Food safety is affected by the decisions of producers, processors, distributors, food service operators, and consumers, as well as by government regulations. In developed countries, the demand for higher levels of food safety has led to the implementation of regulatory programs that address more types of safety-related attributes (such as bovine spongiform encephalopathy (BSE), microbial pathogens, environmental contaminants, and animal drug and pesticide residues) and impose stricter standards for those attributes. They also further prescribe how safety is to be assured and communicated. Liability systems are another form of regulation that affects who bears responsibility when food safety breaks down. These regulatory programs are intended to improve public health by controlling the quality of the domestic food supply and the increasing flow of imported food products from countries around the world.

Common to the adoption of new regulations by developed countries is the application of risk analysis principles. Under these principles, and in line with the World Trade Organization’s (WTO’s) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), countries should base their regulatory actions on scientific risk assessment. In addition, a country should be able to clearly link its targeted level of protection, based on a scientifically assessed risk level, to its regulatory goals and, in turn, to its standards and inspection systems. Finally, the risk management options chosen should restrict trade as little as possible.

Despite similarities in approach among developed countries, to date they have made only mixed progress toward aligning their regulatory requirements. Countries are struggling with the task of identifying key risk issues and choosing regulatory programs to control those risks. They emphasize different risks, apply different levels of precaution, and choose different regulatory approaches. The regulatory systems of countries are a mix of old laws and newer regulations that frequently do not apply consistent standards across products, risks, or countries of origin. Finally, countries may be tempted to use food safety regulations as a means of protecting domestic industries from foreign competition.

These features of food safety regulation in developed countries have several implications for developing countries. First, they determine access to growing markets for food exports, particularly high-value fresh commodities such as those discussed in other briefs in this collection. When standards differ, this can create additional barriers for developing-country exporters. Second, these features determine the issues that will be addressed in international forums, such as the Codex Alimentarius Commission (see Brief 5). Third, they create expectations among developing-country consumers regarding acceptable levels of safety and set examples for emerging regulations in developing-country food systems (see Brief 13).

This brief reviews emerging regulatory approaches and the implications for developing countries.

REGULATORY APPROACHES

Countries regulate food safety through the use of process, product (performance), or information standards. Process standards specify how the product should be produced. For example, Good Manufacturing Practices specify in-plant design, sanitation, and operation standards. Product (performance) standards require that final products have specific characteristics. An example is the specification of a maximum microbial pathogen load for fresh meats and poultry. Finally, information standards specify the types of labeling or other communication that must accompany products.

While these categories provide a neat breakdown, in practice most countries use a combination of approaches to regulate any particular food safety risk. For example, specifications for acceptable in-plant operations may be backed up with final product testing to monitor and verify the success of safety assurance programs. Labeling that instructs final consumers on proper food handling techniques may further back up these systems.

MAJOR REGULATORY TRENDS IN DEVELOPED COUNTRIES

- **Stronger public health and consumer welfare emphasis in decisions by regulatory agencies.** The increasing use of the risk analysis framework for regulatory decision-making focuses attention on the effective control of public health risks as the ultimate goal of regulations, rather than intermediate steps such as assuring that accepted practices are used in production. This in turn leads to a focus on the food supply chain, on identifying where hazards are introduced into it, and on determining where those hazards can be controlled most cost effectively in the chain. This approach is referred to as “farm to table” or “farm to fork” analysis. When the supply chain extends across international borders, risk analysis may encompass farm or processing practices in developing countries.

- **Adoption of more stringent safety standards, with a broader scope of standards.** Food safety standards are becoming more stringent in developed countries on two fronts. First, in many cases food safety attributes that were previously regulated are being held to more precise and stringent standards. For example, rather than assuring meat product safety simply through process standards, those products may be required to meet specific pathogen load standards for *E. coli* or *Salmonella*. Similarly, tolerances for aflatoxin may be lowered as more information and better testing become readily available.
Second, the scope of standards is broadening, as new risks become known. For example, the European Union, the United States, and other countries have instituted strict feeding restrictions to avoid the spread of BSE in cattle. In addition, the European Union has recently established a regulatory program to control human exposure to dioxins through the food supply. These evolving standards create continuing challenges for producers and regulatory agencies in exporting countries.

- Adoption of the HACCP approach to assuring safety. During the 1990s, developed countries made a strong shift toward requiring the Hazard Analysis Critical Control Point (HACCP) approach to assuring food safety. Under HACCP, companies are responsible for analyzing how hazards such as food-borne pathogens may enter the product, establishing effective control points for those hazards, and monitoring and updating the system to assure high levels of food safety. These HACCP systems are usually predicated on the processing plant having an adequate system of sanitary operating procedures already in place. HACCP does not prescribe specific actions to be taken in a plant; the company chooses its methods for controlling hazards. HACCP systems make clear that the central responsibility for assuring safety belongs to a company; the regulator’s job is often shifted from one of direct inspection to providing oversight for the company’s operation of its HACCP plan. Since HACCP is primarily a process standard for company-level activity, inspection to assure compliance is challenging for imported products coming from plants in other countries. Some countries, such as those in the European Union, have mandated HACCP for all levels of the food supply chain, while others such as the United States have mandated it for specific sectors (meat slaughter and processing, for example).

- Adoption of hybrid regulatory systems. Mandatory HACCP may be combined with performance standards for finished products. The performance standards (a minimum incidence of Salmonella in finished products, for example) provide a check on whether the HACCP plan is performing adequately. The increased use of performance standards has been facilitated by the development of more accurate and speedier testing procedures, particularly for pathogens. Eventually such tests may make it easier for exporters to demonstrate and verify a particular level of safety.

- Increased reliance on certification, including traceability. In developed countries, regulatory systems increasingly require that safety assurance actions be documented internally by the company and externally to government agencies. The system may require documentation tracing a food product back through the supply chain to its source or forward through the chain to the consumer. For example, the European Union is moving forward with mandatory traceability for all food products. The quality control systems required by buyers (such as supermarket chains) have frequently moved faster in the direction of certification and traceability requirements than have government programs, leading to a complex interaction of public and private requirements for food producers and suppliers. (How these developments have affected exporters is discussed in Brief 8.)

- Greater transparency for national regulations. National-level regulation has become more transparent in several respects largely because of the requirements of the WTO. National governments must clearly state the reasoning and rationale behind their regulations and notify WTO members about the requirements of a regulation and the timing of its enforcement. Regulations may be challenged under the WTO dispute process. As a result, national regulators can no longer ignore the trade impacts of their regulatory choices. This may make it easier to address food safety standards as barriers to trade.

- Export of some regulatory responsibility and burden. HACCP and other certification approaches to food safety assurance are process oriented. Assuring compliance for imported products may require oversight and inspection of farms or plants in other countries. One approach to accomplishing this is to require that exporting countries have in place a regulatory structure (a competent authority) deemed acceptable to the importing country. This has resulted in some exporting of regulatory responsibility and burden to other countries as the price of entry into developed-country markets (see Brief 9).

CONCLUSION

Developed countries have been building food safety regulatory systems that are increasingly comprehensive (covering more safety attributes) and more stringent (establishing stricter standards for those attributes). They are adopting a mix of regulatory approaches depending on the problem addressed, including process standards such as HACCP, performance standards for testing final products, and even increased labeling to communicate about food safety to consumers. These trends will continue unabated in the future, with the result that over time food safety standards will become increasingly demanding. How these trends are influencing developing countries’ food exports and food markets is discussed in other briefs in this collection.