Examining and Reducing Technical Barriers to Trade

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The North American Free Trade Agreement (NAFTA), along with the Uruguay Round Agreements of the General Agreement on Tariffs and Trade (URA-GATT), have led to reductions in the levels of protection afforded by tariffs, import quotas, and other nontariff trade restrictions. Access to new markets has also meant that U.S. food and agricultural products have increasingly been subjected to technical barriers to trade (TBT). Although TBTs were in place prior to market opening trade agreements, their impacts were often not apparent because high tariffs and restrictive import quotas severely limited or impeded trade. The World Trade Organization has noted that as “classical trade barriers-tariffs and quantitative restrictions-have come down ... attention has turned to “invisible costs” resulting from documentation requirements, procedural delays, and lack of transparency and predictability in ... government rules and regulations.” The emergence of these invisible barriers has created an overall negative trading environment.

While some TBTs may be based upon sound scientific evidence, others are not and have led to their increased use to unduly inhibit trade. As tariffs have been lowered and import quotas eliminated, TBTs have emerged as a serious impediment to trade. During 1996, USDA estimated that U.S. agricultural exports valued at more than $4.97 billion were being subjected to a growing set of restrictive TBTs. More than 300 TBTs have been reported in 63 countries (Roberts and Deremer). An understanding of the interactions of trade agreements with food quality management systems (FQMS) such as the Codex Alimentarius Commission, the Hazard Analysis and Critical Control Points (HACCP) system, and the

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International Organization of Standardization are crucial for reducing the use of TBTs as restrictions to trade. The purpose of this report is to identify the types of TBTs being used, their interactions with FQMS, and the potentials for reducing TBT impacts on agricultural trade.

**Technical Barriers to Trade**

While most TBTs are designed to limit or prevent the importation of products that might contaminate domestic animal herds or plant populations, many do not have a scientific basis and are used to restrict trade in order to protect an industry from international competition. TBTs reduce the efficiency of trading firms, often causing long delays at ports while shipments are reinspected and documentation is verified, leading to higher transactions costs. Some shipments may even be rejected, resulting in the need to reroute the product or sell to a buyer of last resort, resulting in lower prices to producers. When TBTs are implemented without the support of science, they can become serious impediments to trade by causing retaliation from other countries, slowing commerce, causing a backlog of product, and ultimately, having negative impacts on both consumers and producers. Technical barriers to trade can be grouped into three main categories (Roberts and Deremer):

1. **Sanitary and Phytosanitary (SPS)** regulations are implemented by countries to protect human, animal, or plant life or health. The primary purpose of most SPS is to protect the safety and the integrity of the domestic and imported food supply. Sanitary regulations are used to ensure that animal based products such as meats, poultry, and dairy products meet or exceed specified sanitary standards. Phytosanitary regulations are applied to fruits, vegetables, bulk commodities, and other plant based products to ensure that they comply with specified phytosanitary standards. Under provisions of the URA-
GATT, sanitary and phytosanitary (SPS) regulations must rely upon the use of scientific evidence to be implemented or maintained as valid trade restrictions.

2. **Consumer measures** regulate food safety and quality, including labeling, packaging, pesticide residues, nutritional content, and contamination.

3. **Trade measures** are implemented to prevent commercial fraud including shipping and financial documentation, standards of identity and standards of measurement.

Plant health restrictions, food safety regulations, and quality standards are among the most prevalent types of TBTs used to limit the trade of U.S. food and agricultural products (Figure 1). Labeling rules and animal health regulations are less important. While many of these TBTs are legitimate and scientifically based, many are not and effectively limit or totally eliminate U.S. products from export markets.

**Foreign Technical Barriers to Trade**

Japan, the top U.S. agricultural export market, has been accused of implementing TBTs which require redundant food safety tests on many U.S. foods entering the market. Japan also has been reluctant to acknowledge U.S. pest free regions established under the URA-GATT. Mexico, the third largest U.S. agricultural export market, has been accused of implementing unscientific plant health regulations and unnecessary grain fumigation requirements. Mexico also has implemented unnecessarily strict shelf life requirements for imported meats and dairy products. Korea has unscientific fumigation requirements and government mandated shelf life regulations which limit the competitiveness of U.S. products.

While the United States has attempted to negotiate for the elimination of these and other illegal TBTs, progress has been limited by the unwillingness of many countries to submit their domestic food
regulations to international scrutiny. Trade in processed foods valued at $875 million was affected by TBTs in 1996. Horticultural products and livestock and meat products trade valued at $650 million and $520 million, respectively, was negatively impacted by TBTs. Bulk commodities trade of $200 million was also restricted by unnecessary TBTs.

Restrictions by Korea topped the list at just more than $1.0 billion and limited the importation of processed foods and horticultural products (Figures 2 and 3). Japanese TBTs were estimated to affect $471 million and restricted the import of processed foods and horticultural goods. China had TBTs which affected horticultural products and grains, while the European Union's (EU) TBTs limited about $150 million in foods. Mexico had TBTs retarding the import of horticultural products, meats, and grains that were valued at $118 million.

**Food Safety and the Role of Government in Developing Technical Barriers to Trade**

As a result of the URA-GATT and subsequent trade liberalization, concern about the safety of imported foods has increased (Centers for Disease Control and Food and Drug Administration). It is likely, however, that implementation of NAFTA and the increase in imported foods from Mexico is also a significant contributing factor to these concerns. U.S. imports of fresh vegetables from Mexico have increased 50 percent since NAFTA began in 1994. During some winter months, imported produce accounts for three-fourths of all available supplies in retail groceries (Hedberg, et al.). According to the Codex Alimentarius Commission, its own standards, guidelines, and recommendations are now recognized as the reference point for all national food safety requirements, but many countries have been reluctant to fully recognize these standards because of inconsistencies with their own national food safety regulations. Article 5 of the URA-GATT Sanitary and Phytosanitary (SPS) measures agreement requires all Word
Trade Organization (WTO) members to conduct scientific and consistent risk assessments. The perception among many food safety experts, however, is that greater international food trade has increased the risk for cross-border transmission of infectious pathogens, especially food-borne illness and disease.

The United States has among the safest food supplies in the world, despite outbreaks of food borne illness and disease. In 1996, for example, 99.1 percent of the domestic foods sampled by the FDA did not contain pesticide residues which exceeded specified tolerance levels. For imported food samples, 97.4 percent were determined to contain no excessive pesticide residues. Even so, consumers and consumer groups remain concerned about the presence of harmful chemicals in food and the effects of food related illness. While many of these concerns may be misplaced, recent outbreaks of *e.coli* bacteria in meat only serve to reinforce consumer perceptions and fears of tainted food. The impacts of these events on the food industry have been substantial.

The responsibility for the regulation of pesticides in the U.S. food supply is shared by three government agencies: the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the U.S. Department of Agriculture (Food Safety and Inspection Service). The Environmental Protection Agency (EPA) registers and approves pesticides and sets tolerances on pesticide residues in food products. Tolerance levels state the maximum amount of a pesticide residue that is permitted in or on a food if the use of that particular pesticide may result in residues in or on food. These levels are specified as parts per million (ppm) and normally range from .5 ppm-50 ppm. FDA enforces tolerances on imported foods and in domestically produced foods shipped in interstate commerce. The Agricultural Marketing Service (AMS), USDA has conducted a residue testing program directed primarily at raw
agricultural products. The Food Safety and Inspection Service (FSIS), USDA enforces pesticide tolerances for meats, poultry, and eggs.

FDA samples and analyzes individual lots of domestically produced and imported foods for pesticide residues to enforce the tolerances set by EPA. Domestic foods are sampled as close as possible to the point of production in the distribution system. Imported food samples are collected at the point of entry into United States. Sampling of raw agricultural products is emphasized. The sample is analyzed as the unwashed, whole, raw commodity. Processed foods are also included. If pesticide residues exceed legal tolerances in domestic samples, FDA can seize a shipment or file an injunction precluding future shipment for a specified time period. Import shipments may be detained at the port of entry when illegal residues are found. "Detention without physical examination," previously called automatic detention, may be invoked for imports based on the finding of one violative shipment if there is reason to believe that the same situation will exist in future lots during the same shipping season for a specific shipper, grower, geographic area, or country.

Domestic and imported food samples are classified as either "surveillance" or "compliance." Most samples collected by FDA are for surveillance. This indicates that there is no prior knowledge or evidence that a specific food shipment contains illegal pesticide residues. Compliance samples are taken as follow-up to the finding of an illegal residue or when other evidence indicates that a pesticide residue problem may exist.

FDA participates in several international agreements in an effort to minimize incidents of violative residues and remove trade barriers (FDA). The Pesticide Monitoring Improvements Act provides for a standing request for information from foreign governments on pesticides used on their food exported to the
United States. The FDA also provides foreign countries with reports on regulatory monitoring and findings in foods imported from their respective countries, as well as a personal computer database in which coverage and findings are summarized by country/commodity/pesticide combination.

Under NAFTA, the United States, Mexico, and Canada have established a NAFTA Technical Working Group on Pesticides (TWG-P). This group serves as the focal point for all pesticide issues arising among the three NAFTA countries. TWG-P reports directly to the NAFTA Sanitary and Phytosanitary Committee. The purpose of TWG-P is to ensure that pesticide registrations and maximum residue limits (MRL) in the three countries are harmonized to the extent practical, while strengthening protection of public health and the environment (FDA). Projects have been implemented to identify different residue limits in the NAFTA countries and to determine what steps might be taken to harmonize those limits. Members of TWG-P envision the formation and implementation of the North American Pesticide Registration and Tolerance System (NAPRTS) to ensure the safety of foods produced within NAFTA (FDA).

**Food Safety and Sampling of Domestic and Imported Foods**

During 1996, 10,374 surveillance samples of foods were collected and analyzed by FDA for violation of pesticide residue tolerances.\(^3\) Of the 5,062 domestic samples taken, no violative residues were found in 99.1 percent of the samples, 64.4 percent had no detectable residues, and .9 percent had violative residues. This finding is consistent with results from the past several years. Fruits and vegetables represented 63.5 percent of the total domestic sample.

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\(^3\)FDA defines a violative residue as a residue which exceeds a tolerance level, usually specified in parts per million (ppm) or a residue at a level of regulatory significance for which no tolerance has been established.
Of the 4,921 import samples of foods from 91 countries, fruits and vegetables accounted for 83.6 percent of the total. No violative residues were detected in 97.4 percent of import samples, compared to 96.5 percent in 1994 and 96.8 percent in 1995. Of all import samples taken, 2.6 percent contained violative residues, while 64.4 percent of food samples had no residues detected.

Compliance samples taken in 1996, which contained known or suspected pesticide residue problems, had higher violation rates than surveillance samples. Of the 102 domestic and 391 import compliance samples taken, 7.8 percent of the domestic samples contained pesticide residues exceeding specified tolerance levels (12 percent in 1995) and 11.5 percent of import samples had violative levels (11 percent in 1995). These compliance samples were taken as follow-up to violative surveillance samples. Many of these included follow-up samples from the same shipment as the violative surveillance sample, follow-up samples of the same commodity from the same grower or shipper, and audit samples from shipments presented for entry into the United States with a certificate of analysis (i.e., shipments subject to detention without physical examination) (FDA).

Of all compliance samples taken in 1996, 63.4 percent of sampled imports had no residues, compared to only 49.0 percent of domestic samples (Table 1). The highest pesticide violation rates were in fruits and vegetables. For domestic samples, 12.1 of the fruits and 9.8 percent of the vegetables contained violative products. Pesticide residues were detected in 69.7 percent of domestic fruit samples, compared to 56.1 percent of the vegetable samples.

Violative samples for imported fruits and vegetables were higher than those for domestic samples, 22.0 percent and 14.1 percent, respectively. Pesticide residues were detected in 42.4 percent of the fruits and 41.2 percent of the vegetable samples. These results suggest that the overall supply of imported fruits
and vegetables contain more samples without any detectable level of pesticide residues than do the domestic samples, even though the rate of violative import samples is higher.

**Table 1. Compliance Samples by Type of Commodity, 1996**

<table>
<thead>
<tr>
<th>Commodity Group</th>
<th>Total No. of Samples</th>
<th>Samples without Residues, %</th>
<th>Samples Violative, %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domestic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grains and Grain Products</td>
<td>6</td>
<td>50.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Milk/Dairy Products/Eggs</td>
<td>6</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Fish/Shellfish</td>
<td>8</td>
<td>62.5</td>
<td>0.0</td>
</tr>
<tr>
<td>Fruits</td>
<td>33</td>
<td>30.3</td>
<td>12.1</td>
</tr>
<tr>
<td>Vegetables</td>
<td>41</td>
<td>43.9</td>
<td>9.8</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>100.0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>102</strong></td>
<td><strong>49.0</strong></td>
<td><strong>7.8</strong></td>
</tr>
<tr>
<td><strong>Import</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grains and Grain Products</td>
<td>74</td>
<td>59.5</td>
<td>0.0</td>
</tr>
<tr>
<td>Milk/Dairy Products/Eggs</td>
<td>4</td>
<td>75.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Fish/Shellfish</td>
<td>9</td>
<td>88.9</td>
<td>0.0</td>
</tr>
<tr>
<td>Fruits</td>
<td>118</td>
<td>57.6</td>
<td>22.0</td>
</tr>
<tr>
<td>Vegetables</td>
<td>128</td>
<td>57.8</td>
<td>14.1</td>
</tr>
<tr>
<td>Other</td>
<td>58</td>
<td>87.9</td>
<td>1.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>391</strong></td>
<td><strong>63.4</strong></td>
<td><strong>11.5</strong></td>
</tr>
</tbody>
</table>

Imported fruit and vegetable samples varied widely in the incidence of pesticide violations by product type (Figure 4). The highest percent of violative samples occurred in strawberries, papaya, bok choy, and cauliflower (6.5, 9.3, 13.6, and 12.5 percent, respectively). The highest proportion of samples containing no detectable residues also were cauliflower and papaya, with 87.5 and 78.7 percent, respectively. Strawberries and lettuce had a low incidence of no detectable residue, or conversely, a high incidence of detectable residue. For strawberries, 89.1 percent of all import surveillance samples contained some level of pesticide residue, while 79.6 percent of all lettuce samples had some pesticide residues. These levels compare to 90.8 and 64.1 percent of domestic surveillance samples during the same year (Figure 5). Domestic samples also had high levels of detectable residues for raspberries and blackberries at 80.9 and 57.1 percent, respectively, but no violative samples were found.

Products from Mexico were sampled more than those from any other country in 1996, with 1,752 samples submitted (Figure 6). This is consistent with findings from the previous ten years. Chile, Canada, and the Netherlands ranked 2-4 in samples with 976 submitted. Other top ten countries were Guatemala, Thailand, and China which submitted 533 samples. Taiwan, the Philippines, and Japan submitted 122 samples, fewest among top ten countries. Italy, Costa Rica, India, Spain, the Dominican Republic, and Ecuador all submitted more than 100 samples for analysis in 1996. Fewer than 10 samples were submitted from 44 countries exporting foods and other agricultural products to the United States.

**Food Borne Contamination and the Importance of Spin Control**

In 1996 and 1997, both domestic and imported foods were suspected of causing outbreaks of food borne illnesses in the United States. In 1996, cyclospora was traced to California strawberries and to Guatemalan raspberries, even though scientific evidence is unclear about food as a possible vector.
Cyclospora is a parasite causing diarrhea and fatigue and often lasting for several weeks. As news about these outbreaks became public, strawberry prices dropped dramatically, while the negative information virtually eliminated Guatemalan raspberries from the U.S. market. When additional information indicated that the most likely vector for the parasite was contaminated water, some Guatemalan firms attempted to use purified water to regain at least part of their lost market. Most of these efforts proved unsuccessful due to high costs and the failure to convince U.S. inspectors that the product was safe. In addition, there were attempts by producers to mislead inspectors about the availability of portable bathrooms for Guatemalan workers to use while in the fields. Since then, Guatemalan raspberries have been banned from the U.S. market, causing severe economic decline in the industry there.

While scientific evidence is unclear in determining if cyclospora can be transmitted through foods or even contaminated workers, it is clear that contaminated water is an effective vector for the parasite. This example illustrates how industry efforts to reverse public opinion often fail to convince consumers and public officials that a product is safe, when in actuality more than a reasonable doubt may exist about the country of origin and the vector of transmission. It should be noted that Guatemala considers the raspberry ban to be a scientifically unfounded TBT.

In 1997, the California strawberry industry was negatively impacted by news of a hepatitis outbreak. Economic analysts have quantified the impacts of public information on California strawberry growers and determined that negative news reduces grower profits, but positive news can partially offset the negative impacts of adverse information (National Food and Agricultural Policy Project). Although it was estimated that net losses to growers ranged from $12-$21 million between 1994 and 1997, positive information allowed growers to recoup between $24 million and $32 million. Spin control led to substantially higher
net returns to growers than if no attempts had been made to at least partially negate the bad news with good news.

Over the long run, however, estimates indicate that adverse information caused prices to fall by $.60/carton, while positive information resulted in only a $.36/carton increase in price. Not only do producers have a vested interest in trying to control the spin on news stories, but they may have a larger interest to ensure the safety of their products and to maintain a positive product image in the minds of consumers.

**Food Quality Management Systems**

Global food quality management systems (FQMS) and food safety regulations have developed largely independently of each other over the last four decades, but have become more important as industries seek ways to protect themselves from the negative effects of food borne pathogens and contamination. These independent, and largely divergent sets of systems may pose serious threat to the development of the efficient trading regime envisioned by the URA-GATT if methods of coordination and cooperation are not developed to ensure consistency of regulations across nations. Interactions among the Codex Alimentarius Commission, the International Organization of Standardization, the Hazard Analysis and Critical Control Point System, and current and future trading arrangements must be examined and understood to avoid duplication of regulation and overly strict enforcement of food quality standards and food safety measures. Cooperative activity between nations and organizations is a key to maintaining an open, transparent trading system which facilitates the efficient flow of foods and other agricultural products.

*Codex Alimentarius Commission*
Plans to establish an international food program can be traced to the United Nations Conference on Food and Agriculture held in 1943. These early programs were designed to assist governments to improve the nutrient content of important foods and to form and adopt similar international standards to facilitate and protect the exchange of foods and agricultural products between countries.

The Codex Alimentarius Commission, or food code, was officially established in 1962 as a joint effort between the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO). Codex was designed to be the code of food standards for all nations (Joint FAO/WHO Food Standards Program). Codex has 146 member countries, 237 food commodity standards, 41 hygienic and technological practice codes, 3,200 maximum residue levels (MRLs) for pesticides, and technical evaluations on 700 food additives and contaminants.

Codex provides countries with guides for sound agricultural practices concerning pesticide use, food standards for processing products, and hygiene codes for making food safe and acceptable in international trade. Together, these standards are designed to make food safe for consumers.

The Codex meets as a body every other year and is governed by an Executive Committee which meets in years between official sessions. The Executive Committee is geographically balanced, with no two members from the same country. The Codex has 28 general and commodity committees that draft standards and make recommendations for acceptance of those standards. The Codex, member governments, and other interested parties such as food manufacturers, training firms, and consumer groups review standards before they are adopted. The general subject committees are the most comprehensive and consist of the following topics and respective host countries:

Food Labeling (Canada)
Food Additives and Contaminants (The Netherlands)

Food Hygiene (United States)

Pesticide Residues (The Netherlands)

Residues of Veterinary Drugs in Foods (United States)

Methods of Analysis in Sampling (Hungary)

Food Import and Export Inspection and Certification Systems (Australia)

Active commodity committees include:

Fish and Fishery Products (Norway)

Nutrition and Foods for Special Dietary Uses (Germany)

Fats and Oils (United Kingdom)

Milk and Milk Products (New Zealand)

Cereals, Pulses, and Legumes (United States)

Tropical Fresh Fruits and Vegetables (Mexico)

Host countries fund the committees, while the FAO provides about 80 percent of the funding for administration and other operations.

Despite Codex, technical barriers to trade often are disguised as health or food safety measures to protect producers from international competition or to respond to consumer misconceptions about the effects of chemicals used to promote animal or plant growth. An example is the continuation of the European Union (EU) ban on the importation of meats treated with growth hormones and the perceived hazards, despite the lack of scientific evidence to support these claims and a WTO ruling to open the EU
market. In order to limit the potential for TBTs to be used under the guise of health regulations, the Codex is developing more flexible standards for food additives and contaminants.

Codex has developed labeling standards to prevent false claims about foods and special regulations for nutrition labels and health claims. Under the Codex, a food label must contain the following information:

Name of the food,
List of Ingredients (in declining order of quantity),
Net contents and drained weight,
Name and address of the manufacturer,
Country of origin,
Lot identification,
Date marking and storage instructions,
Instructions for use.

The nutrition label is any representation which states, suggests, or implies that a food has particular nutritional properties including energy value, vitamins, and minerals. This label is used as a guideline only, but should include the established recommended daily allowances (RDAs) and should include only those substances that are present in significant quantities (Codex).

Codex has taken the position that new foods developed using genetic engineering, or genetically modified organisms (GMOs) and biotechnology will be evaluated for safety as if they contained food additives. Two recent examples are BST, a synthetic milk production-enhancing hormone and genetically modified pest resistant and climate tolerant crops. While definitions for these new products may well be debatable, Codex has been placed in the position of assessing the safety of newly emerging technologies
and the foods which they produce. Again, this has led to a clash of interests with some countries, primarily the EU which maintains that it has the right to decide which products are acceptable and safe for its consumers. The EU is presently debating the allowance of GMOs into the market under alternative labeling schemes, the most restrictive of which would require that all GMOs be separately labeled.

These new developments in biotechnology and genetic engineering raise two important issues. One relates to consumers’ right to know the contents of the product they are purchasing, regardless of the scientific evidence purporting that it is safe. This is at the crux of the debate in Europe over admittance and sale of GMOs. The other issue relates to the need to segregate GMOs or biotech products from those produced by another means, such as organic or conventional farming methods. This would require additional shelf space and substantially raise distribution and marketing costs because products would need to be segregated from point of production through final retail sale. Resolution of these, and other issues related to the production, marketing, and safety of GMOs and biotech products will certainly shape the future role between Codex and national food safety regulatory bodies in member countries. The outcome will determine the extent to which TBTs will be used to inhibit trade in these newly developed products.

The International Organization for Standardization

The International Organization for Standardization (ISO) is a nongovernmental, voluntary organization of 117 countries which represent generic standards based upon process quality assurance standards developed by the British Standards Institute in 1987. Since then, these standards have received international recognition, becoming widely accepted quality management systems for food in 1994. The main objective of the ISO system is to develop consistent, voluntary industrial standards to facilitate trade. The ISO 9000 series is not, however, a set of standards ensuring the safety of food products.
ISO 9000 standards specify internationally accepted procedures and guidelines to maintain food process quality in product design, production, installation, and service (Zaibet and Bredahl). ISO 9000 is a series of six standards: 8402, 9000, 9001, 9002, 9003, and 9004. ISO 9000 and 9004 relate to internal system design and process quality, while ISO 9001, 9002, and 9003 are for contractual and noncontractual relationships (Zaibet and Bredahl).

ISO compliance is provided through private, third party certification of process quality, not food safety. ISO certification meets the diverse requirements of different legal systems, provides some assurance of international market access, and often results in greater food chain efficiency in some countries. ISO provides another layer of quality management to existing national systems through third party certification that can replace or complement government regulation in some cases. ISO 9000 certification may, in some cases, duplicate national regulatory standards resulting in additional bureaucracy and becoming de facto trade barriers. Japan, for instance, is considering a law that would require foreign firms to be certified by a Japanese company, even thought the firm may already be certified by an approved firm from its own country. This additional certification requirement is, in effect, a domestic content law which would restrict, rather than enhance trade. China and Mexico are considering similar laws.

ISO 9000 certification is becoming more important in contractual relationships, with some manufactures requiring certification for input suppliers. In most cases, however, the ISO process has not replaced food safety or other technical regulations, with the latter remaining under the purview of government. Within the United Kingdom, ISO certification is seen by U.K. government officials and food firms as sufficient due diligence defense in product liability cases (Zaibet and Bredahl).
The International Standards Organization appoints the private certifying firm. This firm advises, coordinates, and finally certifies individual plant level compliance with ISO guidelines. Internal and third party audits ensure the maintenance of certification and adherence to ISO 9000 requirements.

Zaibet and Bredahl estimate that there are significant cost savings to ISO certification in some countries. In their study of the United Kingdom it was determined that average annual cost savings were $200,000 per plant. About seven percent of the total cost reduction was due to reduction in human error, lower rates of nonconformity of product, and a reduced rejection rate. Improvements in management efficiency, lower auditing costs, and reductions in transaction costs also were cited as a significant reason for cost savings due to ISO certification.

The Hazard Analysis and Critical Control Points System

The Hazard Analysis and Critical Control Points (HACCP) system represents a systematic approach to the identification of hazards and the development of a control system to reduce food safety risks associated with these hazards. HACCP focuses on the food industry to target and eliminate critical food safety risks in a specified plant. Harmful biological, chemical, and physical contaminants are targeted. HACCP also is used to verify that control systems are functioning as designed to minimize or eliminate food safety hazards.

HACCP was implemented as a voluntary system in the United States in the 1960s, but has since become an important regulatory regime in the 1990s. In 1995, the FDA adopted regulations requiring HACCP systems in fish and fish products. In 1996, the FSIS required HACCP adoption for meat and poultry processors. It appears that FDA will require HACCP systems in the processing of fruit and vegetable juices in 1998 or 1999 (Food Institute Report). HACCP systems are designed to develop
product and process specific food processing systems to identify food safety hazards that may occur and to ensure that specific actions, such as heat treatment, are used at critical control points to reduce or eliminate potential hazards to acceptable levels. HACCP was adopted by the EU for all foods in 1993 and by the Codex that same year. HACCP is also being used in Canada and Australia.

Similar to ISO 9000, HACCP focuses on the process of food safety by ensuring a safe product every time. HACCP is a subsystem of the ISO process, which does not contain a food safety or HACCP component. The HACCP process employs seven basic principles:

1. Hazard identification at each stage in the production or distribution process, along with measures to prevent hazards,

2. Identify Critical Control Points (CCP),

3. Establish critical limits for prevention at each CCP,

4. Establish CCP monitoring requirements and procedures,

5. Establish corrective action for deviations from critical limits,

6. Develop records keeping procedures to document the HACCP system,

7. Establish verification procedures.

**Potentials for Coordination of Food Quality Management Systems**

The ISO 9000 series contains some elements of HACCP, such as process control, inspection and testing, control of quality records, and internal quality audits. ISO and HACCP overlap so that it is possible for HACCP to be integrated into an existing ISO 9000 system or for the ISO 9000 series to be used to document and implement a HACCP management system. There are, however, some major differences and shortcomings which are important for FQMS coordination and monitoring.
Most FQMS attempt to influence food quality and the process by which foods are produced. Food products are usually classified according to their major attributes or characteristics (Hooker and Caswell):

**Safety**-pathogens, pesticide residues, additives, and veterinary drug residues (sanitary and phytosanitary regulations are used to control these safety considerations);

**Nutrition**-fat content, calories, fiber, sodium, vitamins, and minerals;

**Value**-purity, or the lack of nonhazardous materials, size, appearance, taste, and convenience of preparation;

**Packaging**-package materials and labeling;

**Manufacturing**-the way in which a product is processed.

These characteristics interact to form the overall product image in the mind of the consumer. Organic produce, for example, is often preferred because of its perception of safety, nutrition, value, and lack of processing associated with the product. FQMS attempt to manage and control not only the individual product characteristics, but the interaction of those characteristics with each other and external factors, such as the environment.

Almost 130,000 firms worldwide were ISO 9000 certified in 1996. In recent years, there has been an increasing trend toward certification of food processing firms. More than 1,000 British firms are ISO 9000 certified (Holleran and Bredahl). This compares to 330 in France and about 50 in the United States. Certification is highest among firms producing differentiated products due most likely to market structure and higher transaction costs.
It should be noted here that the ISO 9000 series is designed to enhance the quality of the production process, not the quality of the product. ISO 9000 does not contain a food safety component per se. Clause 19, ISO 9004-1 does recommend preventive measures which are limited to design testing and product recall (Hooker and Caswell). ISO is intended to provide an internal guide for the development of a FQMS. A major shortcoming is that, "if part of the process is unsafe, then the ISO 9000 focus on consistency will ensure that the resulting product will always be unsafe," (Mortimer and Wallace). This latter point emphasizes the need for a HACCP food safety component to the ISO 9000 series.

There have been attempts to use the ISO 9000 series in Codex to serve as evidence of compliance with national food safety standards. Under the current ISO system this may result in a misleading interpretation of the interaction between Codex and ISO, particularly since ISO does not contain a food safety component.

HACCP provides the approach to quality assurance, but does not specify the actions to be undertaken. The goals of a HACCP system are to (Hooker and Caswell):

- Produce a safe product every time;
- Demonstrate safety assurance (due diligence for legal defense); and
- Impart a positive product image to consumers.

HACCP does have a weakness in that it is designed to reduce hazards over individual segments of the food production system rather than reducing risk to consumers (Hathaway and Cook). HACCP should be implemented throughout the food system in order to provide a stronger assurance of food safety and to maximize its effectiveness to achieve product and process safety. Also, HACCP systems implemented in one country may not be equivalent to a system implemented in another. This equivalency
issue is a major problem confronting government regulatory agencies in dealing with food safety standards across national boundaries.

The Uruguay Round Agreements, the North American Free Trade Agreement and Technical Barriers to Trade

Six primary provisions related to SPS exist in the URA-GATT (OECD):

**Basic Rights and Obligations**: measures taken to protect human, animal, or plant life or health, must be based on scientific principles and shall not be applied in a manner that would constitute a disguised trade restriction.

**Harmonization**: SPS, as far as possible, shall be based on international standards, guidelines, or recommendations, where they exist.

**Stricter measures** may be introduced or maintained if, based on scientific evidence, a member country determines that an international standard does not achieve an appropriate level of protection.

**Equivalence**: members shall accept other members’ measures as equivalent if the exporting member demonstrates to the importing member that its measures achieve the appropriate level of protection.

**Transparency**: all changes in SPS regulations shall be published promptly, provide an inquiry point for documents and questions, and allow sufficient time for exporting countries to adapt.

**Special and Differential Treatment**: to account for the special needs of developing countries, longer time frames for compliance with new SPS measures are allowed, along with encouragement of developing countries to participate in relevant international organizations.
The agreement also provides for a dispute settlement body to evaluate and rule on issues related to the use of SPS as illegal impediments to commerce.

The Agreement on Technical Barriers to Trade requires members to ensure that:

1. Products imported from member countries must be accorded treatment no less favorable than domestic goods; and

2. Technical regulations are not adopted or applied that would create unnecessary obstacles to trade.

TBTs must not be any more restrictive than necessary to fulfill a stated objective. National security, protection of health, safety, and the environment are all included as valid objectives. Members are to use international standards to achieve their objectives if such standards exist. The agreement provides that members cooperate in harmonizing TBTs and that members consider accepting equivalent technical regulations of other members, even if those regulations differ from their own.

NAFTA provides for similar treatment of TBTs. Under Article 904, each party agreed not to prepare, adopt, maintain, or apply any standards related measure which would create an unnecessary obstacle to trade (Sookman). Relevant international standards should be used and where practicable, TBTs should be made compatible to facilitate trade. Compatibility refers to bringing different standards of the same scope to a level so that they are identical or equivalent.

**Monitoring Technical Barriers to Trade**

The SPS agreement of URA-GATT does not include provisions to integrate ISO standards into the trading regime of the WTO. Neither is there a role for ISO in the Technical Barriers to Trade Agreement. ISO has approached the WTO to address these issues, however. Food safety is addressed
in both agreements by providing for a dispute resolution system and calling for the adoption of scientific standards used by Codex, the International Plant Protection Convention (IPPC), and the International Office of Epizootics (OIE). The Technical Barriers to Trade agreement emphasizes the need for more awareness of the negative impacts resulting from differences in national standards.

Given the lack of HACCP principles in the ISO 9000 series, serious doubt exists about the ability of ISO to actually facilitate the trade of certifiably safe food products. Short of the harmonization of food safety standards across countries, which is highly unlikely in the near future, effective alternatives to facilitate trade in certified safe foods should be examined.

It is obvious that some degree of cooperation is needed between international institutions and member countries of the WTO to ensure that national food safety regulations and FQMS do not interact to impede international trade in agri-food products. The degree of cooperation is important because it will determine the level of commitment needed from governments to achieve effective trade facilitation, while also protecting the interests of producers and consumers. At least three levels of cooperation should be considered when designing strategies to resolve issues related to technical barriers to trade (adopted from Hooker and Caswell):

**Equivalency**: acceptance of regulatory differences, but agreement on common national objectives related to food safety and technical barriers to trade.

**Alignment**: the gradual pursuit of reducing regulatory differences, usually through one or more voluntary standards organizations such as the ISO.
Harmonization: convergence and standardization of regulations over time, eliminating major differences in national standards. This may be most effectively achieved through a binding process such multilateral trade negotiations in the WTO.

Strategies for Reducing Technical Barriers to Trade

It may not be possible to adopt and pursue any single method of cooperation because of differing views about food safety standards within and between countries. The most effective strategy will likely be the pursuit of all three methods concurrently, attempting to develop the most consistent set of international standards based upon the political and economic issues affecting various food products and commodities. It may be possible to achieve complete harmonization for some commodities, while only achieving equivalency for others. The degree of cooperation should be determined and agreed upon by all parties before attempting to work with any of the international institutions having responsibility for food quality management standards or their development.

A parallel process involving selected international institutions will be important to effectively develop a trade facilitating regime for TBTs. The ISO-9000 series is an important tool for certifying process control, especially in Europe. It is much less important in the United States and has some serious shortcomings related to food safety, namely the lack of consideration of food safety standards in the process of certification and an uncertain relationship with the WTO.

Strategies to reduce technical barriers to trade should focus on operating within the framework of the Codex Alimentarius Commission and the World Trade Organization to ensure that national food safety standards contain a HACCP component and that the resultant standards are recognized and applied.
internationally. Important to the development of this strategy will be considerations not only for food safety, but for biotech products and genetically modified organisms. Codex maintains the infrastructure to facilitate this type of initiative and can access scientists and food safety specialists from around the world to evaluate alternative food quality management systems. WTO is in the process of modifying technical working groups to conduct the next round in 1999 and should be approachable about new initiatives, especially those designed to reduce trade barriers and put into place permanent regulations to preclude TBTs from restricting trade in the future.

A longer term option to pursue is the development of a food safety component, such as HACCP and/or Codex standards under the auspices of the International Standards Organization. It will likely become more feasible to implement TBT reduction within the framework of the ISO after progress is made in Codex and the WTO. Once new standards are agreed upon and implemented by the WTO and its member countries, the ISO series will need to be modified in order to remain current.

Probably the most effective way of ensuring broad-based support for the reduction of TBTs will be to pursue both strategies outlined above. It will be important to form alliances between and within USDA agencies responsible for food safety and technical barriers, such as FSIS, AMS, FAS, and ARS, the EPA and the FDA, along with selected consumer and food groups.

Thorough planning and the formation of some key strategic alliances will aid the reduction of TBTs. Working with the Codex, ISO, and within the framework of HACCP is only the beginning of a successful attempt to dismantle TBTs and ensure that they are not used as impediments to trade in the future. To a great degree, success will depend upon countries’ willingness to participate openly in the process to identify existing TBTs and their impacts. While it is possible to pursue this process bilaterally, which will be a time
consuming and expensive exercise with mixed and unpredictable results. Working through the NAFTA Technical Barrier and SPS process is one possibility, though somewhat limited in scope since only three countries are involved. If NAFTA is expanded to a Free Trade Agreement of the Americas (FTAA), then that organization can provide leverage from which to launch a multilateral TBT reduction effort. The most time and cost efficient method in the absence of a large regional trading bloc will likely be the WTO, the Asia Pacific Economic Cooperation (APEC) forum or some other multilateral fora, such as the Codex Alimentarius Commission.
References


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