Codex adopts the Red Book structure of viewing risk analysis as involving risk assessment, management, and communication.⁸¹ Codex defines risk assessment as a “*scientifically based*” process involving four steps: hazard identification, hazard characterization, exposure assessment, and risk characterization.⁸² Risk management is defined as “the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.”⁸³ Under Codex, risk communication is focused on communications among all interested parties during the risk analysis process “about risk, risk-related factors and risk perceptions.”⁸⁴

Codex decisions are to be guided by risk assessment. Risk assessment is to be based on science, be documented transparently, and use quantitative data to the greatest extent possible. Risk assessment and risk management are to be functionally separated “to protect the scientific

⁷⁸ Codex Alimentarius Commission, Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application, Annex to CAC/RCP 1-1969, Rev. 3 (1997); Codex Alimentarius Commission, Recommended International Code of Practice General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 3 (1997, amended 1999).

⁷⁹ See generally van der Meulen and van der Velde, *supra* note 58.

⁸⁰ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. III (2008), Appendix: Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors Are Taken into Account (Decisions of the 21st Session of the Commission, 1995, amended by Decision of the 24th Session of the Commission, 2001); and Statement of Principle Relating to the Role of Food Safety Risk Assessment (Decision of the 22nd Session of the Commission, 1997). Codex guidance on use of risk analysis by the commission and its subcommittees was greatly expanded in 2003 with the addition of a set of Working Principles for Risk Analysis (2008 Codex Alimentarius Procedural Manual at 67–74) and further elaborated with provisions for applying risk analysis to specific areas of work in 2007 (2008 Codex Alimentarius Procedural Manual at 75–108) and a statement of principles concerning science the extent to which other factors are taken into account.

⁸¹ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 5 (2008).

⁸² WHO/FAO, 2008 Codex Alimentarius Procedural Manual at 73 (2008).

⁸³ *Id.*

⁸⁴ *Id.*

integrity of the risk assessment.”⁸⁵ The commission and its subsidiary bodies have risk management responsibility. Joint FAO/WHO expert bodies and consultations conduct risk assessments.⁸⁶ But Codex procedures recognize that some interaction is necessary from a pragmatic perspective.⁸⁷

The purpose of risk assessment is to provide a quantitative or qualitative estimate of the probability and severity of adverse health effects in a population of concern.⁸⁸ Under Codex procedures, risk assessments are to be based on “all available scientific data,” both quantitative and qualitative, and “should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.”⁸⁹ It “should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy” including “consideration of susceptible and high-risk population groups, acute, chronic, and cumulative or combined adverse health effects.”⁹⁰ Conditions and data from different parts of the world, including developing countries, should also be included in decisions.⁹¹

Under Codex procedures, risk management decisions are to be based on risk assessment and may consider “other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.”⁹² But the primary objective should be protection of consumer health. “Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.”⁹³ Risk management should also “take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse

⁸⁵ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 9 (2008).

⁸⁶ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 3 (2008).

⁸⁷ *Id.*

⁸⁸ WHO/FAO, 2008 Codex Alimentarius Procedural Manual at 73 (def. of risk characterization) (2008).

⁸⁹ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 21 (2008).

⁹⁰ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 24 (2008).

⁹¹ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 22 (2008).

⁹² WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 28 (2008).

⁹³ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 27 (2008).

health effects.”⁹⁴ Codex sees food safety risk management as an adaptive management process, explicitly noting the need to revise decisions and standards over time in light of new data.⁹⁵

Codex procedures were strongly influenced by the role politicization of science played in Europe’s BSE scandals. To avoid this kind of political influence, procedures hold interaction between risk managers and risk assessors to a minimum and seek to make it as transparent as possible. Risk managers are responsible for defining the scope and purpose of the particular risk assessment and the form of outputs needed from the risk assessment.⁹⁶ They may also ask risk assessors “to evaluate potential changes in risk resulting from different risk management options.”⁹⁷

These provisions have the potential to affect the contribution economic analysis can make to food safety policy. Codex standards are a model for national standards, and the Codex guidelines on risk analysis are being looked to as a model for the role of risk analysis in national policy analysis. Although not stated, economics is generally viewed by noneconomists as part of risk management, but economics is also a behavioral science and is widely used to study the influence of human behavior and markets on health risks. As a result, if separation of risk management from risk assessment leads to a separation of economic from other scientific analysis, it may result in less accurate estimates of health risks, because the risk assessment will have ignored the influence of regularities in markets and human behavior on risk.⁹⁸

Negotiations over Codex standards and codes allow nations to develop a common understanding, vocabulary, and frame of reference about what they mean by different terms and expect from different procedures, such as HACCP or hygiene codes. But perhaps the most important harmonizing influence of Codex has been the development of a strong international community of technical experts on food and food safety. In part as a result of Codex, international cooperation and scientific consultation are the norm in food safety technical circles. Codex provides a stable forum for discussion of technical issues. Those discussions influence the direction of national policy development even if an international standard is not adopted. Van der

⁹⁴ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 30 (2008).

⁹⁵ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 35 (2008).

⁹⁶ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 13–15 (2008).

⁹⁷ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 16 (2008).

⁹⁸ See generally Richard A. Williams and Kimberly M. Thompson, *Integrated Analysis: Combining Risk and Economics Assessments while Preserving the Separation of Powers*, 24(6) Risk Analysis 1613–23 (2004).

Meulen and van der Velde describe how these discussions affect lawyers involved in Codex, but the same is true for scientists and this may have an even deeper influence.⁹⁹ Post finds evidence that where Codex acts before nations develop standards, such as in HACCP and microbial risk assessment, it has played a significant role in shaping national policy, but in areas where it acts after national rules have already been established, it has less influence.¹⁰⁰ The new status of Codex under the SPS Agreement seems likely to result in greater politicization of the Codex process. How this will affect the usefulness of Codex as a forum for discussion and development of new concepts is an open question.

3. Crisis and Regional and National Legal Response

EU Reform

From the formation of the European Community in 1958 to the mid-1990s, the focus of European food law was to reduce barriers to the creation of an integrated internal market for foods.¹⁰¹ The BSE and other food safety crises of the mid- to late 1990s changed this.¹⁰² The BSE crisis created public pressure for wholesale reform of European food safety law and put its stamp on the character of that reform.¹⁰³ Because of the timing of the crisis and the influence of

⁹⁹ See generally van der Meulen and van der Velde, *supra* note 58.

¹⁰⁰ See generally Post, *supra* note 58.

¹⁰¹ From the 1960s through 1970s, a central question for European food law was how to control the barriers to internal trade created by the diversity of national requirements on food content and safety. The first approach tried was the creation of uniform European standards on food content and identity, somewhat like Codex standards on food content or ASTM technical standards on products such as machine screws. This approach, sometimes referred to as “vertical” or “positive” harmonization, proved infeasible for use in European food markets because of the simple number and diversity of food products and culturally unacceptable because of the diversity of food cultures across Europe (van der Meulen and van der Velde, *supra* note 58 at 230–31). See also Alberto Alemanno, *Food Safety and the Single European Market*, in *What’s the Beef: Contested Governance of European Food Safety* 237–48 (Christopher Ansell and David Vogel eds., 2006), for an insightful perspective on the evolution of European food law from a critical cultural, legal, and political perspective.

A series of European Court of Justice cases in the 1970s created a new way forward. These culminated with the introduction of the principle of mutual recognition in *Cassis de Dijon* (Case 120/78, ECR 649, 1979). Under the principle of mutual recognition, European Community states may not refuse entry of products produced and marketed in compliance with the laws of another member state simply on the grounds that they do not comply with the laws of the state refusing entry. As one commenter put it, “In essence, the Court’s rule was that, within the context of the common market, what is good enough for consumers in one member state is good for consumers across the Community” (van der Meulen and van der Velde, *supra* note 58 at 234).

¹⁰² Van der Meulen and van der Velde, *supra* note 58 at 299.

¹⁰³ Holland and Pope (2004) at 173.

European states in international trade negotiations, it also put its stamp on Codex norms and through them will influence food safety policy globally into the future.¹⁰⁴

The nature of BSE and the way the BSE crisis was handled, by both national and EU authorities, had a significant impact on subsequent EU reforms. BSE is a newly recognized disease, first identified in UK cattle in 1985.¹⁰⁵ It is a fatal, neurodegenerative disease related to scrapie in sheep.¹⁰⁶ At the time it was identified, the British government maintained that BSE, like scrapie, was not transmissible to other species. Transmission among cattle was traced to the practice of feeding them animal offal and bone meal as a protein supplement. Britain banned this practice in 1988. By the time of its ban, the feeding practices were so widespread in the United Kingdom that they led to an epidemic with more than 180,000 diseased animals by 2004.¹⁰⁷ In 1989, the EU prohibited export of cattle born before 1988 from Britain and subsequently banned British export of offal from cattle older than six months on the basis of animal health concerns.

This move was not initially unreasonable, given experience with scrapie, but it was also in the interest of the British beef industry. At a European level, as long as BSE was only an animal disease, the European Commission (EC) had to act under the advice of the Standing Veterinary Committee (SVC), which was dominated by scientists appointed by the British government. Scientific evidence began to mount that BSE was being transmitted to humans, however.¹⁰⁸ The British government continued to maintain that this was not the case until March 1996, when it announced that the best explanation for new variant cases of Creutzfeldt-Jakob disease (vCJD), which caused brain deterioration and death in humans, was exposure to beef from cattle with BSE. Public confidence in the UK Ministry of Agriculture, Fisheries and Food (MAFF) plummeted.¹⁰⁹ Many people, including those in scientific and political circles, believed

¹⁰⁴ WHO/FAO, 2008 Codex Alimentarius Procedural Manual Sec. V, par. 30 (2008).

¹⁰⁵ See Sebastian Kraphol, *Risk Regulation in the Single Market*, at 126–36 (2008).

¹⁰⁶ BSE is caused by a prion, a form of protein that physically interacts with proteins in the host, deforming the way they fold. Despite the awareness of scrapie in sheep for centuries, prions and the mechanism through which they cause disease were only identified in the 1990s. See Stanley Prusiner, *Molecular Biology of Prion Diseases*, 252 *Science* 1515–22 (1991).

¹⁰⁷ Holland and Pope, *supra* note 104 at 173.

¹⁰⁸ Kraphol, *supra* note 106 at 128–29

¹⁰⁹ “The conclusions presented to the British government by the SEAC prompted the announcement made by the British Health Secretary, on March 20, 1996. His speech before the House of Commons sent shockwaves throughout the world when he announced that there may exist a link between BSE and an apparent new strain of CJD. Media reaction to this news was widespread and at times hysterical causing beef purchases and consumption to plummet.

that the MAFF's responsibility to promote agriculture led to its not seeking out or not taking external scientific expertise on the relationship between BSE and human disease seriously.¹¹⁰ At an EC meeting held several days later, on March 25, 1996, the SVC maintained that existing regulations were adequate to control the disease.¹¹¹ At the EC's insistence, however, the SVC finally voted to ban export of cattle and cattle products from the United Kingdom at the same meeting. In July 1996, the EU Parliament formed a Committee of Enquiry, which presented its report in early 1997, and 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 all contributed to the inability of the EU to respond to the crisis quickly.¹¹²

The Committee of Enquiry report demonstrated the need for reform of Europe's food safety policy structure. Subsequent food safety crises, including increased incidence of verotoxin-producing *E. coli* (VTEC) in meat and dairy products, continuing public concern about genetically modified food, and black markets for diethylstilbestrol (DES) as a feed additive, all contributed to pressure for immediate action.¹¹³ The response to dioxin contamination of feed in Belgium in 2000 demonstrated the need for better, faster communication about food crises among European national food authorities.¹¹⁴ Recommendations for structural change followed

Although there were earlier scares, none had the devastating effect of the recent one." Käferstein, *supra* note 6 at 10. See also USDA Foreign Agricultural Service, BSE Rocks the EU Beef Sector (visited August 23, 2009) <<http://www.fas.usda.gov/dlp2/circular/1996/96-11/bse.html>>.

¹¹⁰ On May 16, 1990, British Secretary of State John Gummer appeared on television feeding his young daughter a hamburger in an effort to assure the public of the safety of British beef. <http://news.bbc.co.uk/onthisday/hi/dates/stories/may/16/newsid_2913000/2913807.htm> (cite from van de Meulen and van der Velde, *supra* note 58 at 240, note 194).

¹¹¹ Kraphol, *supra* note 106 at 129.

¹¹² Report of the Temporary Committee of Inquiry into BSE, set up by the Parliament in July 1996, on the alleged contraventions or maladministration in the implementation of community law in relation to BSE, without prejudice to the jurisdiction of the community and the national courts of February 7, 1997, A4-0020/97/A, PE220.533/fin/A. Also referred to as the Ortega Medina report after the chairman of the committee.

¹¹³ Van der Meulen and van der Velde, *supra* note 58 at 238–39, notes 188–92; Holland and Pope, *supra* note 104 at 173.

¹¹⁴ Raymond O'Rourke, *European Food Law*, at 9 (2005).

quickly in the form of a Green Paper in April 1997 and a White Paper on food safety in January 2000.¹¹⁵

The White Paper lays out the EC's vision for reform of European food safety law and is a guide to subsequent legislative action. In writing it, the EC was driven by a need to "reestablish public confidence in its food supply."¹¹⁶ The experience with BSE and subsequent animal feed crises created a focus on food safety policy extending from farm to fork as a means of assuring that every link in the food supply chain protects consumer health.¹¹⁷ The EC was guided by five central principles: clearly defined food safety responsibilities for all actors in the food supply chain; traceability of food, feeds, and food ingredients to their sources; transparency and separation of scientific analysis from risk management to reduce the role of influence or corruption in food safety policy decisions; risk analysis as the framework for science-based policy; and the precautionary principle to guide risk management.¹¹⁸ The role of the consumer in assuring food safety was also noted, but the emphasis was on the commercial side of the production chain. To avoid the politicization of science such as that which contributed to the BSE crisis, the White Paper places responsibility for risk assessment and science advice with a new European Food (Safety) Authority and for risk management with the EC. In addition, the White Paper includes a schedule for prompt consideration of 84 legislative and policy initiatives. The goals of this massive reform were, first, to update European food law and make it more coherent and comprehensive and, second, to strengthen enforcement and make it more consistent across countries.¹¹⁹

¹¹⁵ The General Principles of Food Law in the European Union, Green Paper, COM (1997) 176; White Paper on Food Safety, COM (1999) 719 (visited Aug. 15, 2009) <http://europa.eu/documents/comm/index_en.htm>. "Green papers are discussion papers published by the Commission on a specific policy area. Primarily they are documents addressed to interested parties—organisations and individuals—who are invited to participate in a process of consultation and debate. In some cases they provide an impetus for subsequent legislation White papers are documents containing proposals for Community action in a specific area. They sometimes follow a green paper published to launch a consultation process at European level. While green papers set out a range of ideas presented for public discussion and debate, white papers contain an official set of proposals in specific policy areas and are used as vehicles for their development" (visited Aug. 15, 2009) <<http://europa.eu/documents/comm/>>.

¹¹⁶ European Commission, White Paper on Food Safety, COM (1999) 719 final at 7 (2000) (visited Oct. 1, 2009) <http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf>.

¹¹⁷ *Id.* at 6.

¹¹⁸ B. Halkier and L. Holm, *Shifting Responsibilities for Food Safety in Europe: an Introduction*, 47(2) *Appetite* 127–33 (2006).

¹¹⁹ Van der Meulen and van der Velde, *supra* note 58 at 244–45.

Ultimately, the decision to limit the function of the European Food Safety Authority to providing scientific advice may be driven by a broader concern about the democratic accountability of EU institutions and EC Treaty provisions that place legislative and management powers in the commission, parliament, and council. But concern for democratic accountability does not explain the requirement to separate risk assessment from risk management under European food safety law. This requirement is clearly related to protecting the integrity of scientific analysis and restoring public confidence in food safety governance.¹²⁰

In subsequent years, most of the legislative agenda recommended in the White Paper has been enacted, much in the form of regulations rather than directives.¹²¹ In January 2002, the European Parliament and Council adopted Regulation 178/2002, the General Food Law (GFL). As a regulation, it was immediately binding on all EU member states.¹²² Compared with its predecessors, the GFL places greater emphasis on horizontal regulations, makes greater use of regulations that set objectives to be achieved rather than govern the means of achieving them, and is less reliant on directives resulting in greater centralization of food safety authority.¹²³ By 2007, the EU had adopted regulations on GMOs, food hygiene, and food contact materials, as well as rules for coordination of food safety law enforcement across Europe. The EC is currently working on modernization of food labeling, pesticide, and food additive legislation, and legislation to govern novel foods.¹²⁴

The GFL lays out basic principles to guide subsequent European food safety legislation, establishing the European Food Safety Authority and the Rapid Alert System. The system developed 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 for rapid action if problems arise, and protection of the integrity of scientific analysis on which

¹²⁰ See, e.g., Dreyer et al., *supra* note 34 at 16.

¹²¹ Under the EC Treaty, “a regulation shall have general application. It shall be binding in its entirety and directly applicable to all Member States.” In contrast, “a directive shall be binding, as to the result to be achieved, upon each member state to which it is addressed, but shall leave to the national authorities the choice of form and methods” (European Community Treaty art. 249).

¹²² Under the EC Treaty, “a regulation shall have general application. It shall be binding in its entirety and directly applicable to all Member States.” In contrast, “a directive shall be binding, as to the result to be achieved, upon each member state to which it is addressed, but shall leave to the national authorities the choice of form and methods” (European Community Treaty art. 249).

¹²³ Van der Meulen and van der Velde, *supra* note 58 at 249 note 216.

¹²⁴ Van der Meulen and van der Velde, *supra* note 58, diagram 7.7.

policy decisions rely. Like the SPS Agreement, which was negotiated at the same time, the GFL seeks to implement a farm-to-table, preventive system of food safety policy based on scientific data and risk analysis. The goal is to ensure “a high level of protection of human health and consumers’ interest in relation to food.” These interests include employing fair trade practices; maintaining the diversity of European food supply, including traditional products; preventing fraud, adulteration, and deceptive practices; and promoting an integrated European market.¹²⁵

The GFL provides one example of what a farm-to-fork approach to food safety control might look like. “Food and feed business operators at all stages of production, processing and distribution” are responsible for compliance with food law, including the GFL requirement that “food shall not be placed on the market if it is unsafe.”¹²⁶ Determination of whether a food is unsafe should take into account *normal conditions of production, processing, distribution, and use*, as well as “information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.”¹²⁷ Food is unsafe if it causes short- or long-term health effects to either the consumer or subsequent generations, taking into account “probable cumulative toxic effects” and, where food is marketed to a particular subpopulation, such as babies, the health sensitivities of that subpopulation. EU law requires use of HACCP plans to ensure that preventive controls are used.¹²⁸

The GFL establishes an EU-wide integrated system of monitoring and enforcement. Although business operators have the primary responsibility to keep unsafe food out of the market, national governments are responsible for creating and maintaining the inspection and enforcement systems needed to ensure compliance with EU law, both for domestic production, processing, and marketing and for imports.¹²⁹ The EU Food and Veterinary Office conducts audits of food safety systems in both EU member states and countries that export to the EU.¹³⁰ Food businesses are required to inform relevant authorities of the existence of their

¹²⁵ General Food Law, Regulation (Ec) No. 178/2002, arts. 1, 5, and 8 (2002).

¹²⁶ General Food Law, Regulation (Ec) No. 178/2002, art. 14 (2002).

¹²⁷ General Food Law, Regulation (Ec) No. 178/2002, art. 14 (3)(a) (2002).

¹²⁸ General Food Law, Regulation (Ec) No. 178/2002, art. 14 (2002).

¹²⁹ General Food Law, Regulation (Ec) No. 178/2002, art. 17 (2002).

¹³⁰ See generally U.S. Gen. Acct. Off., *Food Safety: Selected Countries; Systems Can Offer Insights into Ensuring Import Safety and Responding to Foodborne Illness*, GAO-08-794 at 28–29 (2008).

establishments and to cooperate with those authorities.¹³¹ If food or feed operators have reason to doubt the safety of food or feed, they must withdraw it from the market, and if it has already reached consumers, they must inform those consumers and recall the product.¹³²

A core element of the new law is traceability of foods and sharing of information on potential hazards across Europe. All food and feed businesses are required to be able to trace their products one step forward and back in the supply chain and to inform their national food authority if they have reason to believe that they have put unsafe food into the market.¹³³ A centralized EU-level tracking system—Trace Control and Expert System (TRACES)—tracks the movement of livestock in the EU from origin to slaughter.¹³⁴ Regulation 178/2002 establishes a Europe-wide Rapid Alert System, a communication network managed by the European Food Safety Authority responsible for disseminating information about serious threats to health from food or feed to all EU member states. To prevent circumvention of import controls, the system is also used to notify other European ports of entry of shipments of food that are refused entry.¹³⁵ The system quickly proved its effectiveness in contributing to the rapid control of chloramphenicol in honey in 2004.¹³⁶ In general, the public is to have access to information on the product, the nature of the risk, and the control measures taken.¹³⁷

The GFL is explicit that “food law shall be based on risk analysis.”¹³⁸ The final major component of the new European system of food safety policy is a structure to ensure that this

¹³¹ Art. 6, EU Reg. 852/2004 (visited Aug. 29, 2009) <http://ec.europa.eu/food/international/trade/interpretation_imports.pdf>.

¹³² General Food Law, Regulation (Ec) No. 178/2002, arts. 19 and 20 (2002). Canada also makes product recall mandatory. In the United States, however, the FDA has voluntary, not mandatory, recall authority. GAO reports that although many countries have mandatory recall authority, it has seldom been necessary to use it, because the knowledge that it could be used has generally been enough to secure cooperation of businesses with food authorities. *See generally* U.S. GAO, *supra* note 131.

¹³³ General Food Law, Regulation (Ec) No. 178/2002, art. 18 (2002).

¹³⁴ *See generally* U.S. GAO, *supra* note 131.

¹³⁵ *See* U.S. GAO, *supra* note 131 at 53–54.

¹³⁶ Michael Durham, *A Bitter Taste of Honey*, *Guardian* (July 21, 2004) (visited Sept. 9, 2009) <<http://www.guardian.co.uk/news/2004/jul/21/food.foodanddrink>>; Lindsey Partos, Risk Tool from Commission Detects Aflatoxin in Food Supply Chain (visited Sept. 9, 2009) <<http://www.foodproductiondaily.com/Quality-Safety/Risk-tool-from-Commission-detects-aflatoxin-in-food-supply-chain>>.

¹³⁷ Holland and Pope, *supra* note 104 at 30. The United States has a similar system of posting information on product recalls on the U.S. FDA website. U.S. FDA, Recalls, Market Withdrawals, & Safety Alerts (visited Aug. 20, 2009) <<http://www.fda.gov/safety/recalls/default.htm>>.

¹³⁸ General Food Law, Regulation (Ec) No. 178/2002, art. 6 (2002).

analysis is protected from political influence, in order to avoid the kind of crisis in public confidence experienced in the wake of the BSE scandal. To this end, responsibility for risk assessment and that for risk management are institutionally separated from each other. Article 22 of 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. Risk management decisions are the domain of the European Commission, European Parliament, and European Council. These bodies, as well as member states, may ask the EFSA for a science opinion. The EFSA may also initiate investigations and analysis on its own initiative.¹³⁹ Scientific integrity is further guarded by requirements for disclosure of conflicts of interest by scientists working with the EFSA and by requirements of public meetings and timely publication of agendas, minutes, and opinions.¹⁴⁰ The EFSA has eight core responsibilities: providing scientific opinions; identifying and addressing divergent scientific opinions, particularly among European and national food safety agencies; providing scientific and technical assistance at the request of the EU Commission and member states; independently commissioning scientific studies needed to perform its mission; developing systems to monitor emerging risks and collect relevant data assessing the prevalence of foodborne hazards; facilitating scientific cooperation related to food safety risk assessment in the EU; promoting communication and networking among European organizations relevant to risk assessment, particularly regarding exposure and the prevalence of hazards; and contributing to risk communication for consumers.

The EFSA is governed by a management board of 14 members appointed by the European Council in consultation with the European Parliament from a list proposed by the commission. Four of the members are to have backgrounds in organizations representing consumers or other interests in the food chain. The board reviews and approves the EFSA's work program and budget each year to ensure that it carries out its legislative mission. An executive director appointed by the board from a list of candidates proposed by the European Commission is responsible for administering the EFSA. The executive director works with the commission to develop a proposed EFSA work program and is assisted by an advisory forum of representatives of science agencies from member states. The advisory forum is intended to promote communication across Europe, avoid duplication of scientific effort, and better identify emerging issues. Panels of independent scientific experts are responsible for providing the scientific

¹³⁹ Holland and Pope, *supra* note 104 at 29.

¹⁴⁰ General Food Law, Regulation (Ec) No. 178/2002, art. 38 (2002).

opinions of the EFSA.¹⁴¹ A scientific committee, made up of the chairs of the scientific panels and six independent scientific experts not on any of the panels, is responsible for coordination needed to ensure consistency in work procedures across the panels.¹⁴²

Finally, risk management decisions reached by the European Commission, Parliament, Council, and member states are to take into account the results of risk assessments and scientific advice, but may also consider factors such as societal, economic, traditional, ethical, and environmental concerns, as well as the feasibility of controls. Where a risk assessment has been conducted and scientific uncertainty persists because of inadequate data, the precautionary principle may be invoked, and provisional measures may be taken to protect public health pending more complete scientific information.¹⁴³

The EFSA is not the final arbiter of scientific opinion in the EU, but it is expected to play an increasingly central role. It is also anticipated that conflict will arise over scientific judgment between the EFSA and member states. National governments are engaged in scientific analysis and risk analysis as well. The EFSA has responsibility for maintaining communication among these bodies and identifying divergence in scientific opinion.¹⁴⁴ It remains to be seen how the European Community courts will treat EFSA scientific opinions. *Pfizer Animal Health* establishes a duty on the part of EC institutions to consult EC scientific reports.¹⁴⁵ It stipulates that, though national food safety authorities are not required to seek out an EFSA scientific opinion in developing national rules, they are required to take into account existing EFSA risk assessments.¹⁴⁶ The regulation also creates a general obligation on the part of firms to ensure that food they market is safe.¹⁴⁷ Under Article 14(1), marketing of unsafe food is therefore both a breach of an implied warranty of safety and a breach of general product liability law. National courts are not obliged to consult the EFSA in these cases but are likely to look to its scientific

¹⁴¹ General Food Law, Regulation (Ec) No. 178/2002, art. 28 (2002).

¹⁴² Van der Meulen and van der Velde, *supra* note 58 at 208.

¹⁴³ General Food Law, Regulation (Ec) No. 178/2002, art. 7 (2002).

¹⁴⁴ General Food Law, Regulation (Ec) No. 178/2002, art. 30(1) (2002).

¹⁴⁵ *See generally* Alemanno, *supra* note 102.

¹⁴⁶ General Food Law, Regulation (Ec) No. 178/2002, art. 6(3) (2002).

¹⁴⁷ General Food Law, Regulation (Ec) No. 178/2002, art. 14(1) (2002).

opinion in reaching their opinions. Alemanno argues that an EFSA opinion that a product or practice is unsafe would create a strong presumption against safety.¹⁴⁸

Each EU member state is responsible for disease surveillance and outbreak response within its own country, for informing the European Centre for Disease Prevention and Control (ECDC) of outbreaks that may affect other member states, and for cooperating with other member states and EU-level offices in responding to multicountry outbreaks. The ECDC manages Enter-net, a computerized international intestinal disease surveillance network. All EU member states, Norway, Switzerland, Australia, Canada, South Africa, and Japan participate in this network.¹⁴⁹

Will this system work for Europe? 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.¹⁵⁰ They conclude that the system is likely to result in conflicts in scientific opinion. But, given Europe's diversity in culinary culture, it allows for diversity of judgment about what constitutes acceptable risk. As Alemanno writes:

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 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. In contrast, the assertion made at the EC level about the safety of a product to be marketed throughout the EU is both a claim about its risk component and a political claim aimed at favoring economic integration and free trade within Europe.¹⁵¹

Alemanno maintains that it is appropriate that the European courts and not the EFSA resolve conflicts arising between national and EFSA scientific opinion.¹⁵²

Van der Muelen and van der Velde have examined EFSA opinions and concluded that they have all been related to narrow decisions on particular products or food safety targets.¹⁵³ In

¹⁴⁸ See generally, Alemanno, *supra* note 102.

¹⁴⁹ See U.S. GAO, *supra* note 131 at 53–54.

¹⁵⁰ See generally B. Halkier and Lotte Holm, *Shifting Responsibilities for Food Safety in Europe: An Introduction*, 2006, 47 *Appetite* 127–33; Christopher Ansell and David Vogel, *What's the Beef: The Contested Governance of European Food Safety* (2006); Alberto Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO* (2007); and van der Meulen and van der Velde, *supra* note 58.

¹⁵¹ See Alemanno, *supra* note 102 at 254 citing Chalmers 2003.

¹⁵² See generally Alemanno, *supra* note 102.

their view, risk assessment is informing administrative decisions rather than policy direction. They argue that the institutional isolation of risk assessment and scientific analysis from risk management may actually result in risk assessments being less central to risk management or food safety policy decisions.¹⁵⁴ Yet there do appear to be places where one can point to European policy being risk based. For example, member states base the intensity of import inspection on how risky the product is. Factors that come into play in determining product risk include the nature of the food (e.g., is it of animal or nonanimal origin), the quantity imported, and the sanitary and phytosanitary conditions in the area from which it is imported.¹⁵⁵

National Responses

National governments of many OECD nations have undergone major food safety legislative reform since the 1990s.¹⁵⁶ Within the EU, individual countries responded both to the BSE crisis and to EU-level reforms.¹⁵⁷ Reforms in Australia, Canada, Denmark, and New Zealand were largely motivated 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.¹⁵⁸ New Zealand's moves were part of a reorganization of the entire government in an effort to increase efficiency and enhance its competitiveness in world trade. The United States led this wave of reform, responding to earlier domestic crises related to outbreaks of foodborne illness by adopting HACCP requirements for major food hazards and leading development of microbial risk assessment methods. But it has more recently lagged, struggling to find the political will to rationalize a fragmented and sometimes underfunded system of multiagency control.

¹⁵³ Van der Meulen and van der Velde, *supra* note 58 at 269.

¹⁵⁴ *Id.*

¹⁵⁵ U.S. GAO, *supra* note 131 at 53–54.

¹⁵⁶ The U.S. Government Accountability Office recently reviewed these reform efforts to help inform congressional deliberations on import safety and reorganization of federal food safety authority in the United States (2005, 2008).

¹⁵⁷ Vos and Wendler (2006) report on an extensive multi-institutional effort to provide an empirical comparison of institutional reform efforts in five European countries: Hungary, Sweden, the United Kingdom, France, and Germany. Ansell and Vogel, *supra* note 151, provide a comparison from the perspective of legal and political theory.

¹⁵⁸ *See generally* U.S. GAO, *supra* note 131.

EU member states are under treaty obligation to bring their laws into conformance with the General Food Law and related directives. But the GFL leaves member states latitude in how they implement EU obligations. A few examples provide a sense of how EU member states are adapting GFL requirements to their national governance structures.

In the United Kingdom, BSE created a profound crisis in confidence in national food safety policy. UK government investigations pointed to the dominance of agricultural interests, lack of governmental transparency, and fragmentation of food safety responsibility among multiple agencies as key factors in the crisis.¹⁵⁹ In 2000, food safety authority was consolidated under an independent agency, the UK Food Standards Agency (FSA). The FSA is also the United Kingdom's "competent authority" under EU GFL responsible for implementation of EU food and feed law.¹⁶⁰ In conformance with the GFL, the FSA has farm-to-table responsibility for food safety. The FSA's mandate is to protect "*public health* from risks which may arise in connection with the consumption of food (including risks caused by the way in which it is produced or supplied) and otherwise to protect the *interests of consumers* in relation to food."¹⁶¹ This emphasis on public health and consumers responds to concern about the role agricultural interests played in the BSE crisis. The FSA relies on risk analysis in developing regulations, setting strategic planning priorities, and designing inspection regimes.¹⁶² The integrity of risk assessment is protected by keeping management responsibility within the agency and having risk assessments conducted by advisory committees.¹⁶³

Denmark revised its food safety law in 2005, adopting a risk management system that extends from farm to fork,¹⁶⁴ uses risk classification of food establishments as a basis for determining the frequency of inspections,¹⁶⁵ and separates risk management from risk assessment. The Food and Veterinary Administration, a part of the Ministry of Food, Agriculture

¹⁵⁹ Her Majesty's Government, *The Inquiry into BSE and CJD in the United Kingdom: The Report* (Oct. 2000) (visited Aug. 20, 2009) <<http://www.bseinquiry.gov.uk/report/index.htm>>.

¹⁶⁰ United Kingdom, Food Standards Act 1999, 13-11-99 02:56:34 ACTA.

¹⁶¹ United Kingdom, Food Standards Act 1999 (1999) Chapter 28: 1(2), *emphasis added*.

¹⁶² *Id.*

¹⁶³ September 3, 2009, interview with Derrick Jones, chief economist, UK Food Standards Agency.

¹⁶⁴ Stuart A. Slorach, *Food Safety Risk Management in New Zealand: A Review of the New Zealand Food Safety Authority's Risk Management Framework and Its Application* (2008) (visited Aug. 20, 2009) <<http://www.nzfsa.govt.nz/about-us/risk-management-framework-review/index.htm>>.

¹⁶⁵ *Id.*

and Fisheries, is vested with management responsibilities. Risk assessments are conducted by the Technical University of Denmark.¹⁶⁶

Ireland moved to correct both a perception of regulatory capture by industry interests and fragmentation by creating the Food Safety Authority of Ireland (FSAI) in 1998, a small agency that functions largely through contracts. The Department of Agriculture and Food is contracted to enforce food safety rules governing establishments exporting foods of animal origin or importing products of animal origin. The Health and Safety Executive is contracted to enforce food safety requirements in food establishments and on imports. The FSAI relies on a scientific committee of food safety experts across Ireland to conduct risk assessments, develop risk profiles, and provide scientific advice to be used in risk management decisions.¹⁶⁷

Sweden is looking into creating a single food safety agency with farm-to-table responsibility to replace the three agencies now in place. Currently, the National Food Administration (NFA) is responsible for import controls and for setting and enforcing rules governing large meat packers and food processors. It uses a risk classification system to determine the frequency of inspections and to set inspection fees. The National Fisheries Board and the Swedish Board of Agriculture are responsible for primary production, and municipalities for overseeing marketing and small producers. Both risk assessment and risk management are conducted within NFA, but by different departments. NFA also relies heavily on outside scientific advisors.¹⁶⁸

Outside the EU, different economic and political forces are driving reform, though they are influenced by developments in the EU through Codex. In the mid-1990s, Australia and New Zealand agreed to establish a joint food standard setting system to reduce industry costs and regulatory barriers to trade.¹⁶⁹ Reforms to this system in the early 2000s were motivated by a desire to reduce regulatory burden.¹⁷⁰ Additional reforms in the mid-2000s brought the system

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ Food Standards Australia/New Zealand, Background (visited Aug. 17, 2009) <<http://www.foodstandards.gov.au/aboutfsanz/background.cfm>>.

¹⁷⁰ Food Standards Australia/New Zealand, A Short History (visited Aug. 17, 2009) <<http://www.foodstandards.gov.au/aboutfsanz/historyoff sanz.cfm>>.

into greater conformance with international norms, for example, by separating the risk assessment and risk management and adopting a farm-to-table approach.¹⁷¹

The Joint Food Standards Treaty between Australia and New Zealand adopts a joint system for development and promulgation of food standards and information sharing. Under this regime, the Food Standards Australia New Zealand (FSANZ) has responsibility for administering food standards code and for technical analysis and development of food standards for additives, microbiological limits, labeling, GMOs, and heavy metals through a process of public consultation—standards that are to be based on “rigorous science and assessed risk.”¹⁷² The Australia and New Zealand Food Regulation Ministerial Council has final authority for approval or rejection of these standards and is directed to balance the objectives of ensuring public health and safety and providing food efficiently with minimal regulatory burden. Within Australia’s federal system, state-level food standards were harmonized under a 1991 agreement. Australia and New Zealand are working to harmonize standards in many areas of food safety.

The New Zealand and Australian governments are responsible for setting standards in areas covered by joint standards and for implementing and enforcing jointly set standards. The New Zealand Food Safety Authority has also developed its own capacity to assess and manage risk using a framework that reflects close coordination with WHO/FAO and Codex.¹⁷³ Unlike some European authorities, New Zealand does not institutionally isolate food safety administration from promotion of agriculture. Slorach conducted an extensive review of the New Zealand framework, including its application to risk assessment and management of *Campylobacter* in poultry, aspartame as a food additive, import safety, mercury in fish, and public concern about milk safety, compared with actions taken in Denmark, Ireland, and Sweden.¹⁷⁴ He argues that because New Zealand depends so heavily on high-value agricultural

¹⁷¹ See generally Slorach, *supra* note 165; New Zealand Food Safety Authority (NZFSA), Food Safety in New Zealand: Application of a Risk Management Framework (2008) (visited Aug. 20, 2009) <<http://www.nzfsa.govt.nz/about-us/risk-management-framework/index.htm>>; WHO/FAO, *Food Safety Risk Analysis: A Guide for National Food Safety Authorities*, FAO Food and Nutrition Paper No. 87 (2006); Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application by National Governments: Codex Alimentarius Commission Procedural Manual*, 17th ed. (2007); FAO, *Principles and Guidelines for the Conduct of Microbial Risk Management*, CAC/GL-63 (2007).

¹⁷² See Slorach, *supra* note 165 at 25.

¹⁷³ NZFSA, *supra* note 172.

¹⁷⁴ See generally Slorach, *supra* note 165.

exports, food safety is as much an economic concern as a domestic health concern.¹⁷⁵ New Zealand uses a risk-based approach to the inspection of imports. Risk is defined on the basis of safety characteristics of food products and other factors. New Zealand is moving toward greater reliance on verification of food safety practices by the importer and less reliance on border inspection for lower-risk foods.

A major goal of Canadian food safety reform has been reducing the cost of government, though recent, well-publicized outbreaks may affect public confidence in the safety of the food supply.¹⁷⁶ The Canadian Food Inspection Agency (CFIA) was created in 1997 as an independent agency that reports to the Minister of Agriculture and Agri-Food. This action consolidated food safety responsibilities that had previously been spread among four federal government agencies. The Public Health Agency of Canada is responsible for disease surveillance and participates in outbreak response. Canada interprets separation of risk management and risk assessment as a separation of enforcement from standard setting. The CFIA has primary responsibility for enforcing food safety standards set by Health Canada and is responsible for food inspection and plant and animal quarantine. Health Canada also evaluates the effectiveness of CFIA's enforcement programs.

Since 2005, the Canadian Border Services Agency has been responsible for initial inspection of food imports. CFIA follows up if shipments are questionable. About 2 percent of food shipments and the majority of livestock shipments are inspected. Canada has mandatory cattle radio tagging and identification, but no mandatory traceability of food generally. CFIA has mandatory recall power to respond to food safety failures. This power is rarely used but is viewed as an effective incentive for industry cooperation with government in response to emergency situations. The focus within Canadian food safety policy appears to be moving toward preventive food safety control measures along the entire food chain, risk-based inspection, and product traceability.¹⁷⁷

Japan depends heavily on food imports. In recent years, it has adopted a risk-based approach to import controls. Most food imports are randomly inspected, and all lots of products

¹⁷⁵ *Id.* at 35.

¹⁷⁶ Cable News Network (CNN), Canada Links Toronto Plant to Deadly Listeriosis Outbreak (August 24, 2008) (visited Aug. 19, 2009) <<http://www.cnn.com/2008/HEALTH/08/24/listeria.outbreak/index.html>>.

¹⁷⁷ Government of Canada, Food and Consumer Safety Action Plan (visited Aug. 19, 2009) <http://www.healthycanadians.ca/pr-rp/action-plan_e.html>.

deemed to have a high probability of violation are inspected. Japan bases this plan on the likelihood of violation as affected by food, firm history, and conditions in exporting countries. Priorities for monitoring food imports are revised annually in response to changes in risk profiles. Ordinary, random import inspections are free in Japan, but importers must pay for enhanced inspections as well as for violations of import standards. This has led many Japanese importers to require testing certification from exporters. In the case of serious import violations, the names of the violators are posted on the Ministry of Health, Labor, and Welfare website.¹⁷⁸

In many respects, the United States led the way into the current generation of food safety policy reform. Its efforts were motivated by serious outbreaks of foodborne illness in the 1990s.¹⁷⁹ As discussed above in Section 2 of this paper, the United States drew on a range of tools developed for environmental policy and even space programs. 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.¹⁸⁰ In general, industry and consumer groups have been supportive of the adoption of HACCP, though both consumer groups and the GAO have insisted on the need to tie HACCP to performance standards, like the microbiological criteria adopted in the EU.¹⁸¹

HACCP was one of the first of many steps the United States has taken toward more risk-based food safety management. Throughout the 1990s and 2000s, 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 was focused on developing microbiological risk assessment.¹⁸² Responsibility for risk assessment and risk management is generally within a single agency, but responsibility for each is assigned to different work teams or offices within the agency with interaction to help ensure that risk assessment endpoints are appropriate for risk management purposes. In recent years, both the FDA and USDA have been

¹⁷⁸ See generally U.S. GAO, *supra* note 131.

¹⁷⁹ See *supra* note 3.

¹⁸⁰ National Advisory Committee on Microbiological Criteria for Foods (NACMCF), *Hazard Analysis and Critical Control Point System* (1989); NACMCF, NACMCF, *Generic HACCP for Raw Beef*, 10 *Food Microbiology* 449–88 (1993); NACMCF, *The Role of Regulatory Agencies and Industry in HACCP*, *Intn'l J. of Food Microbiology* 187–95 (1994); NACMCF, *Hazard Analysis and Critical Control Point Principles and Application Guidelines*, 16 *J. of Food Protection* 1246–59.

¹⁸¹ Holland and Pope, *supra* note 104.

¹⁸² See Post, *supra* note 58 at 152–58, for a brief history and analysis.

using risk profiling to focus inspection resources and increase their effectiveness.¹⁸³ With recent import problems, the FDA has been looking toward more risk-based approaches to managing import safety.¹⁸⁴ The United States has also invested in improvements in disease monitoring to provide the information basis for risk-based targeting of policy by federal and state governments—most importantly through development of FoodNet, a nationwide active surveillance system, and PulseNet, which uses genetic fingerprinting in tracing the sources of outbreaks.¹⁸⁵

Given the central role U.S. scientists and technical experts have played in the development of 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 adoption of international norms, whether through statutory or administrative law or through government-facilitated industry action, such as marketing orders. The United States clearly sees international cooperation on food safety as not only a means of protecting its trade interests, but also, more fundamentally, an essential element in protecting the safety of the U.S. 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. One of these, the Quadilateral Group, provides a forum for food safety experts from Australia, Canada, the United States, and New Zealand to discuss emerging issues and best-practice standards as they affect the four countries, and offers support for shared interests at Codex sessions.¹⁸⁶

The United States is beginning to move toward a farm-to-fork approach to food safety, but it is being done on a more case-by-case basis than in Europe, often in response to food safety

¹⁸³ USDA, Food Safety Inspection Service, Public Health Based Inspection (visited Aug. 15, 2009) <http://www.fsis.usda.gov/regulations/Public_Health_Based_Inspection/index.asp>; Food Protection Plan and Import Safety Action Plan, Statement of David Acheson, Assist. Commissioner for Food Protection, FDA, before the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce (Nov. 13, 2007) (visited Aug. 15, 2009) <<http://www.fda.gov/NewsEvents/Testimony/ucm109636.htm>>.

¹⁸⁴ *Id.*

¹⁸⁵ U.S. Centers for Disease Control, FoodNet—Foodborne Diseases Active Surveillance Network (visited Aug. 19, 2009) <<http://www.cdc.gov/FoodNet/>>; U.S. Centers for Disease Control, PulseNet (visited Aug. 19, 2009) <<http://www.cdc.gov/pulsenet/>>.

¹⁸⁶ Quadilateral Food Safety Group (visited Aug. 20, 2009) <http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/QuadrilateralandTrilateral/Quadrilateral/default.htm> [sic.]. See also New Zealand Food Safety Authority Profile 2007 at 11.

incidents. For example, outbreaks of shiga-toxin *E. coli* in leafy greens in 2006, which resulted in 3 deaths and 200 illnesses, have pushed produce growers and regulators to work on developing better control systems.¹⁸⁷ Draft FDA guidance on produce safety takes a supply chain approach but is voluntary.¹⁸⁸ The United States bans feeding offal to cattle and regulates pesticide use on farm and the nontreatment use of antibiotics.¹⁸⁹ On the whole, farmers have resisted on-farm regulation. As farms consolidate and become more industrialized and larger scale, pressure to regulate them is likely to increase. Because each state has two senators, providing rural, agricultural states with votes disproportional to their population, it remains unlikely that a regulatory approach to the farm portion of farm-to-table food safety policy will be adopted in the United States. 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.

¹⁸⁷ Miranda Hitti, FDA Sets Fresh-Produce Safety Rules, WebMD Health News, March 12, 2007 (visited Oct. 1, 2009) <<http://www.webmd.com/food-recipes/food-poisoning/news/20070312/fda-sets-fresh-produce-safety-rules>>.

¹⁸⁸ U.S. FDA, Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Draft Guidance (July 2009) (visited Aug. 12, 2009) <<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm173902.htm>>; U.S. FDA, Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance (July 2009) (visited Aug. 12, 2009) <<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174171.htm>>; U.S. FDA, Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance (July 2009) (visited Aug. 12, 2009) <<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174200.htm>>.

¹⁸⁹ Substances Prohibited from Use in Animal Food or Feed, 21 C.F.R. Part 589 (2008). Pesticide use inconsistent with the labeling is prohibited under FIFRA 7 U.S.C. § 136. See Labeling Requirements for Pesticides and Devices, 40 C.F.R. § 156.10(i)(2) (1998). Similarly, the FDA regulates drug use on a drug-by-drug basis. Use of antibiotics as feed additives are regulated by the drug label (visited Aug. 29, 2009) <<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/default.htm>>. The FDA also has an educational program on judicious use of antibiotics in feed aimed at preventing antibiotic resistance (visited Aug. 29, 2009) <<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm>>. Legislation has been proposed to strengthen restrictions on use of antibiotics in feed as growth promoters (Preservation of Antibiotics for Medical Treatment Act of 2009, H.R. 1549, 111th Cong. (2009)). See Preservation of Antibiotics for Medical Treatment Act of 2009, Statement of Joshua M. Sharfstein, M.D., Principal Deputy Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services, before the House Committee on Rules, July 13, 1009 (visited Aug. 29, 2009) <<http://www.fda.gov/NewsEvents/Testimony/ucm171715.htm>>; Chris Baltimore, *Consumer Groups Point to Holes in Cattle Feed Rules*, Reuters (Jan. 3, 2004) (visited Aug. 29, 2009) <<http://www.organicconsumers.org/madcow/feedrules1304.cfm>>.

One of the basic structural problems in U.S. food safety regulation is that responsibility is fragmented among as many as 15 agencies.¹⁹⁰ Primary responsibilities are placed in 4 agencies: USDA (meat, poultry, and processed egg products), EPA (setting pesticide tolerances), Commerce (seafood), and FDA (all other foods including food additives and economic adulteration).¹⁹¹ 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. As discussed above, similar fragmentation was the driver behind food safety reform in the United Kingdom and the European Union. A very long-standing political debate has been ongoing over whether to consolidate food safety responsibility in the United States into a single agency.¹⁹² Despite a recent string of nationwide foodborne illness outbreaks and highly publicized failures of import controls, however, there does not appear to be the political will to consolidate. In part, recent difficulties with the formation of the Department of Homeland Security have raised questions about such consolidation.¹⁹³ Current legislative proposals focus on the more limited goal of strengthening FDA food safety authority.¹⁹⁴

Conclusion

Despite recent campaigns for more localized food production, the reality is that for most people in the United States and other developed countries, their food supply is becoming more globalized. This does carry significant benefits for consumers. We are a long way from the 1920s, when my mother viewed a fresh orange in her Christmas stocking as a special treat. But globalization *as well as* changes in domestic food processing and production clearly raise new challenges.

¹⁹⁰ GAO has written multiple reports on this issue over the past 20 years and in 2007 put food safety on its “high-risk list” largely as a result of fragmentation. See U.S. GAO, *Revamping Oversight of Food Safety* (visited Sept. 1, 2009) <http://www.gao.gov/transition_2009/urgent/food-safety.php>.

¹⁹¹ See U.S. GAO, *Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources*, GAO 05-213 (March 2005).

¹⁹² See *supra* notes 108 and 109.

¹⁹³ Mimi Hall, *Ex-Official Tells of Homeland Security Failures*, USA Today (Dec. 27, 2004) <http://www.usatoday.com/news/washington/2004-12-27-homeland-usat_x.htm>.

¹⁹⁴ Food Safety Modernization Act of 2009, H.R. 875, 111th Cong. (2009) (visited Oct. 1, 2009) <<http://www.govtrack.us/congress/bill.xpd?bill=h111-875>>.

The United States is operating under food safety statutes that remain in large part unchanged since their adoption in 1906. Responsibility for food safety regulation is spread among four major departments, all of which have other major missions in addition to food safety. Even in the absence of legislative reform, the United States has played a central role in the development of an international consensus on how to modernize food safety policy. This consensus is enforced by economic incentives such as the desire of multinational food firms to avoid disruption and liability and protect their brand names and market share. It is also enforced by the desire of national governments to promote their countries' exports. And ultimately, it is enforced by the threat of trade sanctions and by national law.

The lack of legislative reform in the United States has resulted in federal agencies' attempting to modernize food safety regulation "with one hand tied behind the back." In the end, U.S. food safety policy is modernizing, but more slowly and less effectively than it could with updated statutory authority. This is a good moment for legislative reform in the United States, not only because the series of highly publicized failures over the past several years clearly demonstrates the need for change, but also because decades of work in this country and abroad have created a clear understanding of the kind of structure that is needed. At the same time, an independent mind needs to be brought to the adaptation of international guidance to U.S. conditions. Lessons from comparative law must always be undertaken with a critical eye. Just as U.S. case law has been known to go astray in response to extreme facts, so too do domestic crises in other countries influence their laws and their roles in international negotiations in ways that may not provide wise guidance for the United States.