



## COVER STORY

### Industry Waits for Green Light on Harmonized Food Safety Standards

By Sarah Fister Gale

Growing international food trade has added layers of complexity to processing strategies as food companies struggle to accommodate the food safety regulations of every destination country while attempting to rein in production costs.

International trade in raw materials and high-value food products has expanded enormously over the last decades, fueled by changing consumer tastes and advances in production, transport and supply-chain technologies. Trade in raw and processed food is a \$400-billion-a-year business with trade in high-value food products such as fresh and processed fruits and vegetables, fish, meat, nuts and spices now accounting for more than 50 percent of the total agro-food exports of developing countries, while the share of traditional commodities—such as coffee, tea, cocoa, sugar, cotton and tobacco—has declined.

Overall, according to the World Bank, demand for food will increase dramatically in the next 20 to 30 years, as the world's population grows by two billion people—mostly in developing countries. Growing populations and increased urbanization, coupled with increased wealth, will drive worldwide demand for safe, high-quality food. This will create opportunities for continued expansion in trade in high-value products, especially among developing countries.

While the growth in demand creates exciting opportunities for food companies, getting those products back and forth across borders can prove challenging. In the quest to use ingredients from all over the earth and provide them to consumers on a global distribution scale, the dividing lines between countries can be maddening barriers to progress. Each country's unique food safety regulations, import and export requirements and expectations for tracking and traceability throw up roadblocks to this "one world" mentality, creating obstacles to distribution that frustrate the industry, slow adoption of new technologies, and limit the ability of companies and countries to disseminate food products to those most in need.

These obstacles are challenging, though they aren't without merit, notes Roger Frost, communications manager for the International Organization for Standardization (ISO). "One weak link can result in unsafe food that is dangerous to health—and when this happens, the hazards to consumers can be serious and the cost to food chain suppliers considerable. As food safety hazards can enter the food chain at any stage, adequate control throughout is essential."

Concerns stemming from public health issues such as cases of bovine spongiform encephalopathy (BSE, or mad cow disease), avian flu epidemics and pathogen related foodborne illnesses, or uncertainties pertaining to potential foodborne hazards such as acrylamide, dioxin and pesticides, all fuel the demand for greater accountability and reduced access to countries when consumer perception dictates that those countries' products carry food safety risks.

The ISO estimates there are about 20 different schemes in various countries worldwide relating to food safety and the supply chain, each providing for various levels of checks, balances and procedures. This generates risks of uneven levels of food safety, confusion over requirements and increased cost and complication for suppliers that find themselves obliged to conform to multiple programs. "When there are differing requirements that purport to meet the same aim of ensuring food safety there is a potential for redundancy, increased cost, complexity, confusion and varying levels of food safety," Frost points out.

For example, the use of chlorine is allowed in many countries to destroy pathogenic bacteria on produce but in many other countries it is forbidden for food contact applications. Similarly, plant sterols have been cleared for use in many nations but are still at issue in others. And, for the sterilization of food by high-pressure treatment there are no regulations yet.

Unfortunately, the justifications for many legislative acts and the rulemaking that creates trade barriers are often based more on perception of risk or media-fostered hysteria than in scientific fact. Regulations are formed based on a country's experiences with food safety, inherent food safety risk levels in each country's food supply, its ability to control these risks, and differences in consumers' food safety perceptions. In some cases the science used to inform and bolster food safety policymaking is insufficient, inconsistent or contradictory, preventing the promulgation of laws that have a clear and evident benefit to protecting public health. Regrettably, say industry experts, due to unintentional or intentional restrictive legislative and regulatory measures that give rise to trade barriers, the ultimate result is that the global availability of safe food is curtailed.

"Too often science is used as an excuse to pander to domestic producers looking for means to restrict imports," explains John Reddington, vice president international trade with the American Meat Institute (AMI), citing a recent example in which AMI and other leading governmental and industry groups advocating the adoption of globally agreed, science-based import/export guidelines have met with such an obstacle.

"The science on allowing trade for meat and poultry during periods in which a country has BSE or low-path avian influenza is fairly well understood and offers no human or animal health hazard," Reddington states. "In fact, the World Organization for Animal Health (OIE) has adopted guidelines to allow for the trade of these meat and poultry

products from countries that have had cases of mad cow and avian flu, so long as certain conditions are met. The problem to date is that many countries still do not accept these standards for imports, even though they agreed to accept the standards in a vote taken at the OIE.”

#### **New Technology: Highway or Sidewalk?**

The differences in food safety regulations and legislation between countries also trigger a red light to the advances offered by science and technology, says Larry Keener, general manager of International Product Safety Consultants, based in Seattle, WA. He notes that although many food companies throughout the world have contributed significantly to research and development (R&D) efforts to improve food safety technologies, industry is understandably hesitant to apply newly developed capabilities on an international scale in an uncertain, maze-like regulatory environment.

“A food company does not want to incur the staggering costs of a foodborne illness outbreak associated with its products, including potential legal liability, the costs of recalling product and damage to the brand or company’s reputation that results in loss of consumer confidence and decreased sales,” notes Keener. “But neither does a business want to invite increased overhead, unnecessary expenditures or bear the economic brunt of investing in new food safety technology that is recognized by the regulatory authorities in some target markets and not in others.”

Paul Hall, Ph.D., senior director, microbiology and food safety, Kraft Foods North America, agrees. “If a technology provides an advantage we will do the work to show that it is equivalent to existing test methods, but it takes resources to accomplish that,” he says. Kraft employs full-time experts who are responsible for making sure the company is in compliance with the unique regulations of the countries and companies it does business with. Kraft Foods uses the International Committee on the Microbiological Specifications for Foods (ICMSF) standards as the minimum requirements for food safety testing, performing additional testing if a market demands. “The ICMSF standards get us into the majority of countries and allows for some flexibility,” Hall notes. And while Kraft attempts to conform to the requirements of every country, sometimes the logistical costs and headaches associated with customizing production for the needs of a particular market aren’t worth the trouble. “If the volume is too small, we may opt not to send it,” Hall says.

For larger companies like Kraft Foods, having the support of a staff of experts reduces some of the regulatory compliance burden; however, large companies make up only a small percentage of the total global food industry, and small- to medium-sized companies don’t always have the money and expertise to support such initiatives. This is why it is important for companies to get involved with global food safety law harmonization efforts, says Keener. “Smaller-sized U.S. food companies that wish to export product or import ingredients or raw materials from outside the country can benefit from involvement with industry and other groups working toward harmonization of food safety standards and regulations. One of the most significant benefits to be gained from this involvement is that a non-multinational food company gets access to resources and information on the types of food safety technologies and test methods that are accepted in target overseas markets.”

#### **Codex Sets the Pace**

The challenge faced by the industry today is to create consensus on a global basis for a single set of regulations that will both meet the food safety and security needs of all countries and be reasonably adopted by any food company, no matter the size. “Both individual companies and the industry as a whole will benefit from implementing a globally harmonized set of requirements for food safety management, based on international consensus among the major stakeholders,” ISO’s Frost says. “This will reduce the costs of suppliers having to conform to multiple requirements and reduce the possibility of multiple requirements leading to confusion that in turn can generate risks to food safety.”

However, it’s not an easy or inexpensive task. “The process of setting food standards is rigorous and long and, in most cases, it is also costly,” says Kazuaki Miyagishima, secretary of the Codex Alimentarius Commission (CAC), a joint Commission of the United Nations (UN) Food and Agriculture Organization (FAO) and World Health Organization (WHO) whose mission is to develop global, science-based food standards. “It has to be that way to ensure that the food consumers’ purchases are not only safe but of the quality they expect.”

The CAC works with national governments to establish uniform worldwide product standards that can benefit producers and consumers alike. It offers a forum where member governments volunteer time, resources and energy to negotiate mutually agreeable solutions to protect the health of consumers and ensure fair practices in the food trade.

“The objective of Codex is to protect the health of consumers while ensuring fair practices in international trade in food,” says Ed Scarborough of FDA and the U.S. manager for Codex Alimentarius. “As long as Codex standards, guidelines and recommendations continue to be based on sound science, they provide a baseline for international harmonization, thus facilitating trade; they can serve as national regulations for countries that lack the infrastructure of the more developed countries; and they serve as benchmarks for settling trade disputes under the agreements of the World Trade Organization (WTO).”

Indeed, one of the primary principles of the WTO Sanitary and Phytosanitary Standards (SPS), codified to prevent unnecessary trade barriers, ensure the sovereign right of nations to protect public health and to prevent misuse of food safety legislation for protectionism purposes, is that international standards that define the safety of a product should be set by the CAC. In August, John H. Silliker Lecturer and retired Nestle Foods corporate microbiologist Michael Von Schothorst told IAFFP conference delegates, “Fortunately, we can turn to Codex for a number of important standards, codes and guidelines, including those governing best practices in HACCP, Good Hygiene/Manufacturing Practices (GHP/GMP), food safety risk assessment, inspections, certifications, and more. Although, Codex standards are not ‘the Bible,’ they are an excellent foundation from which industry can develop

specific process parameters based on performance criteria.”

Meeting Codex standards also can open doors to new trading partners, so countries strive to do so. For example, the Near East Coordinating Committee, one of CAC’s six regional committees, met earlier this year in Amman, Jordan, bringing together food specialists from 14 of the 17 Near Eastern member countries to establish regional standards for a number of that region’s food specialties. The hope is to eventually propose these same standards to the CAC for global recognition.

“We would like to see all countries become involved in international bodies such as OIE and Codex,” adds AMI’s Reddington. “And, once those bodies adopt standards for protecting animal and human health, that they be applied by the exporting and importing countries.”

#### **GHI Strives for Global Road Rules**

In concert with the aims of CAC, the Global Harmonization Initiative (GHI) Working Group is striving to gather and consider the latest research on food safety issues to ensure the most effective regulations are adopted. GHI is one of the leading global organizations working to promote a unified standard for food safety, by involving industry experts and food scientists from around the world. In 2004, the International Division of the Institute of Food Technologists (IFT) and the European Federation of Food Science and Technology (EFFoST), in cooperation with Food Safety Magazine and Elsevier Science, launched GHI to try to eliminate differences in food safety regulations and legislation. Soon, many other organizations joined this working group, including the International Union of Food Science and Technology (IUFoST), the Federation of European Microbiological Societies (FEMS), the Food Chemistry Division of the European Association for Chemical and Molecular Sciences (EuCheMS) and the European Hygienic Engineering and Design Group (EHEDG).

The need for such a group was clear, notes Huub Lelieveld, retired senior technologist with food and personal care product manufacturer Unilever and co-chair of GHI. “We know there exist undue barriers to free trade that masquerade as food safety protections, and that these must be eliminated. This situation can exist as a result of differences in food safety regulations and related legislative measures between nations. Hardly anyone is to blame as food regulations have a long history of having been drawn up as a response to food safety incidents.”

The objective of the group is to discuss, globally, the scientific issues that buttress the decisions made by individual governments and international regulatory bodies in order to achieve global consensus on the science of food regulations and legislation to ensure the global availability of safe and wholesome food products for all consumers. “GHI will collect and evaluate available evidence and circulate the findings among the food scientists from all over the world, for debate and comments, eventually reaching a consensus statement,” Lelieveld says. “The group intends to obtain consensus on the science that is or should be used by regulators, making it easier to agree on harmonized requirements.”

GHI anticipates that elimination of such regulatory differences will also make it more attractive for the private sector to invest in food safety research and development, consequently strengthening the competitiveness of each nation’s food industry and of the industries supplying the food sector. Harmonizing global regulations, says the group, will facilitate the application of new technologies, encouraging the food industry to invest in new tools to ensure better safety and quality for consumers.

“It is not the intention of GHI to advocate carelessness or poor science in risk assessment,” Lelieveld says. “It is our view that it is a waste of time and resources to require approval in several countries, each demanding similar data produced by different protocols. What is needed are globally agreed protocols and a system to ensure that those protocols are followed accurately. Once checked and perhaps double-checked, the results should apply universally.”

He also points out that there are food safety related issues that have to do with consumers wanting to eat healthier. “In the case of ingredients that promote health, there may be rules to prevent the use of such ingredients because they are new and there is uncertainty about whether the substance has any possible negative effects on health in addition to claims of positive health effects. Many compounds are essential for good health in certain concentrations but can be toxic in another, higher concentration,” he says. “Such concerns are justified, but it hampers trade if proof of safety has to be produced for many countries, each in a different way, and each using different protocols.”

Food safety regulations promulgated and passed based solely on method’s capability have resulted in the careless application of such regulations to the detriment of commerce and the consuming public, he continues. “For 500 years we’ve known that toxicity is a matter of concentration. Many compounds are essential for good health in certain concentrations while toxic in another higher concentration.”

Complicating matters further is the growing demand from consumers for food without chemical preservatives, even if these preservatives have a long-time, proven safety record. As a result, efforts to find new methods for food sterilization that maintain the quality and integrity of the product and are allowable under international regulations. “Harmonized regulations for food sterilization will reduce the threshold to introduction,” Lelieveld says.

Much research has been done to meet consumer demands for safe, fresh, minimally processed foods, and with some modicum of success, adds GHI co-chair Keener. “Novel technologies that exert little or no effect on the nutrient content of foods have been developed and there are more in the pipeline, however, differences in regulations between countries related to food safety provide expensive scaffolding that often hampers the introduction of novel ways of food processing and preservation. The outcomes of food scientists’ attempts to meet consumer demands for healthier food are frequently thwarted because of differences in scientific methods, economic expedencies, political necessity or public health demands.”

### **ISO Removes Road Blocks**

With similar goals in mind, ISO recently released ISO 22000, which is a specific standard for food processors setting out safety management procedures that will play a key part in the efforts by governments and regulators to keep contaminants out of the food chain.

"ISO 22000 provides a global industry with a global response to ensuring food safety," Frost says. "Food safety is a joint responsibility of all the actors in the food chain and requires their combined efforts. ISO 22000 is therefore designed to allow all types of organization within the food chain to implement a food safety management system."

The standard was developed within ISO by food industry experts from 23 countries, along with representatives from international organizations, including the Confederation of the Food and Drink Industries of the European Union (CIAA), the CIES Business Forum's Global Food Safety Initiative (GFSI) and the World Food Safety Organization (WFSO), and in cooperation with the CAC. It will be a key method for global processors to ensure that their suppliers around the world are following approved food safety standards and will apply to organizations ranging from feed and primary producers through food manufacturers, transport and storage operators, to subcontractors, retail and foodservice outlets. Related businesses such as producers of equipment, packaging material, cleaning agents, additives and ingredients also will be affected.

"ISO 22000 will make it easier for organizations worldwide to implement the Codex Hazard Analysis and Critical Control Points (HACCP) system for food hygiene in a harmonized way," Frost says. "Also, food safety management systems that conform to ISO 22000 can be certified—which answers the growing demand in the food sector for the certification of suppliers—although the standard can be implemented without certification of conformity, solely for the benefits it provides."

ISO is also working with the UN's International Trade Center on a checklist for small businesses and developing countries, while FAO and WHO have a number of projects to assist them in building the scientific capacity necessary to fully participate in the Codex standard-setting process.

### **Footing the Bill**

Some studies have concluded that for a global standard to be agreed upon and used universally, wealthier countries should pick up the burden in bringing poorer countries up to speed on food safety strategies. A recent report from the World Bank, *Food Safety and Agricultural Health Requirements: Challenges and Opportunities for Developing Country Exports*, notes that recent food safety issues such as those related to E. coli breakouts, BSE, tainted animal feed products, and the contamination of berries and olive oil have contributed to more stringent food safety and agricultural health standards in high-income countries. The WTO Sanitary and Phytosanitary Standards (SPS), characterized by the report as a "double edged-sword," place particular demands on developing country producers and exporters of high-value food products, such as fruit, vegetables, fish, meat, nuts and spices, the report stresses.

The report goes on to note that rich countries provide only \$75 million per year to developing countries for enhancing SPS management capacities, a figure that does not meet the emerging demand of revamping the way key industries are organized and manage risks in many poor countries.

"By providing additional assistance, rich countries would help level the playing field and especially help poor countries to better prepare for evolving standards," says Kevin Cleaver, director of the World Bank Agriculture and Rural Development Department. "Countries that invest in new supply chain technologies are more likely to remain competitive and thrive in this emerging market."

The World Bank has stepped up its own efforts in assisting developing countries by supporting the preparation of country action plans and reconstruction of supply chains. The Bank also initiated the establishment of the Standards and Trade Development Facility (STDF), which is a cooperative effort with other UN agencies and regulatory bodies designed to improve standard setting in developing countries.

"In the end, the goal should not be to compromise on either food safety or on facilitating trade, but to find the optimal balance," Frost says. "We can achieve that by bringing to the table the stakeholders and developing an international consensus on the state-of-the-art on the subject at issue."

### **JIFSAN Announces New Initiative for Food Safety Training in Exporting Nations**

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) of the University of Maryland unveiled in August a new food safety training program designed to improve the quality of food entering the U.S. ([www.jifsan.umd.edu](http://www.jifsan.umd.edu)). The program will be implemented by the new JohnsonDiversey International Food Safety Initiative announced at the annual conference of the International Association for Food Protection (IAFP).

"Even though food safety awareness has increased around the world, we continue to hear news of disease outbreaks and contaminated food," said Dr. Robert E. Brackett, director of the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN). "Producers and manufacturers recognize that food safety is a crucial issue and critical to promoting international trade as food export, particularly to the U.S., has dramatically increased. We must do all we can to ensure food safety."

The U.S. imports more than 12%, or \$58 billion, in food from outside its borders. More than 85% of all

fresh and frozen seafood consumed in the U.S. is imported and will rise to more than 90% in 2005. South and Central America exports to the U.S. more than 8 million tons, about 20% of all fruits and vegetables.

"With food exportation occurring around the globe, improving food safety from the beginning of the supply chain is critical," said Dr. David Lineback, director of JIFSAN, "The most effective way to protect food and avoid importation of contaminated food is to educate food providers about the best practices for safe food handling right in their own countries."

By establishing the JohnsonDiversey International Food Safety Initiative (JDIFSI), JIFSAN will expand its current food safety training program in countries exporting food to the U.S. JDIFSI is designed to identify and train local trainers in the food industry in exporting countries. Using the knowledge and materials provided in food protection and safe handling, trainers will go on to train agricultural and aquacultural workers, food processors, exporters, regulators and educators. The first training program is being developed for the seafood industry and will be held in Asia next year.

"This initiative will create a linkage between JIFSAN and the food industry promoting best practices in food safety in participating foreign countries," said Serban Teodoresco, director of JohnsonDiversey Consulting. "The result will be better coordination and more effective food safety practices in exporting countries."

This is important, added Dr. Brackett, particularly in light of a five-fold increase of the number of food products entering the U.S. market in last several years. "It is truly a global food network, and any [action taken] in one country can affect every country," he noted. "What were once other countries' problems are now our problems, and thus, we want to make sure that the food safety practices in those countries are same as those we expect from our domestic food industry-even as we compare and formulate international food standards for trade."

Training personnel in food safety on site in the country of origin, Dr. Brackett continues, better ensures that foods are produced safely before they are exported and JIFSAN's experience in conducting these educational programs in the countries of imported products' origin has proved a very successful approach.

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