Food Safety and Quality: Regulations, Trade, and the WTO

Laurian Unnevehr (University of Illinois, USA) and Donna Roberts (Economic Research Service, USDA)

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Food and agricultural products are unique in posing potential biological risks to human, animal, and plant health. SPS measures to address these risks are presumed to pose potential barriers to trade. The 1995 SPS Agreement concluded as part of the Uruguay Round established a framework for addressing disputes regarding these measures and ensuring that they impede trade as little as possible. When it was concluded, many assumed that reduced market barriers to agricultural trade would make the role of SPS measures more apparent and important in trade. In fact, reductions to market barriers have been modest, as discussed elsewhere in this conference. But even so, SPS measures have received increased attention in trade discussions.

This increased attention arises from two trends in the international food system. First, regulation of food safety, animal, and plant health is evolving rapidly in developed countries. While some trends in regulation are consistent with minimizing trade distortions, the general trend towards more stringent regulation of a wider range of risks and quality attributes raises new potential barriers to agricultural trade. These trends are often entwined with increased consumer demand for credence attributes of food products in general, because quality and safety are often jointly produced.

Second, non-traditional agricultural exports from less developed countries to developed countries, particularly of fresh and minimally processed products, are growing rapidly. This trade arises in part due to the lack of traditional protection for some of these commodities, such as seafood and tropical fruits. But such products frequently have high risks for certain kinds of SPS hazards, which may be exacerbated by trade over long distances. As developing countries work to meet higher and evolving food safety standards, they have raised concerns about whether such standards will impede their participation in world trade. Taken together, these two trends in the international food system pose continuing challenges to the SPS Agreement and to efforts to reduce barriers to agricultural trade.

Despite the intent in the Uruguay Round to provide a durable multilateral framework to discipline the use of food safety and quality regulations, proposals submitted by countries both leading up to and following the Doha Ministerial Conference in November 2001 indicate that a remarkable divergence of views has emerged about this framework since the conclusion of the last trade talks. Developing country proposals signal frustration with the increasingly exigent standards faced by their exports, the new obligations to justify their own regulatory regimes, or both. Their concern is that without more progress on meeting these challenges, their participation in international trade will be further marginalized, regardless of the progress made in reducing other trade barriers.

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1 Paper presented at the international conference on Agricultural Policy Reform and the WTO: Where are We Heading?, Capri, Italy, June 23-26, 2003. Authors are Professor, Dept of Agricultural and Consumer Economics, University of Illinois; and Senior Economist, Economic Research Service, USDA. Roberts writes in her own capacity, and the ideas here should not be taken to represent those of her employer.
in the Doha Round. The proposals of some developed countries, however, would likely increase the challenges faced by developing countries. These developed countries argue that the adequacy of current WTO rules has been called into question by new production technologies, new disease outbreaks, and new demands for regulations that are responsive to consumer concerns. They call for modification of WTO rules to give governments more latitude in the regulations of risk and differentiation of products for the benefit of consumers. Some developing countries have supported these proposals, but most (particularly from the Cairns Group) see them as running strongly counter to their interests, making it still more difficult to gain access to developed country markets and diverting attention from the core agenda of lowering other barriers to trade.

The Doha Declaration calls for negotiations on issues directly and indirectly related to food regulation in a number of different venues. Some negotiations were concluded at the Ministerial Conference itself, where countries agreed to initiatives related to implementation of the SPS and TBT Agreements to further the integration of developing countries into the global food system. The agricultural negotiations are to address “non-trade concerns” including food safety, labeling, and animal welfare. The trade and environment negotiation group will address how WTO rules are to apply to WTO members that are also parties to environmental agreements, including the Cartegena Protocol, which authorizes use of the precautionary principle in risk management. The Declaration also directs the WTO’s Trade and Environment Committee to continue its work on environmental labeling. In short, although no country has formally proposed re-opening the SPS or TBT Agreement, the WTO will be immersed in issues during the Doha round that will further define the principles for global food regulatory governance.

The objective of this paper is to examine the WTO’s record on food safety and quality issues in order to ascertain its strengths and weaknesses, particularly with respect to the primary objective of the Doha Agenda, which is helping developing countries. Thus, we begin by examining the performance of the SPS Agreement to date in reducing barriers to trade and mitigating disputes. Next, we consider the challenges ahead for the global trading system arising from the two trends mentioned above. Finally, we consider the potential for current negotiating proposals regarding changes to the SPS under the Doha Agenda to mitigate barriers to trade.

How well has the SPS agreement worked?

This question can be answered either from the perspective of those pursuing more open trade or from the perspective of those advocating more consumer protection. In either case, the short answer is that the SPS agreement has worked fairly well. Many countries have implemented new measures and regulations, as protected by their right to national sovereignty in setting risk standards. At the same time, the SPS agreement has

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2 The WTO initiated “implementation negotiations” to address the needs of developing countries in May 2000 after the Seattle Ministerial failed to launch a new round of trade negotiations (WTO, 2001d).
fostered approaches that are least trade distorting and has mitigated many potential disputes. We examine the performance of the agreement with respect to each of its major principles: Transparency, Scientific Risk Assessment, Equivalence, and Harmonization.

Transparency has clearly improved under the SPS agreement. An enquiry point has been established by 85 percent of the members so that potential exporters can obtain clarification about standards and measures. The notification and counter-notification systems are widely used to inform other member countries of changes in standards and to raise concerns or objections.

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 since 1995. More than half of these counter notifications (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 identified the measures of developed countries in the majority of counter notifications related to human health.

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, a statistic that indicates the significant disruption to international trade caused by the BSE outbreak. This impact is related to the fact that cattle, the vector of BSE, are the source of so many food and industrial products, including meat and milk for human consumption, gelatin for pharmaceutical purposes, semen for breeding, and other by-products used in cosmetics, commercial animal feed, and other products. 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. Another emergency event, the discovery of elevated levels of dioxin in Belgian animal feedstuffs, similarly led to immediate restrictions on exports of a wide array of European animal products in 1999. Thus, the notification and cross-notification

3 Other WTO committees have formally adopted the term “counter notifications” to reference objections or requests for additional information from trading partners. 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.
system has been particularly useful in mitigating trade issues arising from emergency measures undertaken in response to new or unexpected risks to the food supply.

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 disputes to reach the WTO Appellate Body since the Agreement came into effect, the regulations at issue were judged to violate this requirement. However, the impact of the science-based risk management requirements of the SPS Agreement extends far beyond formal dispute settlement results. \textit{For many 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.}

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. 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.

Risk assessments, however, do not avert disagreements over measures that reflect extremely conservative approaches to mitigating scientifically verified risks. For example, eleven countries (supported by eleven 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 which exporters also regarded as onerous. The requirement to use measures that are no more restrictive than necessary to achieve a chosen 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 and adopted a less costly sampling procedure to enforce its new standards (WTO 1998b). However, not all complaints were resolved: developing countries, particularly 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 heterogeneous policy choices despite a strong international consensus about the risks and benefits of this technology. The FAO, the International

\footnote{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 United States).}
Atomic Energy Agency (IAEA), and the WHO concluded in 1980 (and in several follow-up studies) that the irradiation of any food up to a specified dose is safe and does not alter the nutritional content of food. 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. EU authorities have been considering irradiation regulations for more than ten 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, irradiation opponents note European consumer concerns about this technology, and question the “technological need” for this form of pathogen control (European Communities 2001).

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 templates for best regulatory practices related to food safety. Eventual agreement on risk management principles in Codex may further narrow the scope for trade disagreements, but it is unrealistic to expect that these principles could eliminate disputes. 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. Even if based on science, options that severely limit market access to achieve extremely incremental health benefits are likely to be contentious.

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. The Agreement also requires members to enter into consultations for bilateral and multilateral equivalence agreements upon request. 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 theoretically 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 policy instruments for managing microbial risks.

There is no systematic accounting of negotiation of equivalence arrangements to date, but their use is not common in international food trade. The administrative burden of equivalence determinations is often significant, involving evaluation of infrastructure, overall program design and implementation, and specific technical requirements. Six

6 Although the SPS Committee has urged members to submit information on their bilateral equivalence arrangements, few have done so (WTO 2001b). Gascoine (1999) discusses reasons for limited early use of equivalence in international food trade.
years of negotiations over matters that extended to details such as the colors of wall paint in food-processing facilities were required for a framework agreement recognizing equivalence of some SPS measures for selected animal products that was signed by the United States and the EU in July 1999. 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.

Often, differences hinge not only on the equivalence of different process standards themselves, but also on how conformance with different standards is ascertained. For example, differences over government and industry roles in certification led to the U.S. rejection of Australia’s 1997 “Project 2” proposal to replace government officials with company-paid inspectors in meat export plants. Some Australian officials thought that this decision lacked a legitimate rationale, but nonetheless did not bring the matter to the WTO (World Food Chemical News 1997b). Similar differences over the appropriate degree of public oversight have held up EU recognition of the equivalence of the US production and inspection systems for food grade gelatin. Exports from the US 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 most US gelatin safety measures are equivalent to corresponding EU measures. However, the EU has been unwilling to import US 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. 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

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6 U.S. regulators subsequently approved Australian exports under a re-vamped program which increased the role of government oversight, but re-deployed government resources from traditional inspection duties to verification of control strategies (USDA, Food Safety Inspection Service 1999).

7 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).
may export to the United States, I can ship to Canada, and none are allowed to export to Australia.  

More systematic assessment of the impact of equivalence in global food trade will eventually be possible because of a recent decision by the SPS Committee to increase the transparency of equivalence arrangements.  

In spite of considerable activity to develop equivalence arrangements, significant constraints remain.  First, the time and resources required for equivalence determinations can be significant. 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).

Secondly, recognizing the equivalence of an alternative regulatory regime may require national regulators to offer the same alternative to domestic producers, requiring, in turn, new or revised domestic regulations. And 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).

The SPS Agreement’s endorsement of harmonization stems from repeated complaints by exporters that complying with divergent SPS measures substantially increases the transactions 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 on a per unit basis. Harmonization can also benefit consumers. This outcome is more likely 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, production practices, and the incidence of 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.

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. Under-

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8 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.

9 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 systems-wide basis (WTO 2001c).

10 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.
investment 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 four 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).

The nature of international standards is also important in assessing their impact on trade and trade disputes. Over the past decade, the 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 differences in their requirements for meat imports, as the EU’s 1997 ban on U.S. poultry meat exports 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.

To sum up, the SPS agreement has facilitated trade through increased transparency and application of scientific risk assessment to SPS measures. Many disputes have been resolved, but disagreements remain regarding the role of science, precaution, and “other legitimate factors” in setting standards. These disagreements set the stage for continued disputes among developed countries, as we discuss below. Little progress has been made in the areas of equivalency or harmonization, both of which would likely facilitate trade from less developed countries. Next, we turn to a consideration of the challenges ahead for the SPS Agreement.

The Challenges Ahead

As mentioned in the introduction, two trends create continuing challenges for the SPS agreement. The first of these trends is the rapid evolution of food safety regulation in developed countries during the 1990s. Food safety regulatory agencies are increasingly:

(1) Using risk analysis to design regulation,
(2) Recognizing that a farm to table approach is often desirable for 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,\(^{11}\)

(5) Adopting more stringent 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 regulatory developments arise from increased scientific understanding of food safety issues, growing consumer affluence, and changes in the way that food is produced and consumed (Unnevehr and Roberts 2002).

New regulatory initiatives and the growth in world food trade have several implications for how food safety standards impact international trade in food products, and for potential trade disputes. First, the simultaneous move towards improved safety among the 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. USDA’s survey of 35 countries that export meat and poultry to the United States provides evidence in support of the demonstration effect (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 one-half had adopted HACCP for at least some of their non-exporting establishments. Such convergence likely reduces the potential for trade disputes.

New kinds of regulation or public intervention that focus on voluntary information provision, such as provision of 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 on fruits and vegetables, so-called Good Agricultural Practices (GAPs) (FDA 1998). While not mandatory as a requirement for market access, these guidelines provide a basis for exporters to privately certify food safety to produce wholesalers in the U.S. Another example is the USDA certification program for meat producers exporting to the EU. Although the specific EU requirements for meat products differ from those in the US, firms can export to the EU if they voluntarily apply to USDA for certification that they meet EU requirements; a USDA certificate 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 nations.

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\(^{11}\) HACCP systems identify potential sources of pathogen contamination and other food safety hazards, and establish procedures to prevent contamination and adverse impacts to humans through these foods.
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 (Calvin et al. 2002).

The imposition of new, higher standards can lead to trade disputes, as well as remaining differences among countries in how standards are developed and applied. 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 during the 1990s (Unnevehr 2000, Henson and Loader 1999), particularly for fish, seafood, fruits and vegetables. U.S. FDA detention data for imports provides one indicator of where difficulties may arise in meeting food safety standards. The most common food safety related reasons for detentions are either pesticide residues on vegetables or microbial contamination of seafood. Most of these detentions occur for imports from less developed countries. The EU has banned imports from less developed countries for food safety violations several times during the last decade, including actions against Bangladesh (shrimp) and Kenya (Nile perch). New standards can also cause difficulties for less developed countries. As discussed above, the proposed new standards for aflatoxin in the EU had a disproportionate impact on exports from LDCs (Otsuki et al. 2001). These countries may not have adequate infrastructure to ensure basic sanitation in processing and transport and may lack public oversight to certify certain kinds of SPS compliance. These examples show that food safety issues can be problematic in these markets, and can work against other sources of comparative advantage for developing countries.

Where new or more stringent standards are in the form of process standards, there are 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). Similarly, other kinds of process controls such as record-keeping or traceability requirements can impose costs on trading partners. Whether such requirements are necessary to achieve an equivalent risk outcome 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 indicates that the probability of BSE appearing in the United States is negligible (Schwartz, 2001). Another area of increasing process requirements arises from growing concerns about biosecurity. In the U.S., the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 extends government authority to require record keeping by food producers and distributors, and also requires prior notification of import shipments and their point of entry. Within the U.S., some food industry groups have objected to the costs imposed by these new regulations, and they are expected to raise the costs of trade.

Traceability requirements are recordkeeping systems used to help keep foods with different attributes separate from others (Golan et al. 2002)
Process standards may also be established for food quality— not safety— attributes associated with production practices and geographic origin of food products. These attributes are also of growing importance to consumers and have the potential to create trade barriers. Such attributes include production practices such as those that influence animal welfare or sustainability, as well as labeling regulations to protect use of names of historic geographic origin (EU) or to indicate country of origin (US). Mandatory product differentiation, traceability, labeling and associated costs of monitoring and verification of production practices can introduce additional technical barriers to trade. While not directly related to SPS agreement, these areas often fall together with other “consumer concerns” in terms of perceived trade-offs for policy makers between responding to consumer demand and opening up markets to trade. Furthermore, these attributes may be jointly managed with food safety in practice, and thus regulations may be perceived by producers as similar in impact or even indistinguishable from safety related process standards.

Strong differences remain with respect to consumer risk preferences, consumer perceptions, and the role of non-science issues in regulatory decision making. This is in spite of widespread agreement regarding the elements of food safety regulation outlined above. These differences create potential for trade disputes among counties. Both consumer risk preferences and consumer perceptions are at issue in the long-standing disagreement between the U.S. and the EU over use of growth hormones in beef. Non-science issues such as concern about preserving 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. Opposition to GMOs arises from several potential concerns, including their potential risks to the safety of the food supply and to the environment (eg through the transfer of exotic genes to wild relatives). Furthermore, non-science issues are at stake in the dispute over modern biotechnology, such as ethical concerns about genetic modification. Because food safety issues in this case are difficult to separate from other contentious issues, potential trade barriers arising from regulation of GMOs will cut across existing agreements under the WTO and will in some cases extend beyond the WTO framework (eg the Cartagena protocol).

Roberts et al (2001) defined two different approaches to GMO regulation emerging in the world which set the stage for current controversies. These are the “substantial equivalence” approach adopted by the U.S., Canada, and Argentina and the “precautionary principle” adopted by the EU and Japan. Differences in approach lead to two controversies: The first is the ability of exporters to ship GMOs to importers who have not approved the specific variety; the second is whether or not such GMOs or their products must be labeled and separated from other varieties of the same crop/product.
Exporters such as the U.S. and Canada maintain that their approved GMOs are substantially equivalent to their conventional counterparts which are generally recognized as safe. Therefore they should not need to be excluded from markets or labeled. Importing countries such as the EU, Japan, and a few other European nations have adopted an approach based on precaution. This approach includes more rigorous requirements for pre-market approval, as well as import bans on non-approved GMOs and labeling requirements. Labeling and traceability requirements in the EU are viewed as part of a system for monitoring any adverse impacts of GMOs (see Box 1). Australia and New Zealand use the substantial equivalence approach for pre-market approvals, but have also adopted labeling regulations based on “consumer right to know” (see Box 1). Thus, their approach differs from that of other exporters.

Regardless of what transpires regarding pre-market approvals of GMOs, labeling regulations and their associated supply chain requirements are already impacting international trade (eg., Bullock and Desquilbet 2002). Regulations that are being adopted in several countries, including those in the EU, Japan, and Australia/New Zealand (Table 1) differ in their implications for trade. The information required by the labels differs significantly in terms of when labeling is required (eg. novel proteins present or not? major ingredient or any ingredient?). All three regulatory regimes specify the acceptable methods for meeting labeling requirements, and thus set both process and product standards. For example, the newest EU regulations require recordkeeping back through the supply chain regarding separate GM “events”. Thus crops with multiple modifications or products combining multiple GM products would require extensive records.

Disagreements among developed countries about how to regulate this new technology pose difficulties for less developed countries. This was dramatically demonstrated by the controversy over shipments of U.S. maize to southern African countries for famine relief in 2002. Some countries refused shipments of unmilled maize on the grounds that it could be planted and lead to the inadvertent introduction of GMOs into their domestic agriculture. Although these countries have little immediate prospect of exporting maize, they were reluctant to allow the establishment of GMOs. Many of these countries have implemented measures to control the introduction of GMOs and a few countries, most notably China, are considering labeling regulations (Roberts et al. 2001).

In summary, the dynamic nature of food trade, evolving consumer demands, the identification and understanding of new hazards, and differences in regulatory approach and capacity provide potential for new and continued disputes over differing food safety standards. Perhaps most challenging for the future is the growing number of process standards and the continued differences regarding the role of science in regulatory decision making. These two trends converge in the issue of GMOs, which may be particularly problematic for resolution in the WTO. The developing countries will be adversely affected by a lack of agreement among developed countries about these issues, as they will face varying standards in different markets and may not have the capacity to
segregate production. In the next section, we consider whether marginal changes proposed for the SPS agreement can help the WTO to meet these future challenges.

**How Are WTO Members Proposing to Address These Challenges?**

Several less developed countries have proposed specific ways to reduce the barriers raised by SPS measures and to reduce the burden of new international obligations under the SPS Agreement in Phase 1 of the agriculture negotiations (Table 2), including mandatory technical assistance (Mauritius) or adoption of international standards that take less developed countries’ circumstances into account (India). WTO members did agree to take some concrete steps to improve implementation of the current agreements at the Doha Ministerial (WTO 2001d). These initiatives include 1) development of a program to advance implementation of the equivalence obligation; 2) increased technical and financial assistance to enable developing countries to increase their participation in the international standards organizations and to fulfill their obligations (such as the creation of enquiry points) under these agreements; 3) longer time frames for developing countries to comply with the measures of importing countries, as long as staggered implementation still allows the importing country to realize its appropriate level of protection; and 4) increased technical assistance to help developing countries to comply with new standards if they pose significant impediments to trade.\(^\text{13}\)

Given our analysis above, only the fourth effort is likely to have substantial benefit. Better guidelines on equivalence will only benefit the less developed countries if they are actually put into practice by the developed countries, and past experience in this regard is not encouraging. The establishment of international standards has also not facilitated trade as discussed above except in terms of establishing broader frameworks for regulation. The transactions cost of participation in the international agencies is very high for less developed countries (Henson and Loader 1999), and the returns have yet to be demonstrated. One potential meta-standard that may aid less developed countries is the Codex effort to set out guidelines for HACCP that can be adapted to developing food systems (Jansen 2001). Such efforts may aid the development of domestic food regulation in middle income countries, but are unlikely to facilitate trade with developed markets to any great extent. Proposals to apply differing standards are also unlikely to be productive, as neither consumers nor producers in high income markets would tolerate such discrimination.

Technical assistance may be helpful if it can be focused on the provision of public services for exporting industries, such as animal and plant disease control, or inspection and certification for food growers, handlers, and processors. During the last decade, substantial public and private investments have taken place to meet standards and to certify production in many less developed country export markets (see Box 2). Where

\(^{13}\) Other issues on which no agreement could be reached were referred back to subsidiary WTO bodies (e.g., the SPS and TBT Committees) who are to discuss them further and report back to the committee overseeing all of trade negotiations in this round.
individual firms can undertake efforts and receive the benefits of market access, such investments are feasible. But when an exporting industry must rely on public sector efforts to facilitate trade, technical assistance may be necessary to ensure that such efforts are successful and are recognized in the importing market.

Beyond the specific initiatives which came into effect at the Ministerial Conference, the Doha Declaration commits WTO members to further negotiations on a number of issues related to food regulation through several different venues. Most importantly, the Declaration confirms that non-trade concerns will be part of the negotiations on agriculture, in addition to the three Uruguay Round pillars of market access restrictions, export subsidies, and domestic support measures resulting from national farm policies. In the Uruguay Round, countries also identified food security and rural development as non-trade concerns that required specific exemptions from the rules set out in the Agreement on Agriculture. In the Doha Round, some developed countries have identified food safety, food labeling, and animal welfare as additional non-trade concerns meriting special treatment (Table 2). They have proposed modification of rules set out in the agriculture agreement and in other agreements as they apply to agricultural products.

These proposals, reflecting some of the regulatory and market trends identified above, present challenges to the existing rules and to further integration of developing countries into the global economy. Specifically, several WTO members, primarily from Europe, advocate explicit recognition of the legitimacy of 1) the precautionary principle and 2) mandatory labeling of production processes to address consumer concerns related to food safety, animal welfare, culture, ethics and the environment. We now discuss those two issues and how they relate to the controversies over GM regulation and labeling. In both cases, general principles and trade rules are under discussion, but the political context for the discussion is the difference in viewpoints regarding GM foods.

The precautionary principle has been the subject of informal discussions in Phase 2, initiated by the EU and Japan. Article 5.7 of the SPS agreement allows measures to be adopted in cases of uncertainty or insufficient information, but also calls for timely review of new information to support such measures. The EU has proposed that WTO members agree to a written understanding, interpretation, or guidance on the criteria for the implementation of Article 5.7 “to avoid the increased risk that extreme and unjustified measures will be applied, and that the [WTO] will be confronted with an escalating number of disputes.” Specifically, the EU proposes six criteria for the application of precaution which, in its view, endorses the interpretations of the Appellate Body in the two SPS dispute cases where the use of precaution was at issue: EC- Hormones and Japan – Varietal Testing. These criteria are proportionality; non-discrimination; consistency; consideration of the benefits and costs of action and inaction; development of new scientific information to justify continuing use of provisional measures, and; reliance on respected (but not necessarily majority) scientific views. Japan’s paper recommends closer coordination on food safety between the WTO and other multilateral

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14 See Roberts et al. 2001 for a discussion of the findings in those two cases.
organizations, primarily the OECD and Codex, given consumers’ increased concerns about GM foods, BSE, dioxin, and other potential food hazards.

The proposed EU criteria are the same as those set out the “Communication from the European Commission on the Precautionary Principle” and the “Communication from the European Commission on Food Safety” issued in 2000, which draws on recent research on risk analysis and decision science (EC Commission 2000). The Commission states that “uncertainty does not justify inaction”, but adds numerous qualifications, such as the need for precautionary measures to be proportionate. The EU’s proposed understanding would hold provisional measures to a higher standard (from a decision science perspective) than routine measures. While three of the guidelines (non-discrimination, consistency, and development of scientific information) simply reiterate existing rules under the SPS Agreement, the agreement does not require routine measures to be based on a consideration of their costs and benefits as the proposed guidelines for provisional measures would. Endorsement of these stronger decision criteria for establishing SPS measures might ultimately be useful for fostering less trade restrictive measures, but a broader application of cost/benefit principles has not been proposed.

From a political perspective, it seems that the EU proposal seeks to establish the precautionary principle formally within the SPS agreement, and provides the supporting decision criteria in an attempt to make it acceptable to opposing views. The Commission’s approach is similar to U.S. guidelines for regulation in Executive Order 12866, which requires, among other things, that regulations maximize net benefits (EOP, 1993). Thus, there should be a basis for agreement on the validity of this approach. However, other countries, such as the U.S. and some members of the Cairns group, have seen this proposal as unnecessary. In their view, Article 5.7 has functioned well and further guidelines are unnecessary and they remain firmly opposed to incorporation of these principles into the SPS agreement.

Risk assessment and precautionary principle issues will be the focus of an intended U.S. suit against the EU in the WTO for an alleged EU moratorium on approval of GMOs. In June 1999, the EU put a hold on further approvals of GM crops, but EU officials say this was lifted in 2002 and that new approvals are in process. It is not clear how the criteria proposed by the EU would be utilized in this dispute over approvals of GM crops, and whether the potential costs, benefits, and risks of inaction and action would be debated. Alternatively, the debate may shift to the costs of “co-existence” between GM and non-GM agriculture, as resolution of the GM food disputes must eventually address differences in labeling regulation as well as crop approvals.

Proposals by the EU, Switzerland, and Japan have advanced the legitimacy of mandatory labeling for production and processing methods (PPMs) attributes in both Phase 1 and Phase 2 of the agriculture negotiations. These proposals seek to develop guidelines which explicitly acknowledge the right of WTO members to adopt mandatory labeling regimes for PPMs for food and agricultural products (including those that do not materially affect the end product) subject to some conditions which could reduce opposition to such proposals. The EU, for example, proposes that the creation of such
schemes, including the drafting of criteria and the necessary operational procedures, be transparent. It is clear (indeed, sometimes explicit) that these proposals seek to establish the legitimacy of mandatory labeling regimes for GMOs, which have drawn lengthy objections from the United States, Canada, and other countries when notified to the WTO (WTO 2002c). However, the call for allowing required labeling of PPMs, in addition to notification of such regimes to the WTO, has led to trade tensions beyond those in evidence in the debate over GMO labeling. Proposed requirements for country-of-origin labeling for perishable foods, eco-labeling of forestry products, traditional expressions for wine and spirits, and other labeling regimes have drawn objections from members at almost every meeting of the TBT Committee (WTO 2002c). Opponents see mandatory labeling of production process as an unnecessary technical barrier to trade, and voluntary labeling as a less trade distorting alternative that serves consumer demand.

Labeling is commonly proposed when there is a lack of consensus about regulation (Golan et al. 2002), and GMOs are clearly one such case. Labeling has the virtue of facilitating choice, and is viewed by the EU as part of a strategy for eventual “co-existence” of GM and non-GM agriculture. Acceptance of labeling may well be a political compromise that exporters must live with. But the current EU labeling regulations and associated traceability requirements go far beyond any food safety goal as they apply even where novel proteins are not present and they will impose substantial costs back through the supply chain. Consumer choice might be better facilitated with mandatory labeling when novel proteins are present combined with clear public standards for voluntary positive and negative labeling when GMOs have been used in the product. This approach would also have the virtue of allowing less developed countries wider latitude in adoption of GM crops.

The level of support for recognition of the proposals on food safety, food quality and animal welfare is difficult to discern from the most recent modalities paper prepared by the chair of the agricultural negotiating group. It appears that most members recognize the difficulty of addressing these issues within the current agricultural negotiations and are focused on achieving progress on reducing traditional forms of protection. Nevertheless, the political importance of safety and quality means that concerns about these issues continue to surface, as the current GMO suit illustrates.

**Concluding Remarks**

The private sector is evolving rapidly to meet demands for process attributes throughout the world, and in many cases is setting standards that will supercede public ones (eg. Caswell et al. 1999). These efforts frequently involve international trade, and often exports from less developed countries. They may also utilize new technologies or management approaches that facilitate quality control and assurance. This market evolution is encouraging, because it demonstrates that private incentives can overcome technical barriers to trade. The WTO is the place of last resort for disagreements over such technical barriers. It is clear that much progress has been made since 1995, much of it without fanfare, on the successful resolution of SPS issues, particularly those arising
from new hazards or standards. The SPS agreement is in many ways a remarkable achievement, but it may or may not be adequate to address challenges arising from the current regulatory and trade environment. The GMO controversy promises to provide a major new challenge to the global trading system, because it challenges several principles that are not yet well-defined, such as the role of precaution and consumer perceptions. At the same time, the substantial costs facing some LDCs in meeting SPS standards in high income markets reduces their potential gains from trade. Accommodating these two challenges will require both compromise as well as clarity regarding the longer run benefits from a more open global market for food.
Box 1—How well does labeling address public policy goals?

Food safety is one public policy goal used to justify mandatory labeling of GM foods. Most food safety experts agree that acute or chronic toxic effects from GMO foods or foods produced with GM ingredients are extremely unlikely. It is more difficult to assess the likelihood of allergic reactions because the science base for understanding allergic reactions to food is weak (Bucchini and Goldman, 2002). This uncertainty provides a major stated motivation for the proposed extensions of labeling and traceability regulation in the EU (and elsewhere), using the precautionary principle as justification. In other words, the regulations are to address unknown and unforeseen consequences of the new technology. The proposed EU regulations would make it easier to figure out ex-post whether or not GMOs were associated with any particular food safety or environmental outcome. The proposed requirement to keep supply records regarding specific GM events makes this possible, although it may still be difficult to establish links between GM consumption and health outcomes with any scientific validity.

Consumer right to know or consumer choice are frequently stated as reasons for mandatory labeling of GM products. Consumers may demand information about methods of production or product characteristics that does not relate to public health or environmental risks recognized by regulators. Consumers, or some important subset of consumers, may have ethical objections to modern biotechnology, are concerned about environmental effects of production, want to support local farms, or are concerned about animal welfare.

These needs have historically been met by voluntary labels (e.g., kosher, organic) but the public sector is increasingly being asked to play a role. The public sector can certify voluntary labeling schemes that provide these types of information by providing uniform recognized standards and third party verification. The public sector may be well-positioned to set guidelines that are science-based and credible to consumers. Usually the costs are borne by industry through user-fees, and passed through to consumers who demand the safety or quality attributes. Such voluntary arrangements work well for positive credence attributes.

Mandatory standards for information disclosure can ensure that information is provided to consumers about negative attributes that producers may not want to disclose, and that such information is provided in a consistent manner. Producers may have incentives to withhold information or to provide inconsistent information. Or, consumers may lack the ability to effectively demand information which might have value to them once provided. A related argument for mandatory labeling is that it might restore consumer confidence through setting a public standard that applies to the entire industry, in cases where public confidence has been shaken by past misinformation. Another argument for mandatory labeling is that it might set the stage for verifying the positive consumption attributes in the next generation GM foods.
Box 2—Successful Efforts in LDCs to Meet SPS Standards in DCs

A number of cases are now documented where a combination of public and private efforts, usually with technical assistance, has helped LDC industries to be successful in meeting SPS standards in export markets. These cases include:

- Raspberries exports from Guatemala were shut down following their implication in an outbreak of *cyclospora* illness in the U.S. in 1996. The Guatemalan industry instituted training, made investments in field sanitation, and established certification procedures that improved food safety and reestablished exports in 1999. These efforts were the result of technical assistance from the U.S. public and private sectors, in cooperation with a new public-private agency established within Guatemala. (Calvin et al, 2002)

- Snow peas exports from Guatemala to the U.S. were quarantined in 1995 when they threatened to introduce a new plant pest into the U.S. Research established that the pest was not new to the U.S., and the market was reopened in 1997. This research was carried out cooperatively by U.S. and Guatemalan scientists, with support from the U.S. government. (Norton et al, forthcoming)

- Shrimp exports from Bangladesh to the EU were quarantined in 1997, following sanitation problems. Bangladesh shrimp exports to the U.S. are also frequently detained for sanitary violations. Investments by the Bangladesh government and the industry in new standards, training, and sanitation, undertaken with multilateral technical assistance, resulted in the gradual reopening of exports. Two-thirds of exporting plants certified to export to the EU by 2002. These investments also set the stage for diversification into value-added shrimp products that have raised export returns. (Cato and Subasinge, forthcoming)

- Fish exports from Kenya to the EU were banned in 1996 and again in 1998, due to concerns about sanitation. To meet EU requirements, all exporting plants instituted new sanitation control procedures and the Kenyan government put into place new standards and oversight. Plans are underway to consolidate fish processing in a few centralized locations, where sanitation measures and oversight will be concentrated. (Abila, forthcoming)

While these cases demonstrate that LDC industries can meet higher SPS standards in DCs, they also have raised questions about the nature and distribution of benefits from trade. In some of the above cases, the structure of the exporting industry changed and the number of producers participating in the export market declined. In the Guatemalan raspberry case, for example, only two farms are now exporting. It is possible that broader benefits to LDC producers from enhanced market return and to LDC consumers from improved safety in domestic food will result in the long run from the training and demonstration effects of meeting higher standards, but that remains to be seen.
References


WFCN 1997b. FSIS offering few suggestions for Project 2, Australian official says. 26 November, 16.


WTO. Update Phase2: Backgrounder. Agriculture Negotiations: Food safety.  

WTO. Update Phase 2: Backgrounder. Agriculture Negotiations: Consumer information and labeling.  


<table>
<thead>
<tr>
<th>Table 1: Elements of Current Labeling Regulations</th>
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<tbody>
<tr>
<td><strong>Label if GM protein/ DNA present</strong></td>
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<tr>
<td>EU 2000</td>
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<tr>
<td>All ingredients</td>
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<tr>
<td><strong>Label if GM used in producing, but no novel material in product</strong></td>
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<tr>
<td>EU 2000</td>
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<tr>
<td>no</td>
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<tr>
<td><strong>Tolerance level (unintentional contamination)</strong></td>
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<tr>
<td>EU 2000</td>
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<tr>
<td>1%</td>
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<tr>
<td><strong>IP/ Traceability/ documentation required</strong></td>
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<tr>
<td>EU 2000</td>
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<tr>
<td>Document avoidance procedures or else must state ingredients as GM</td>
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<tr>
<td>Country</td>
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<tr>
<td><strong>Mexico</strong></td>
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<td><strong>Kenya</strong></td>
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<td><strong>CARICOM</strong></td>
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<td><strong>Small Island Developing States</strong></td>
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<td><strong>Mauritius</strong></td>
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1 SIDS includes Dominica, Jamaica, Mauritius, St Kitts and Nevis, St Lucia, St Vincent and the Grenadines, and Trinidad and Tobago.
<table>
<thead>
<tr>
<th>Country</th>
<th>Propositions, notes, and discussion papers</th>
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<tbody>
<tr>
<td>Japan W/91</td>
<td>A review should be conducted to examine whether the existing agreements are sufficient to respond to new issues that have emerged since the UR agreements, including GMOs; improving food safety should be examined; labeling of all foods so as to protect consumers should be undertaken, including the labeling of GMOs; appropriate international rules for the labeling of GMOs should be established by Codex</td>
</tr>
<tr>
<td>European Union W/90</td>
<td>The negotiations should: clarify the application of the precautionary principles; ensure that labeling schemes are appropriately covered by the WTO; and ensure that trade liberalization does not undermine efforts to improve the protection of the welfare of animals</td>
</tr>
<tr>
<td>Cuba, Dominican Republic, El Salvador, Honduras, Kenya, India, Nigeria, Pakistan, Sri Lanka, Uganda, Zimbabwe, and Haiti (W37)</td>
<td>SPS measures continue to block market access; failure to recognize equivalence of measures is a major problem</td>
</tr>
<tr>
<td>Barbados, Burundi, Cyprus, Czech Republic, Dominica, Estonia, EC, Fiji, Iceland, Israel, Japan, Korea, Latvia, Liechtenstein, Madagascar, Malta, Mauritania, Mauritius, Mongolia, Norway, Poland, Romania, Saint Lucia, Slovak Republic, Slovenia, Switzerland and Trinidad and Tobago (W/36)</td>
<td>WTO policy reform must account for consumer concerns, thereby linking food production to cultural and/or ethical issues including food safety and quality</td>
</tr>
<tr>
<td>European Union W/19</td>
<td>To ensure that trade does not undermine efforts to improve the protection of animal welfare</td>
</tr>
<tr>
<td>European Union W/18</td>
<td>To establish labeling rules which protect consumers against deception</td>
</tr>
<tr>
<td>USA W/15</td>
<td>Disciplines should be focused to ensure the processes covering trade in products developed through new technologies are transparent, predictable, and timely</td>
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Source: Roberts et al. 2001