

Resolving Trade Disputes Arising from Trends in Food Safety Regulation

The Role of the Multilateral Governance Framework

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Summary

This chapter examines current trends in food regulation, to see how they may influence international trade and to ascertain if, when, and how multilateral mechanisms can resolve trade conflicts. New approaches to food safety regulation that emerged in industrialized countries during the 1990s include:

- The growing use of risk analysis,
- Establishing public health as the primary goal of food safety regulation,
- Emphasizing a farm-to-table approach in addressing food safety hazards,
- Adopting the Hazard Analysis and Critical Control Point (HACCP) system as a basis for new regulation of microbial pathogens in food,
- Increasing the stringency of standards for many food safety hazards,
- Adding new and more extensive regulation to handle newly identified hazards, and
- Improving market performance in food safety through provision of information.

These regulatory trends have several implications for how food safety standards affect international trade in food products. Some new regulatory developments are likely to mitigate potential barriers to trade. For example, new kinds of regulation or public intervention that focus on voluntary provision of information (e.g., certification for certain kinds of production practices) can

facilitate trade, even when standards and requirements differ among countries. Other trends, though, may impede trade. For example, if new or more stringent standards are in the form of process standards, (e.g., under HACCP systems), it can be difficult to determine if imported products are as safe as those produced domestically. Whether certain kinds of process requirements are necessary to achieve an equivalent risk outcome can be subject to dispute.

The 1995 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), negotiated by World Trade Organization (WTO) members, recognizes the need for countries to adopt SPS regulations while establishing a framework to reduce their trade distorting aspects. Under these rules, WTO members reported 187 complaints related to food safety regulations from 1995 to 2001, which provides some evidence of the extent to which new food safety regulations have created barriers to trade.

Three of the principles under the SPS Agreement—science-based risk assessment, equivalence, and harmonization—directly address some aspects of food safety regulation that create the potential for trade disputes. Progress toward realization of these principles is reviewed here to see how well the SPS Agreement and supporting institutions have addressed emerging issues arising from regulatory trends. The agreement's requirements for the use of scientific risk assessment, for example, have led to the resolution of a number of disputes. Less progress can be reported in reducing transaction costs to trade through equivalence or harmonization. Multilateral institutions continue to work on projects—such as identifying the types of technical assistance that best help developing countries meet food safety requirements in key export markets—to achieve welfare-enhancing trade.

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Introduction

New developments in food safety regulation, including new and more stringent standards for many hazards, occurred in many countries during the past decade. Both existing and emerging measures to protect human health can affect trade in agricultural products by increasing the costs of imports or prohibiting them entirely. The imposition of new performance standards (such as maximum residue levels for pesticides) or process standards (such as the required use of filters for irrigation water) may alter the cost of foreign supplies relative to domestic production. Requirements for certifying compliance with importers' standards may effectively prohibit imports from countries that lack adequate regulatory infrastructure, even if individual foreign firms can meet importers' standards. Such costs from reduced trade must be balanced against the public health benefits of safer food, and the market benefits of increased consumer confidence. It is the balance of such costs and benefits among countries that makes these measures so controversial in international trade.

During the last round of multilateral trade negotiations, exporters voiced concerns that sanitary and phytosanitary (SPS) measures to protect animal, plant, or human health were sometimes used to shield domestic industry from foreign competition, and that such protectionist pressures would increase as other trade barriers such as tariffs fell. The 1995 Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) was therefore negotiated by the WTO to provide a set of multilateral rules that would recognize the legitimate need for countries to adopt SPS regulations while establishing a framework to reduce their trade distorting aspects. To implement this agreement, the WTO relies in part on three multilateral standards organizations, and also draws on the expertise of other international scientific organizations. Together, these institutions, along with their principles, rules, standards, and enforcement mechanisms, comprise the multilateral governance framework for food safety regulation (Josling et al., forthcoming).

The impact of SPS measures on trade and welfare is largely unknown, primarily because we lack systematic information on the incidence of these measures themselves and because of underdeveloped methods of economic assessment (Beghin and Bureau, 2001; Maskus and Wilson, 2001; Roberts et al., 1999). However, there is substantial evidence that disagree-

ments over SPS measures are becoming more important over time due to several trends. Reduction in traditional trade barriers, growth in trade of fresh and minimally processed foods, growth in trade of livestock products, and increased consumer awareness and demand for safety have all contributed to increased disagreements over SPS measures and allegations that they pose barriers to trade (Unnevehr, 2000; Henson and Loader, 1999; Dyck and Nelson, 2000; Buzby and Roberts, 1999).

Resolving trade conflicts over food safety regulation is viewed as possibly one of the biggest challenges facing the international trade system. It is widely recognized that a perceived failure to accommodate legitimate differences in food regulations could increase opposition to trade liberalization in general. Effective governance of the interface between food safety regulation and trade relies on the efforts of multilateral institutions and national regulatory authorities.

Current Trends in the Regulatory Environment

Several changes in the global food system—increased scientific understanding of foodborne hazards, increased international trade in food products, and changes in how consumers obtain and prepare food—have brought renewed attention to food safety regulation in many countries. The science of public health is now better able to identify new foodborne pathogens and other hazards, estimate the incidence and severity of foodborne illness, and trace hazards to their sources. Increased public awareness of microbial pathogens has raised public concern about this type of foodborne hazard. In industrialized countries, consumers carry out less food preparation, consume more fresh and minimally processed foods, and consume more meat and seafood products. A greater share of consumption is now imported in many countries, including many fresh products. These changes in consumption patterns alter the sources and incidence of risk and reduce consumer control over food safety, at the very time that increasingly affluent consumers are demanding a higher level of safety.

Some well-publicized crises have brought these changes to the attention of the public. In 1993, an outbreak of *Escherichia coli* O157:H7, a new and more virulent strain of *E. coli*, was linked to consumption of undercooked hamburger contaminated with the bac-

terium. The outbreak caused over 700 illnesses and 4 deaths in several Western States. This pathogen drew further U.S. media attention later in the 1990s when outbreaks were associated with unpasteurized fruit juice and bagged salad lettuce. In 1996, bovine spongiform encephalopathy (BSE), or “mad cow” disease in cattle, was linked epidemiologically to the emergence of new variant Creutzfeldt-Jakob disease (vCJD) in humans who had consumed meat contaminated with the BSE causative agent. Consumers in the UK and elsewhere in Europe where BSE has been found in cattle were especially affected. And in 1999, supplies of several animal-derived foodstuffs produced in Belgium were contaminated with dioxins associated with animal feed prepared from tainted fats and oils. The resulting food recalls and disruptions in trade crippled the Belgian economy. These outbreaks or incidents have often resulted in new food safety regulation.

New approaches to food safety regulation emerged in industrialized countries during the 1990s following these changes in science, markets, and consumer awareness. The following discussion presents seven main trends in regulation worldwide:

- (1) The growing use of risk analysis,
- (2) Establishing public health as the primary goal of food safety regulation,
- (3) Emphasizing a farm-to-table approach in addressing food safety hazards,
- (4) Adopting the Hazard Analysis and Critical Control Point (HACCP) system to regulate microbial pathogens in food,
- (5) Increasing the stringency of standards for many food safety hazards,
- (6) Adding new and more extensive regulation to handle newly identified hazards, and,
- (7) Improving market performance in food safety through provision of information.

The new approach to food safety regulation is based upon risk analysis, which includes risk assessment, risk communication, and risk management. Risk assessment is to be science-based, and includes identification of the sources and incidence of the risk, as well as identification of possible control strategies. The results of risk assessment must then be communicated, inviting public participation in the risk management process. Risk management entails choosing the

appropriate level of protection and selecting suitable interventions or control options.

This approach to food safety regulation was recommended in reports by the National Research Council of the National Academy of Science (NRC, 1985; NRC, 1987) for U.S. food safety regulation, and is generally embraced by U.S. agencies. For example, FDA and USDA have recently carried out risk assessments for *S. enteritidis* in shell eggs, *E. coli* O157:H7 in hamburger, BSE in beef cattle, antibiotic-resistant *Campylobacter* in poultry, *Vibrio vulnificus* in shellfish, and *Listeria monocytogenes* in ready-to-eat meat products. These risk assessments have generally been undertaken to see whether new regulation is warranted. The 2002 European Food Law embraces this approach as well, as do all of the European food safety agencies in member states of the European Union. The Joint Institute for Food Safety and Applied Nutrition at the University of Maryland lists several publicly available food safety risk assessments carried out by government agencies in other countries, including Canada, Denmark, the Netherlands, and the United Kingdom (JIFSAN, 2002).

The primary goal of food safety regulation is public health. In the past, some food safety agencies have had multiple mandates relating to other issues such as food quality, industry promotion, or animal health. To more clearly focus food safety regulation on public health and consumer protection, several countries have reorganized their food safety regulatory agencies in order to refocus and to integrate previously scattered functions:

- Australia and New Zealand established the Australia and New Zealand Food Authority or ANZFA in 1991 to create uniform food regulation in both countries; in July 2002, the Food Standards Australia-New Zealand agency was established and charged with setting standards for primary products;
- Canada established the Canadian Food Inspection Agency in 1997 to unify inspection activities previously spread across several agencies;
- France established the Agence Francaise de Securite Sanitaire des Aliments (AFSSA) in 1999 to provide systemwide authority for risk assessment and intervention;
- The United Kingdom Food Standards Agency was created by an act of Parliament in 1999, and is set

up to be a quasi-independent watchdog to protect public health and consumer interests;

- Ireland created the Food Safety Authority in 1998;
- The European Union (EU) created a new Food Safety Authority in early 2002, following earlier reorganization of EU directorates in 1997 to address consumer protection in response to food safety concerns following the BSE crisis (Vos, 2000).

In the United States, FDA has always had public health protection as its sole mandate. However, 12 Federal agencies have some responsibility for food safety, and many have other public goals in addition to public health. To better focus food safety activities in the U.S., greater coordination among the various regulatory agencies has been established at the Federal level (President's Council on Food Safety, 2001).

Regulatory agencies increasingly recognize that *a farm-to-table approach is often desirable for addressing food safety hazards*. Many foodborne hazards can enter food at many points during the production process. Once present in food, some hazards can multiply or cross-contaminate other foods during transportation, processing, and preparation. Thus, control of foodborne hazards may involve interventions at many points in the food production and distribution system. Interventions at one level may influence control options at subsequent points in the supply chain from producer to consumer. Finally, there may be tradeoffs among controls at different levels in terms of the risk reduction achieved and the costs incurred. Thus, for many hazards, the ideal risk assessment examines the entire food production and distribution system.

The farm-to-table approach is clearly articulated in the new EU Food Law as a principle for future food safety regulation. However, the EU policy also recognizes that different kinds of regulatory measures may be needed at the farm level, due to the difficulties of controlling hazards in a farm environment. In the United States, the farm-to-table approach was used in developing new regulatory approaches to *S. enteritidis* in eggs (see box).

Countries are increasingly adopting the Hazard Analysis and Critical Control Point (HACCP) system as a basis for new regulation, often of microbial pathogens in food. HACCP requires identification of critical control points and development of procedures for monitoring controls and addressing any failures in control. Often, firms or industries are given some flex-

Box 3.1—Farm to Table Risk Assessment for *Salmonella enteritidis* in Eggs

The risk assessment of *Salmonella enteritidis* (SE) carried out by the FDA and the USDA's Food Safety and Inspection Service and Animal and Plant Health Inspection Service examined the interdependence among control options at different stages of processing and handling. It provided the basis for an action plan (President's Council on Food Safety, 1999). The risk assessment model indicated that multiple interventions would achieve more reductions in SE illness than would a single point of intervention.

The action plan identifies a set of activities at each stage of the production chain. Producers and packer/processors can choose between two strategies designed to give equivalent performance in terms of reduction in SE at the egg production and packer/processor stages. The first strategy focuses on farm-level testing and egg diversion; the second strategy directs more resources to the packer/processor level and includes a lethal treatment, or "kill step" (and HACCP plan) at this stage. Both strategies include regulatory presence on the farm (e.g., control of chicks from SE flocks) and at the packer/processor (e.g., washing, mandated prerequisite programs of sanitary controls). In addition to these interventions, the action plan sets refrigeration standards for the distribution and retail stages to ensure that reductions in SE are preserved at later stages in the food supply chain.

ibility in determining control points and critical limits, so that implementation of HACCP is adaptable to many different contexts. The imposition of regulations mandating HACCP systems reflects a growing recognition that it is important to prevent and control hazards before they reach the consumer.

In 1996, the USDA's Pathogen Reduction/HACCP Regulation mandated the use of HACCP in meat and poultry slaughter and processing plants in order to reduce microbial pathogens (USDA, 1996). The FDA mandated HACCP for seafood plants in 1995 (FDA, 1995), and for fruit juice in 2001 (FDA, 2001). Canada also requires HACCP for fish, seafood, meat, and poultry plants. In the European Union, HACCP was mandated in 1993 for the entire food system, though it has been implemented in different ways within member countries.

Over and above the general principles in the new regulatory approach, *there is also a trend toward more stringent standards for many food safety hazards.* HACCP regulations frequently consolidate existing codes of hygienic practice or sanitation standards with new requirements. For example, the 1996 Pathogen Reduction/HACCP Regulation for U.S. meat and poultry plants also required written sanitation procedures and pathogen tests to verify that HACCP is reducing hazards. These standards are in addition to previous sanitation requirements for plants. In the EU, earlier HACCP directives have been replaced by a new directive in 2000 that extends requirements for recordkeeping and corrective action.

Standards for other kinds of hazards have changed. The U.S. Food Quality Protection Act, passed in 1995, mandates that no harm result to infants and children from aggregate exposure to all pesticide residues. This has brought about a reassessment of all currently registered pesticides, beginning with the widely used class of chemicals called organophosphates. In the EU, new, unified standards were proposed for aflatoxins on crops in 1998. In unifying standards across member states, the new standards reduced allowable levels of residues in most countries. Comments on this change from EU trading partners led to some revisions in the unified standard that was implemented in 2001 (and modified in 2002).

In addition to more stringent food safety standards, *newly identified hazards have brought about new and more extensive regulation.* For example, BSE poses both animal and human health risks. Its mode of transmission among cattle or between animals and people is not fully understood. New regulations in the United Kingdom and elsewhere—regarding animal age at slaughter, monitoring of animal herds, testing of animal brains at slaughter, exclusion of specified risk materials (brain, spinal cord, eyes, tonsils, etc.) from meat products and meat cuts, and exclusion of mammal products from cattle feed—are designed to reduce the risk of transmission. These regulations are extensive, covering every step of the food production and distribution system from animal feed to meat butchering. They also have had an impact on a wide range of byproducts, including gelatin used in pharmaceuticals.

Another example of newly identified hazards is the growing awareness of potential transmission of antibiotic resistance from food animals to humans. This has led to new regulations regarding the nontherapeutic use

of antibiotics in food animals, most notably in the EU, where such uses are banned entirely. In the U.S., such uses are under review, and the FDA has issued new guidelines for assessing the risk of resistance to antibiotics used in feeds.

Other new approaches to food safety regulation attempt to *improve market performance through provision of food safety information.* These approaches include the use of voluntary guidelines or standards, provision of third-party certification, provision of information through labeling, establishing legal liability for food safety, and establishing voluntary or mandatory systems for traceability (table 3.1). Such interventions may improve performance by providing information or incentives that encourage consumers to choose safe food and reward producers for its provision. The public role in these new approaches, and the degree to which they are mandatory or voluntary, varies among countries.

Unresolved Public Policy Issues

These new trends in food safety regulation have come about mostly over the past decade. As these trends are still evolving in many countries, three public policy issues remain unresolved. First, the role of scientific and economic analysis in risk management varies widely among countries. In the United States, regulations must be science-based. Economic analysis is mandated for major regulations with an estimated economic impact over \$100 million and for all food safety regulation within USDA (Executive Office of the President, 1993). Economic analysis played a role in the design of the Pathogen Reduction/HACCP Regulation, as analysis of the fixed cost implications led to staggered implementation dates for plants of different sizes. In the European Union, risk management decisions may include “other legitimate factors” that extend beyond scientific and economic analysis (Henson, 2001). Such factors include consumer concerns, the environment, animal welfare, and other political or economic factors, such as the impact on small farms. In Australia and New Zealand, cost-benefit analysis with risk assessment is extensively used. For example, in the 1998 redesign of food safety regulation, the regulatory approach that was chosen balanced expected benefits to consumers and industry against the costs of regulation to industry and government. Such analysis in Australia, Canada, and New

Table 3.1—Information-based approaches to food safety interventions

Approach	Example	Public sector role	Food safety benefit
Guidelines	UK voluntary guidelines for farms to reduce <i>Salmonella</i> in pigs U.S. voluntary Good Agricultural Practices to reduce microbial hazards in fresh fruits and vegetables	Public sector can develop guidelines or certification that is science-based, directed toward public health, and credible to consumers	Reduces hazards, but only where guidelines or certification adopted; and reduce transaction cost in markets for safety.
Third-party certification	USDA Quality Through Verification program certifies that fresh produce is produced under HACCP Netherlands IKB programs for livestock producers		
Labeling	U.S. required safe handling labels on fresh meat and poultry products EU novel food regulation requires labeling of novel foods	Identify where information critical to facilitate consumer choice; respond to consumer demand for information	Reduces market failure where information previously lacking; alters hazard incidence in some cases
Liability	UK 1990 Food Safety Act	Establishes responsibility for food safety	Improves safety by providing incentives for producers to follow practices that minimize hazards
Traceability	EU Food Law establishes as principle for food safety policy Japan requires traceability in beef sector	Establish information and marketing channel requirements	Facilitates tracing problems in case of outbreak; can provide incentives for producers to improve safety

Zealand pays particular attention to international markets and the impact of new regulations on trade as an important economic dimension.

Second, controversy surrounds the role of standards. In the United States, a recent court decision declared that USDA could not shut down a meat grinding plant for failing to pass a performance standard based on *Salmonella* incidence. The USDA is currently reviewing the role of microbiological performance standards, and it is not yet clear what role these may play in addition to sanitation process standards. In the EU, the mandate for HACCP in all parts of the food production and distribution system is not always practical for small retail establishments, so in many cases regulation instead relies on codes of hygienic practice (Jansen, 2001). These more prescriptive process standards do not really follow the HACCP model of prevention and control.

The role of process and performance standards in regulating different kinds of hazards is changing. Inputs that are added during the production process are often subject to performance standards, such as tolerances for pesticide residues. However, some inputs are subject to process standards such as withdrawal times for antibiotics in animals or required recordkeeping for use of growth hormones. It is more difficult to set performance

standards for microbial hazards, as they can enter the food supply at many points during production and distribution, and can grow or cross-contaminate other foods. Regulation of microbial hazards has often meant setting process standards, such as standard sanitation procedures or codes of hygienic practice. Microbial hazards may be more frequently subject to performance standards in the future, as the need to verify HACCP systems is recognized and new tests are developed that provide more timely and specific results.

A third unresolved issue is regulatory agency capacity and authority. In many cases, existing regulations require review or removal in order to implement new kinds of regulation. This kind of review took place in Canada, the United States, and the United Kingdom to reduce regulatory burden and to ensure consistency in how regulations are applied. Another issue is whether existing regulatory authority extends throughout the food system. When it does not, then certain kinds of intervention may not be possible. The EU Food Law establishes regulatory authority for the entire food production/distribution system, but such authority does not exist to the same extent in the United States. USDA's Food Safety and Inspection Service does not have authority to regulate at the farm level. In some cases, FDA or the USDA's Animal and Plant Health

Inspection Service may regulate food safety at the farm level, but this is not the focus of either agency.

What Are the Implications for International Food Trade?

Regulatory trends, associated unresolved public policy issues, and the growth in world food trade have several implications for how food safety standards affect international trade in food products. First, *the simultaneous move toward improved safety among industrialized countries creates the potential for convergence around higher standards*. That is, as developed countries with major markets adopt new regulations, there is incentive for other countries to follow suit (Vogel, 1995). New regulations are undertaken in some countries in response to other countries' actions. This rationale has been explicitly mentioned in regulatory impact analysis in Australia and Canada, for example. USDA's survey of 35 countries that export meat and poultry to the United States also attests to the demonstration effect of stringent food safety standards in importing countries (*World Food Chemical News*, 2000). More than a third of the 29 respondents to the survey indicated that they had adopted HACCP in all (not just exporting) establishments, while nearly half had adopted HACCP for at least some of their nonexporting establishments. Such convergence likely reduces the potential for trade disputes.

New kinds of regulation or public intervention that focus on provision of voluntary information, such as certification for certain kinds of production practices, can facilitate trade, even when standards and requirements differ among countries. The FDA developed guidelines for minimizing microbial hazards, so-called Good Agricultural Practices (GAPs) (FDA, 1998). While not mandatory for market access, these guidelines provide a basis for exporters to privately certify food safety to produce wholesalers in the U.S. (see chapter 5). In another example, a USDA certification program for meat producers enables U.S. firms to export to the EU if they voluntarily apply to USDA for certification that they meet EU requirements (which are different from U.S. regulations). A USDA certificate then accompanies export shipments.

Although some new regulatory developments might mitigate potential barriers to trade, *the appearance of new hazards, or increased trade volumes from new sources, can lead to food safety incidents or disputes in trade*. A disease outbreak or newly identified hazard

often leads to disruptions in trade and may strain relations with trading partners. In the Belgium dioxin crisis, the Belgian government was criticized for not providing timely information to other countries that imported implicated products. The BSE discoveries in the United Kingdom disrupted trade between that country and other members of the EU. In the United States, the first food-related outbreak from *Cyclospora* in the United States led to an import ban on Guatemalan raspberries (see chapter 5).

The imposition of new, higher standards—as well as remaining differences among countries in how standards are developed and applied—can also lead to trade disputes. In particular, *rising standards and the rapid change in food safety regulation in the industrialized countries creates challenges for developing countries*, many of which have seen rapid growth in food exports since the 1990s (Unnevehr, 2000; Henson and Loader, 1999). For example, the proposed new standards for aflatoxin in the EU had a disproportionate impact on exports from developing countries (Otsuki et al., 2001). These countries may lack infrastructure to ensure basic sanitation in processing and transport, as well as public oversight to certify certain kinds of safety. The issue of equivalence in safety outcomes has been identified by developing countries as important in implementation of the SPS Agreement.

New or more stringent process standards entail greater difficulties in determining whether an equivalent safety outcome has been achieved. While HACCP may be widely accepted as an approach to food safety, specific HACCP regulations for specific food sectors may result in different outcomes. As required HACCP systems may or may not be linked to specific performance standards, it can be difficult to determine if imported products are as safe as those produced domestically (Hathaway, 1995). Other kinds of process controls, such as recordkeeping or traceability requirements,² can impose objectionable costs on trading partners. Whether such requirements are necessary to achieve an equivalent risk outcomes can be a matter of dispute. For example, the United States is concerned that new EU regulations regarding control of feeds to prevent BSE could impose unreasonable costs on the U.S. feed industry, given that the EU's own risk assessment indi-

² Traceability requirements are recordkeeping systems used to help keep foods with different attributes separate from others (Golan et al., 2002)

cates that the probability of BSE appearing in the United States is negligible (Schwartz, 2001).

Strong differences remain with respect to consumer risk preferences, consumer perceptions, and the role of nonscience issues in regulatory decisionmaking. Both consumer risk preferences and consumer perceptions are at issue in the longstanding disagreement between the U.S. and the EU over use of growth hormones in beef (see chapter 4). Nonscience issues such as the preservation of small farms are a consideration in EU decisions about inputs like growth hormones or r-BST (recombinant bovine somatotropin, a synthetically produced version of a naturally occurring hormone intended to increase milk production). Differences in perception and willingness to assume unknown risks are evident in more recent disagreements over the acceptability of genetically modified organisms (GMOs) and labeling of foods produced through modern biotechnology. Furthermore, nonscience issues such as ethical concerns about genetic modification are at play in the dispute over modern biotechnology. Food safety issues may be difficult to separate from other contentious issues in cases like these.

In summary, changes in regulatory approach may lead to some convergence in food safety standards, but the dynamic nature of food trade, the onset of new hazards, and differences in regulatory approach and capacity still instigate disputes and disruptions to trade.

Disruptions to Trade From Food Safety Regulation: Evidence From the WTO

The SPS Agreement was established under the WTO in 1995, as a result of the 1986-93 Uruguay Round of Multilateral Trade Negotiations. This Agreement provides a framework for determining the legitimacy of SPS measures that restrict trade and for resolving potential trade conflicts. Its requirement for regulatory transparency, key to enabling judgment about the purpose or design of a measure, is achieved by “notifications” (to the WTO) of proposed changes in regulations that could affect trade. Trading partners are then entitled to comment on the proposed changes. If differences cannot be resolved in bilateral discussions, countries can raise the matter in the WTO SPS Committee. These complaints provide some evidence of the extent to which new food safety regulations have created barriers to trade.

Complaints Raised in the WTO’s SPS Committee

WTO members submitted more than 2,400 SPS notifications to the WTO between 1995 and 2001. Each notification indicates, among other things, what the proposed measure is, which product or products it is applied to, if it is based on an international standard, and when it is expected to come into force. These notifications provide an opportunity for trading partners to raise questions or objections to proposed measures in the SPS Committee before they are adopted as regulations. WTO members have taken advantage of this notification process, registering 187 complaints (or counter notifications) in the SPS Committee between 1995 and 2001 (table 3.2).³ More than half (108) were related to human health measures (i.e., food and feed regulations). Developed countries were most often the source (68 percent) as well as the target (67 percent) of counter notifications that identified food and feed regulations as unjustified trade impediments. Both developed and developing countries cited the measures of developed countries in the majority of counter notifications related to human health. The complaints by developed countries (42) outnumbered those by developing countries (30) in this category, suggesting that access to the same scientific information and technologies still leaves ample scope for disagreement over food safety measures.

An examination of the counter notifications by commodity and hazard provides some insight into the sources of current tensions over regulations in international agricultural markets. Most notable are the number of counter notifications related to the regulation of transmissible spongiform encephalopathies (TSEs), which include BSE. TSE measures alone accounted for nearly half of the counter notifications related to food safety regulations since 1995, indicating the significant disruption to international trade caused by the BSE outbreak (table 3.3). This impact is related to the fact that cattle, the source of BSE, provide so many food and industrial products, including meat and milk for human consumption, gelatin for pharmaceutical purposes,

³ Other WTO committees have formally adopted the term “counter notifications” to reference complaints recorded in the minutes or reports of committee meetings. The SPS Committee has not done so. Complaints are variously recorded under “information from members,” “specific trade concerns,” and “other business” in the committee minutes. The term *counter notification* is used here to help distinguish the complaints raised in the SPS Committee from the complaints that proceed to formal dispute settlement in the WTO.

Table 3.2—Complaints (counter notifications) in the SPS Committee against trade partners, 1995 - 2001¹

Respondents:	Complaints by developed countries				Complaints by developing countries				Total
	Human health	Plant and animal health	Other ²	Subtotal	Human health	Plant and animal health	Other	Subtotal	
Developed country	42	15	1	58	30	23	1	54	112
Developing country	31	18	1	50	5	16	1	22	72
Multiple countries	--	1	--	1	--	2	--	2	3
Total complaints	73	34	2	109	35	41	2	78	187

¹ Entries exclude "repeat interventions" made by WTO members who registered complaints against the same measure more than once.

² Includes complaints about administrative issues and horizontal regulations that address multiple health objectives.

Source: WTO Summaries of the Meetings of the Committee on Sanitary and Phytosanitary Measures, G/SPS/R series, 1995-01 and authors' calculations.

Table 3.3—Distribution of complaints (counter notifications) related to human health measures in the SPS Committee, 1995 - 2001¹

Commodity	Complaints against measures regulating:							Total
	TSEs ²	Food additives	Foodborne pathogens	Toxins and heavy metals	Veterinary residues	Pesticide residues	Other ³	
Multiple animal products	44	--	--	8	--	--	--	52
Meat and meat products	4	--	8	2	2	--	--	16
Multiple agricultural products	--	1	--	13	--	--	2	16
Dairy/Eggs	--	--	6	1	--	--	2	9
Processed products	--	--	--	5	--	1	3	9
Feedstuffs	2	--	--	1	2	--	--	5
Horticultural products	--	--	--	--	--	1	--	1
Cereals	--	--	--	--	--	--	--	0
Total	50	1	14	30	4	2	7	108

¹ Entries exclude "repeat interventions" made by WTO Members who registered complaints against the same measure more than once.

² transmissible spongiform encephalopathies (TSEs) include bovine spongiform encephalopathy (BSE).

³ Complaints related to measures that regulated multiple hazards or genetically modified products, or had unknown objectives.

Source: WTO Summaries of the Meetings of the Committee on Sanitary and Phytosanitary Measures, G/SPS/R series, 1995-01 and authors' calculations.

semen for breeding, and other byproducts used in cosmetics, commercial animal feed, and elsewhere. The EU and Switzerland together registered more than half of these complaints, which were often directed at the initial emergency measures adopted by countries in 1996. The EU itself later became the target of 10 complaints following implementation of its new, extensive BSE regulations. Examples include Chile and Peru's complaints against the EU's ban on the use of fish meal in ruminant feed, and Australia's complaint against EU restrictions on selected cosmetics.

The discovery of elevated levels of dioxin in Belgian animal feedstuffs also led to immediate restrictions on exports of a wide array of European animal products

in 1999 (see chapter 8). The EU subsequently raised objections to the emergency dioxin measures of nine of its trading partners who, in the view of EU officials, maintained restrictions on animal products when these actions were no longer justified.

The fact that more counter notifications (82) were related to the regulation of animal products than any other product category is not surprising in view of the significant impact of the BSE and dioxin events.⁴ The number of counter notifications (14) related to pathogen

⁴ This total reflects counter notifications related to restrictions in the following categories: multiple animal products (52), meat and meat products (16), dairy and eggs (9), and feedstuffs (5).

control measures for meat, dairy, and eggs was also a factor in the number of complaints against measures regulating animal products. The regulation of other products drew far fewer complaints. Together, the number of counter notifications related to regulations applied to “multiple agricultural products” (16), processed products (9), horticultural products (1), and cereals (0) accounted for fewer than one-fourth of the total counter notifications related to human health measures.

The WTO Secretariat has aggregated the 108 separate food safety-related counter notifications into 40 issues or “special trade concerns.” The Secretariat reports resolution or partial resolution in 16 of these cases (WTO, 2001a).

Has Multilateral Oversight Helped Resolve Trade Disputes?

The framework that governs the interface of trade and food safety regulation includes the SPS Agreement and the multilateral organizations that are charged by the WTO to further implementation of the agreement. The SPS Agreement rests on two premises: that basing domestic standards on international norms will reduce conflicts and lower transaction costs, and that requiring scientific justification for standards that deviate from these international norms makes it more difficult for countries to shelter domestic industries behind unnecessarily restrictive SPS regulations. The role of international standards and the work of scientific organizations are therefore critical to the WTO’s objectives of averting trade disputes and increasing welfare-enhancing trade.

Provisions of the SPS Agreement

Prior to 1995, rules for SPS measures in the 1947 General Agreement on Tariffs and Trade (GATT) had allowed measures that were “necessary to protect human, animal or plant life and health” but stipulated that measures should not constitute disguised restrictions or create unnecessary trade barriers. The WTO SPS Agreement reiterates earlier commitments under the GATT, but also requires regulators to: (1) base measures on a scientific risk assessment (*science-based risk management*); (2) recognize that different measures can achieve equivalent safety outcomes (*equivalence*); and (3) allow imports from distinct regions in an exporting country when presented with

evidence of the absence or low incidence of pests or diseases (*regionalization*).⁵ Adoption of international standards (*harmonization*) is encouraged, but not required (see box).

In addition to setting out the rights and obligations of WTO members, the SPS Agreement also establishes enforcement mechanisms. These mechanisms include the notification procedures and the establishment of an SPS Committee to discuss these issues on a continuing basis. WTO dispute resolution mechanisms for resolving conflicts between countries in a timely manner are also available. These mechanisms include formal consultations between the parties to a dispute, followed by adjudication by a WTO panel and the WTO Appellate Body if required.

Institutions in the Multilateral Governance Framework

Other intergovernmental organizations besides the WTO itself contribute to the implementation of the SPS Agreement by creating international standards or advancing scientific understanding of foodborne risks and their mitigation. The SPS Agreement identifies three organizations to promote harmonization through adoption of international standards: the Codex Alimentarius Commission (Codex) for human health measures; the International Office of Epizootics (OIE) for animal and human health measures; and the International Plant Protection Convention (IPPC) for plant health measures. Firms and governments have relied on the standards of these organizations—sometimes referred to as the “three sisters”—to facilitate the international exchange of agricultural goods for several decades, but their role has become more prominent since the SPS Agreement. The agreement does not require countries to adopt international standards, but those that do so are presumed to be in compliance with their WTO obligations.

While the SPS Agreement itself does not reference any other institutions, the SPS Committee also draws on the expertise of official observer organizations. The World Health Organization (WHO) and the Food and Agriculture Organization (FAO), which are well positioned to convene expert scientific panels on issues of emerging importance and to distribute their findings, are

⁵ Regionalization is more germane to the regulation of plant and animal health than food safety.

Box 3.2—Principal Provisions of the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures

The SPS Agreement requires:

- Science-based risk management (*Articles 2 and 5*): SPS measures must be based upon scientific principles and sufficient scientific evidence; more particularly, measures must be based on a risk assessment. Measures should be chosen so as to minimize distortions to trade and must be no more trade restrictive than necessary to achieve a country's "appropriate level of protection." Members are to avoid variation in the levels of health protection provided by its measures if this variation creates a disguised restriction on trade. Countries may adopt a provisional measure to avoid risk, but must seek information and carry out a risk assessment to justify permanent use of a trade-restricting measure.
- Equivalence (*Article 4*): A WTO member must accept that the SPS measures of another country are equivalent to its own if it is objectively demonstrated that the exporter's measures achieve the importer's appropriate level of protection, even if the measures themselves differ.
- Regionalization (*Article 6*): A country is required to allow imports from regions that are free or nearly free of pests or diseases.¹

These obligations are balanced by a recognition of:

- National sovereignty (*Article 3*): A country may choose a measure that differs from the interna-

tional standard to achieve its appropriate level of protection as long as it complies with the other rules of the Agreement. This recognizes that individual nations may be unwilling to subscribe to uniform measures for all hazards.

The Agreement endorses:

- Harmonization (*Article 3*): Members are urged (but not required) to adopt international standards. A country that does adopt the standards of the three designated international organizations is presumed to be in compliance with its WTO obligations.

The Agreement also establishes enforcement mechanisms, including:

- Notification: A WTO member is required to publish its regulations and provide a mechanism for answering questions from trading partners.
- WTO SPS Committee: The WTO Committee meets three to four times a year to develop guidelines and discuss contentious SPS measures on a continuing basis.
- Dispute settlement: Mechanisms include formal consultations between the parties to a dispute, followed by adjudication by a WTO panel if required. Decisions by trade dispute panels may be appealed to the WTO Appellate Body.

¹ This provision is more germane to the regulation of plant or animal hazards.

among the most influential observer organizations. Their work on BSE, biotechnology, and other issues has been key to the resolution of some conflicts, particularly those arising over emergency measures adopted by countries in response to newly identified hazards.

Implementation of the SPS Agreement

Three of the principles under the SPS Agreement—science-based risk management, equivalence, and harmonization—directly address some aspects of food safety regulation that create the potential for trade disputes.

Science-Based Risk Management

The obligation to base regulations on scientific risk assessment clearly reduces the latitude for disingenuous use of SPS regulatory interventions. In each of the three SPS disputes⁶ to reach the WTO Appellate Body since 1995, the regulations at issue were judged to violate this requirement.

⁶ The three cases were EU—Hormones (brought by the U.S. and Canada); Australia—Salmon (brought by Canada); and Japan—Varietal Testing (brought by the U.S.).

However, the impact of the risk management requirements extends far beyond formal dispute settlement. The clear obligation to base measures on science has led to the resolution of many issues before they advance to dispute settlement. In particular, food safety measures that discriminate among sources of supply attract close scrutiny, and sometimes are seen to lack scientific rationale. For example, an exemption to a ban on sauces containing benzoic acid that Australia had granted to New Zealand during their transition to a common food standards system was replaced with a tolerance level for all imports following a Philippine complaint in the SPS Committee. Similarly, Spain modified its regulatory regime for cadmium and copper residues in squid that held imports to higher standards than EU products in response to a U.S. complaint.

Disagreements over less overtly discriminatory measures have been resolved by means of updated risk assessments. For example, Australia rescinded its 1994 ban on three kinds of raw milk cheeses from Switzerland following completion of its 1999 risk assessment that indicated that Swiss processing protocols attained at least the same level of pathogen destruction as pasteurization in hard cheeses (though not for semi-hard or soft cheeses). Further study similarly led Korea to amend its new Food Code to exempt poultry meat destined for further processing and cooking from its zero tolerance standard for *Listeria*, thereby allowing imports of Thai frozen chicken to resume (WTO, 2002a).

While the obligation to base measures on risk assessments can often avert trade disputes, it cannot do so in all cases. Relevant risk assessments may not be available to inform regulatory responses to new hazards. Emergency measures have only accounted for 17 percent of the total SPS measures notified to the WTO, but because such measures are generally very trade restrictive, they often give rise to complaints if importers fail to modify policies as new evidence emerges. For example, many countries suspended imports of European dairy products immediately following the March 1996 announcement of a possible link between BSE and its human variant, vCJD. Most countries rescinded these bans when the OIE and the WHO reaffirmed that existing scientific data did not indicate that these products are BSE vectors. However, the EU had to repeatedly petition Argentine regulators before they modified restrictions on dairy products—including Belgian chocolate, German milk powder, and Swedish cacao oil butter—in 2001.

Risk assessments also do not avert disagreements over measures that reflect extremely conservative approaches to mitigating scientifically verified risks. For example, 11 countries (supported by 11 others) objected to the EU's proposed regulation to lower tolerances for aflatoxin, a naturally occurring carcinogenic class of chemicals, in a wide range of foodstuffs in March 1998 (WTO, 1998a). The new tolerances were to be enforced by new sampling procedures that exporters also regarded as onerous. The World Bank estimated that the new regime for cereals, dried and preserved fruits, and edible nuts would result in an annual export loss of \$650 million for nine African countries while achieving 1.4 fewer deaths per billion inhabitants than Codex standards (Otsuki et al., 2001).

The SPS Agreement protects a country's right to choose its "appropriate level of protection," stating only that when choosing these levels, members should (not "shall" which indicates a legal obligation) "take into account the objective of minimizing negative trade effects." The U.S. Statement of Administrative Action to Congress states that this provision, along with other language in the Agreement, "explicitly affirms the rights of each government to choose its levels of protection including a 'zero risk' level if it so chooses" (President of the United States, 1994). The national sovereignty principle reflected in the risk management provisions of the Agreement thus provides leeway for a country to adopt measures that achieve incremental risk reductions regardless of the cost (for its trading partners or its domestic consumers). These provisions were necessary to secure the support of developed countries during the negotiations, but by allowing policies that vary significantly from the norm they widen the scope for trade disputes, even among developed countries themselves.

The requirement to use the least trade restrictive means to achieve the appropriate level of protection did contribute to the resolution of many of the complaints related to the EU's proposed aflatoxin regime. The EU eventually decided to adopt the international standard for aflatoxin in groundnuts (15 parts per billion (ppb)) in lieu of the 10 ppb level it had originally proposed, agreeing with exporters that further processing (for confectionary products) or sorting (for direct human consumption) would lower residues to 10 ppb in final products. The EU also adopted a less costly, but equally rigorous sampling procedure to enforce its new standards (WTO, 1998b). However, not all complaints were resolved: developing countries, particu-

larly Bolivia and Argentina, continue to raise objections to some of the aflatoxin tolerances that were not revised (WTO, 2002a).

Other considerations besides scientific evidence and risk aversion sometimes factor into risk management decisions, leading to divergent policies that restrict trade. For example, recent developments in the regulation of food irradiation illustrate how other factors can lead to dissimilar policy choices despite a strong international consensus about the risks and benefits of this technology. The FAO, the International Atomic Energy Agency (IAEA), and the WHO concluded in 1980 (and in several followup studies) that the irradiation of any food up to a specified dose is safe and does not alter the nutritional content of food. In fact, the WHO encourages the use of irradiation in order to reduce the incidence of foodborne diseases caused by microorganisms (European Communities, 2001). The United States has long approved the use of irradiation for spices, and has more recently approved its use for a number of other food products, including meats and meat products, fruits and vegetables, and juices. However, other developed countries have been more reluctant to allow the use of this technology. European, Canadian, and Australian regulators currently allow dried herbs, spices, and other minor products to be irradiated, but have encountered resistance to permitting irradiation of other products from consumer and domestic industry representatives.

In fact, EU authorities have been considering irradiation regulations for more than 10 years. Despite the repeated recommendations of the EU's Scientific Committee on Food to allow the irradiation of products such as fish, fresh meats, poultry, produce, and raw milk cheeses, consumer concerns about the safety of this technology and related questions about the "technological need" for this form of pathogen control persist (European Communities, 2001). Current EU Commission proposals for a list of products that may be irradiated have drawn criticism from the United States in the SPS Committee as the list includes only a few products such as frogs' legs, peeled shrimp, herbs, spices, and seasonings (WTO, 1998c).

While countries' increasing reliance on scientific risk analysis to inform food safety policies has led to a convergence of standards, a number of gaps remain. This is true even among trading partners who are at the forefront of this trend, as the WTO counter notifications indicate. For some of these complaints, the

SPS Agreement's requirements to base measures on scientific risk assessments and to use the least trade restrictive means for achieving public health goals have led to the quick resolution of trade conflicts, particularly those involving transparently discriminatory measures. The Agreement's science requirements have also prodded authorities to revisit regulations whose longevity could be attributed to simple inertia rather than overt protectionism. The SPS Agreement provides no further elaboration of risk management principles, other than the recommendation to minimize trade effects when choosing levels of risk reduction. The countries that negotiated the SPS Agreement judged that it was inappropriate for the WTO to be more prescriptive about risk management, seeing Codex as the better forum for the development of best regulatory practices related to food safety.

Some guidance has been provided by Codex⁷ but, as yet, there is still disagreement over the role of precaution and "other legitimate factors" in Codex debates as well as in regulatory policy (as in the aflatoxin and irradiation cases) (Codex Alimentarius Commission, 2001). Eventual agreement on risk management principles in Codex may further narrow the scope for trade disagreements, but these principles are unlikely to eliminate disputes over the question of the best course of action to take, given the scientific evidence. Science is descriptive, not prescriptive; a risk management decision will therefore always require a choice among different policy options, each with different costs and benefits. Options that severely limit market access to achieve extremely incremental health benefits are likely to be contentious, even if based on science.

Equivalence

Article 4 of the SPS Agreement requires members to accept other countries' measures as equivalent to their own if an exporter can demonstrate that its measures achieve the importer's desired level of SPS protection. This provision recognizes that regulatory flexibility allows countries to allocate scarce resources efficiently rather than identically. The Agreement also promotes trade based on equivalence of SPS measures by requiring members to enter into consultations for bilateral

⁷ Two of the most important Codex documents providing risk management guidance are the "Statements of Principle on the Role of Science in the Codex Decision-making Process and the Extent to which Other Factors are Taken into Account" (or "General Principles") and the "Working Principles for Risk Analysis."

and multilateral equivalence agreements upon request by the exporter.

Equivalence determinations usually involve process standards, since countries are better able to compare performance standards, which stipulate observable and/or testable attributes of end products. An enormous number—and arguably a growing proportion—of SPS measures are process standards. The equivalence obligation therefore has the potential to yield significant benefits in international markets for products such as cheeses, meats, fresh produce, and seafood for which process standards are key to managing microbial risks.

Although the SPS Committee has urged members to submit information on their bilateral equivalence arrangements, few have done so (WTO, 2001b). Consequently there is no systematic accounting of achievements to date.⁸ However, the use of equivalence is still rare in international food trade (Gascoine, 1999.) The United States and the EU did sign a framework agreement for recognizing equivalence of some SPS measures for selected animal products in July 1999, after 6 years of occasionally high-profile negotiations over matters as minute as the colors of wall paint in food-processing facilities. This framework agreement applies to \$1 billion in EU exports of dairy products, fish, and meat to the United States, and \$1 billion in U.S. exports of fish, hides, and pet food to Western Europe. The exporting country must still comply with the importing country's measures that are not included in the framework agreement, including those regulating food and feed additives and animal drug residues. Both the EU and the United States also recognize the equivalence of some measures for selected meat and dairy products from Australia, Canada, and New Zealand. However, numerous regulatory differences remain in contention even between countries generally recognized as having rigorous regulatory standards that are rigorously enforced.

⁸ More systematic assessment of the impact of equivalence in global food trade will be possible in the future as the result of the Committee's recent actions to increase the transparency of equivalence arrangements. The Committee revised its recommended procedures to provide for the notification of equivalence of SPS measures in 2001 and finalized the notification format in June 2002. In its Decision on the Implementation of Article 4, the Committee noted that equivalence could be accepted for a specific measure or measures related to a certain product or categories of products, or on a systemwide basis (WTO, 2001c).

Often, differences hinge not only on the equivalence of different process standards themselves, but also on how conformance with different standards is ascertained. There is inevitably more discretion in enforcement of process standards than for performance standards, which is why institutional capability and integrity figures so importantly in equivalence determinations. In many instances, equivalence is controversial because judgment about such matters, unsurprisingly, differs between exporters and importers. In other instances, there is disagreement between governments and domestic consumer groups.

Different views on the appropriate roles for the private and public sector in conformity assessment have likewise given rise to trade disputes among developed countries. For example, the United States rejected Australia's 1997 "Project 2" proposal to replace government officials with company-paid inspectors in meat export plants. Some Australian officials thought that this rejection lacked a legitimate rationale, but did not bring the matter to the WTO (*World Food Chemical News*, 1997b). U.S. regulators subsequently approved Australian exports under a revamped program that increased the role of government oversight, but redeployed government resources from traditional inspection duties to verification of control strategies, in line with changes being considered under USDA's HACCP-based inspection models project (USDA, 1999).

Differences over government and industry roles in certification have also held up EU recognition of the equivalence of the U.S. production and inspection systems for food-grade gelatin. U.S. exports to the EU have been suspended since June 2000, when the European Commission's new BSE-related regulations came into force. The European Commission has indicated that all U.S. gelatin safety measures, with the exception of two issues pertaining to the source of raw material and certain end-product specifications, are equivalent to corresponding EU measures. However, the EU is currently unwilling to import U.S. gelatin until there is more FDA oversight of industry self-certification of compliance with the two "non-equivalent" measures (WTO, 2002a).

Given the problems that developed countries have had with equivalence, developing countries have questioned whether this provision of the SPS Agreement will actually provide many export opportunities for them (WTO, 1998d). Some equivalence arrangements between developing and developed countries do exist,

especially for seafood products.⁹ However, developing countries—echoing the claims of developed countries—have argued that developed countries often require “compliance” rather than equivalence of measures. Even developing countries that have had substantial success as agricultural exporters—such as Brazil, Mexico, and Thailand—have gone on record to note the difficulties in gaining recognition of equivalence (WTO, 1999; WTO, 2001a). Globally, the limited access to developed country markets for poultry meat illustrates both the potential and challenge of equivalence. Of the 144 countries that are WTO members, only 15 are eligible to export fresh, chilled, or frozen poultry meat to the EU, 4 may export to the United States, 1 can ship to Canada, and none are allowed to export to Australia.¹⁰

Developing countries aired their concerns related to equivalence and other SPS Agreement commitments in “implementation negotiations” undertaken by the WTO General Council in May 2000 after the 1999 Seattle Ministerial Conference failed to launch a new round of trade negotiations (WTO, 2001d). In response, the SPS Committee began to consider how it could advance implementation of the Agreement’s equivalence provisions. To date, the Committee has identified options for expediting equivalence determinations, urged the international standards organizations to produce equivalence guidelines, and developed procedures to increase the transparency of such arrangements through notification (WTO, 2001c). The standards organizations quickly supported the WTO’s initiative: both Codex and the OIE have completed draft guidelines for judging equivalence.¹¹

⁹ The EU, for example, has stated that 62 countries have been recognized as implementing an equivalent system of inspection and certification for fishery products; another 41 await equivalence evaluations, but can currently export fishery products to individual member States on the basis of bilateral agreements (WTO, 2002b).

¹⁰ In addition to the four countries that are permitted to export fresh, frozen, and chilled poultry to the United States (Canada, Great Britain, France, and Israel), some plants in northern Mexico may also re-export U.S.-origin poultry meat to the United States after minimal processing.

¹¹ Codex adopted “Guidelines for the Judgement of Equivalence Agreement Regarding Food Imports and Export Inspection and Certification Systems” (GL-34) in 1999, but has yet to adopt its “Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.” The OIE’s “Judgement of Equivalence of Sanitary Measures relating to International Trade in Animals and Animal Products” is also still under consideration by members.

Together, these efforts may further the objective of regulatory flexibility, but significant constraints remain. First, the administrative burden of equivalence determinations is often significant, involving evaluation of infrastructure, overall program design and implementation, and specific technical requirements. The United States has stated that its experience indicates the potential for equivalence may be limited because the actual trade benefits often do not justify this administrative burden (WTO, 2000).¹² Second, recognizing the equivalence of an alternative regulatory regime may require national regulators to offer the same alternative to domestic producers, requiring new or revised domestic regulations. Finally, measures may be specified in legislation, leaving little scope for regulators to consider other options. For example, the U.S. Egg Products Inspection Act of 1970 requires continuous inspection of processed eggs by government inspectors, a standard that is currently met by only one other country (i.e., Canada).

Harmonization

The SPS Agreement’s endorsement of harmonization stems from repeated complaints by exporters that complying with divergent SPS measures substantially increases the transaction costs of trade. Firms that ship products to several different markets stand to gain more from harmonization than from equivalence if harmonization results in lower production and certification costs per unit.

Harmonization can also benefit consumers, especially if the origins of regulatory heterogeneity are the result of chance events, information differences, or interest group capture. Harmonization is more likely to be inappropriate if incomes, tastes, and risks are the primary sources of variation in national regulations. Differences in risk perceptions, available market information, the incidence of risks in production, and traditional methods of food processing and preparation all lead to differences in food safety outcomes among countries. Thus, the benefits of a food safety standard may exceed its costs in one country, but not necessarily elsewhere.

¹² The United States has also cautioned that equivalence does not imply mutual recognition: under the equivalence provisions of the SPS Agreement, market access is contingent on a scientific determination that an exporter’s alternative measure achieves the level of SPS protection required by the importer, not on reciprocity.

However, the impact of harmonization on trade appears to have been constrained as much by the lack of international standards as by normative considerations since the SPS Agreement came into force. The majority of 1995-99 notifications from WTO members stated that no international standard existed for the notified measure. Underinvestment in the development of international standards has led not only to too few international standards, but also to too many outmoded standards, which may account, in part, for the low adoption rate for those standards that do exist. Over the first 4 years of the SPS Agreement, partial or full acceptance of international standards as a percentage of total notified measures was highest for the lower-middle income countries (38 percent), followed by high-income (22 percent), lower income (20 percent) and upper-middle income countries (17 percent) (Roberts et al., 1999).

Still, international standards did settle some trade disputes. The OIE's continually updated assessments of potential vectors of BSE have been especially important in the wake of a crisis that has affected so many traded products. Countries cited OIE recommendations as the basis for resolution or partial resolution of 3 of the 13 "specific trade concerns" related to BSE measures. In these cases, Chile, India, and Slovakia (as well as Argentina) lifted bans on imports of dairy products or animal genetics as the result of the OIE's repeated assessments that these products would not transmit the disease (WTO, 2001a). The BSE outbreak has been a dramatic, but not isolated, example of a new hazard spawning new and extensive regulation. Information dissemination via international standards will be important not only to health authorities, but also to the trade system in these instances.

The nature of international standards is also important in assessing their impact on trade and trade disputes. Over the past decade, international standards organizations have allocated more of their resources to the development of metastandards—which identify common *approaches* to risk identification, assessment, and management—rather than international standards *per se*. Exporters' anticipated gains from international metastandards may be smaller than from international standards, as adherence to the same general guidelines still leaves scope for countries to develop different regulatory regimes for foodborne risks. For example, countries that follow Codex's 1997 General Principles of Food Hygiene guidelines, which provide a template for HACCP programs, still have substantive differ-

ences in their requirements for meat imports, as the EU's 1997 ban on U.S. poultry meat illustrates. Thus, the international standards organizations have contributed more to the trading system in recent years by setting out scientific approaches to regulation than by promulgating standards that are identical across adopting countries.

Conclusions and Implications

Recent trends in food safety regulation create the potential for both more and less dispute in international food trade. Disputes may be eased by the similarity in regulatory trends and approaches among industrialized countries, such as the growing use of risk analysis and the adoption of HACCP requirements. Disputes may arise from the increased stringency of food safety standards; sudden actions taken in response to a food safety crisis; the difficulty of determining equivalence of risk outcomes from new process standards; differences in risk management approaches; and differences in the capabilities of countries at different levels of development.

The principles and mechanisms established in the SPS Agreement appear to be well-targeted to the potential sources of disputes, averting, diffusing, and resolving a number of food safety-related disputes since 1995. The SPS Agreement's requirements for transparency of regulatory regimes have promoted symmetry of information among WTO members. The establishment of the SPS Committee has provided a forum for airing grievances and made it easier to identify and track contentious regulations. These mechanisms have facilitated the resolution of disputes between countries at every level of development.

The large number of complaints by developed countries against the measures of other developed countries suggests that some gaps remain in convergence around SPS regulatory principles. The requirements to base measures on science and adopt minimally trade distorting measures still leaves scope for substantial disagreement among countries at the same level of development.

Differences in the use of precaution are one source of variation in food safety policies. Under the SPS Agreement, countries have been able to adopt measures that are substantially more conservative than the norm, as the EU's new aflatoxin regime illustrates.

Countries are also able to exercise caution by provisionally adopting measures to mitigate risks that are not fully understood. Most countries did so when the BSE crisis emerged in 1996, initially banning all bovine products from all 15 members of the EU. However, the right to exercise caution is balanced in the Agreement by the obligation to seek additional information to justify the permanent use of a measure, an obligation that benefited European exporters as more evidence emerged about the country/product sources of BSE risk. The balance struck by the SPS Agreement in the BSE case and in other instances seems to have accommodated legitimate variation in policies attributable to risk aversion or uncertainty, while disallowing trade restrictions that are based on protectionism or inertia.

The SPS Agreement has been less successful in reducing transaction costs to trade resulting from diverse regulations. Determining equivalence in risk outcomes has proven challenging. At a minimum, it may raise monitoring costs to determine that complex process standards are followed in the exporting country. Further difficulties arise when production practices and the incidence of risks vary widely across countries, making it difficult to determine if a process standard will lead to an equivalent risk outcome. Institutional barriers are also a factor, as when policy instruments are specified in legislation.

Thus, food safety standards, especially process standards, are likely to be contentious in international trade. The international standards organizations have improved the functioning of food markets, but more by improving the quality of regulation (which benefits consumers) than by reducing the transaction costs of exporting to different markets (which benefits exporters).

Multilateral institutions continue to work on an array of projects to improve the current governance of food safety and trade. For example, the Codex Commission aims to increase the relevance of its standards in international trade by adopting a “fast track” approval procedure for some standards, creating more working groups to address new issues, and increasing the number of its meetings to speed the adoption process. These institutional innovations are likely to lead to more immediate and concrete results than the continuing debate over the development of risk management principles. Other initiatives, such as the identification of the types of technical assistance that best help developing countries meet food safety requirements in key export markets, could also yield important benefits. But responsibility for increasing welfare-enhancing trade ultimately rests with national authorities who determine whether the spirit as well as the letter of their international obligations are fulfilled.

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