### HACCP as an international trade standard

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HACCP as an International Trade Standard

Julie A. Caswell and Neal H. Hooker

The widening international use of Hazard Analysis Critical Control Point (HACCP) approaches by regulators and industry should facilitate trade of food products as countries and companies adopt roughly similar food safety assurance systems. First and foremost, however, adoption of HACCP principles is motivated by a desire to improve food safety, particularly by the control of food-borne pathogens, in a manner that passes benefit-cost or market tests. For regulators, trade facilitation is an important but often clearly secondary goal of HACCP adoption. That it is part of the goal set is due in part to recent trade agreements that seek to limit nontariff barriers to trade arising from food safety (sanitary and phytosanitary) regulations. The pressure to reduce these barriers has led to a focus on HACCP adoption as a vehicle for reconciling regulations across countries through various means of regulatory rapprochement. This goal hierarchy, with improved safety first and trade facilitation second, is useful in explaining the likely operation of HACCP as an international trade standard in the next decade.2

HACCP Principles

The HACCP approach was first developed in the 1960s, with a widespread movement toward its adoption for assuring microbial food safety developing since the late 1980s (Mortimore and Wallace). Consistent sets of HACCP principles were adopted by the National Advisory Committee on Microbiological Criteria for Foods in the United States in 1992; by the European Union for meat products in 1992, and for foodstuffs in 1993; and by the United Nations' food standards body, the Codex Alimentarius Commission (Codex), in 1993. HACCP principles stress identifying where hazards are likely to occur in a processing chain, the critical control points (CCP) for the hazards, preventative measures to be taken to keep hazards within critical limits at each CCP, establishment of monitoring procedures, clear response to violations of critical limits at each CCP, record keeping, and continued validation and updating of the HACCP system.

HACCP is a process-oriented approach to assuring food safety. It recognizes that end-point performance testing of each product is often impractical, especially if the significant hazards are distributed heterogeneously throughout the product. In this case, a simple sampling procedure can fail to detect a potentially disastrous hazard a significantly high proportion of the time. Such a heterogeneous distribution combined with an uncertain frequency of risks is common to microbial food safety hazards, especially in protein foods such as meat, poultry, and seafood. Thus, it is not surprising that several countries are now applying the preventative HACCP principles to these foods.

In use, HACCP is a multidisciplinary-science-based approach to the issue of food safety. It is best considered as a philosophy with structure, based on principles that allow a certain degree of flexibility. The key objective of any HACCP system is to produce a safe product every time, to demonstrate that the process is safe.
(e.g., as part of a “due diligence” defense), and to provide and promote confidence in the product. In addition, a HACCP system can increase the participation of all of the work force, as advocated by management systems such as Total Quality Management; serve as a step toward a larger quality management program, such as International Organization for Standardization (ISO) accreditation; and prove to be a cost-effective technique by which the process is updated (Mortimore and Wallace).

HACCP in the Context of Recent Trade Agreements

Barriers to trade posed by tariffs have been steadily declining under evolving international trade relationships. The recently completed Uruguay Round of the General Agreement on Tariffs and Trade/World Trade Organization (GATT/WTO), for example, continues this process by reducing tariff levels on agri-food products and initiating tariffication of some nontariff barriers to trade. In this setting, concern has focused on the potential for an opening of the floodgates of other types of nontariff barriers to trade. To keep the gates closed, trade agreements and trading blocs have turned to adoption of provisions such as those in the WTO and North American Free Trade Agreement (NAFTA) on sanitary and phytosanitary (SPS) regulations. These agreements for the first time specify that national-level regulations must be based on appropriate science and risk assessment processes and be applied evenly to domestic and imported products. The overall goal is an equivalency of the effect of regulations, not the regulations themselves. These agreements also strongly emphasize increasing the openness and transparency of national-level regulations (Hooker and Caswell). Regulations that do not fit these criteria may be challenged under the WTO agreement.

A concerted, cooperative effort to address nontariff barriers to trade arising from country-level regulation requires coordinated activity, which we term regulatory rapprochement. Strategies for rapprochement can be grouped into three categories (Jacobs):

- Harmonization: standardization of regulations in identical form;
- Mutual recognition: acceptance of regulatory diversity as meeting common goals (sometimes called reciprocity or equivalency); and
- Coordination: gradual narrowing of relevant differences between regulatory systems, often based on voluntary international codes of practice (sometimes called alignment).

It is useful to consider these strategies as a spectrum, as presented in figure 1. The continuum begins with no rapprochement; moves to coordination, which is a broad range of weak forms of rapprochement; then to mutual recognition; and finally to the strongest level of rapprochement, harmonization.

Harmonization has most often been applied via minimum input, process, or product performance standards for particular food attributes. Mutual recognition involves agreement among a group of countries that a good legally produced within the bloc will be legal for sale throughout the bloc regardless of whether it meets the host country’s domestic standards. It has most often been applied to value attributes (e.g., recipe standards) because countries frequently do not like to give up control over food safety. Coordination covers a wide variety of efforts to align policy through consultations, adoption of voluntary standards, and other means. A total lack of rapprochement is possible but increasingly rare as international trading relationships take on growing importance for countries.

The efficacy of HACCP as an international trade standard will depend on the degree to which regulatory rapprochement between countries is exercised in its adoption. Trade facilitation requires that differences in applying HACCP principles between nations and trading blocs be reconciled by some form of regulatory rapprochement that works out the degree of equivalency between HACCP regimes. HACCP as a case study will highlight the relative abilities of the rapprochement approaches used by trading partners to lessen nontariff barriers to trade that can arise as it is applied.

HACCP as an International Regulatory Standard

Differences arise when HACCP becomes a regulatory regime rather than maintaining its original form as a voluntarily adopted management tool. When used by a company, HACCP is a process-oriented means to attain a performance goal of safe products. But is HACCP a performance or process standard when it becomes a government regulatory requirement? The answer depends on how the government implements HACCP. It will predominantly be a performance standard if regulators require com-
HACCP in Practice

To date there are real differences between European Union (EU), North American, and World Trade Organization approaches to regulatory rapprochement for HACCP. In the European Union, the development of HACCP-based regulatory regimes has been harmonized across countries. In 1992, Council Directive 92/5 (Article 7 of the Annex, EEC 1992) for meat products advocated HACCP-like principles. Subsequently, more direct HACCP principles were advanced in the 1993 directive on the hygiene of foodstuffs (EEC 1993) and extended to cover all food companies. Now being implemented, these directives and associated guidelines should result in a reasonably homogeneous level of food safety assurance within the EU. This will facilitate within-bloc trade and trade between third party countries and EU members.

The North American approach to regulatory rapprochement for HACCP corresponds most directly to a weak form of coordination, with Canada and the United States pursuing HACCP plans in parallel. Canada’s adoption is most advanced (with a planned implementation date of April 1996 for all agri-food sectors), while U.S. HACCP plans for seafood, meat, and poultry are at the proposal or early implementation stage. While the parallel movement toward HACCP may ease regulatory differences between the United States and Canada, neither full mutual recognition or harmonization is anticipated in the foreseeable future. For example, in its HACCP proposal for meat and poultry, the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) anticipates relying on current procedures to review foreign countries’ inspection systems to ensure their approaches to food safety are equal to that of the United States. Differences in microbiological food safety regulation between the trading partners are likely to continue to have the potential to pose significant nontariff barriers to trade.

The Codex/WTO approach to regulatory rapprochement is weaker still, reflecting the vast differences in regulatory regimes around the world. The WTO encourages member countries to ratify the Codex HACCP standards but has no means of leveraging this adoption except if one country challenges another’s food safety system as unscientific and an unjustified nontariff barrier to trade. However, countries will have strong incentives to adopt HACCP approaches so their companies can compete effectively in international markets.

In the short run, the EU approach is likely to be most effective in facilitating food product trade, limiting nontariff barriers to trade, and targeting microbiological food safety attributes. The North American and WTO approaches are at an earlier stage of development, resulting in a higher continuing potential for such SPS regulation to generate barriers to trade.

3 We are not aware of any Mexican plans to adopt an HACCP regime.
On the Equivalency of National-Level HACCP Systems

The use of a HACCP framework for regulatory oversight of food safety, especially microbiological safety, by more countries has the potential to facilitate a move to the right on the rapprochement spectrum shown in figure 1, away from little coordination to stronger forms, including possible mutual recognition or harmonization of standards. An obstacle to stronger levels of rapprochement are difficulties in assessing the equivalence of different HACCP programs. Assessing this equivalence is an example of the central dilemmas involved in all SPS-related trade problems. First, a central body, Codex, has determined a set of minimum HACCP principles without giving much detailed guidance on how they should be applied. Second, countries may put in place stricter-than-minimum programs as long as they can be scientifically justified and are the least trade-restrictive possible (FAO). Finally, equivalency requires that the burden of proof of product quality be placed on the exporting country. Recognition of equivalency between national programs thus requires a large number of bilateral or multilateral negotiations between trading partners.

Debate on equivalency issues is under way, most notably at the Food and Agriculture Organization's Expert Technical Meeting held in Vancouver, Canada, in 1994 (FAO). A series of papers was presented discussing the role of governments in developing and applying HACCP-based systems, the constraints faced by developing countries in implementing such advanced food control systems, and how HACCP can be applied to different sectors of the food industry. The meeting concluded that Codex must play a key role in providing leadership in the implementation and coordination of HACCP plans, as well as being the basis for all discussions on determining equivalency. It also called for a concerted effort, to ensure that HACCP and other SPS regulations are truly food safety related and thus justified, and for an expanded role for mutual recognition agreements, especially between developing and developed economies.

Problems with Prerequisites

In practice, use of HACCP is embedded in larger national or trading bloc regulatory systems whose goal is to assure food quality. Harmonizing HACCP will lower only a section of the regulatory hurdles. A further complicating factor is that most HACCP regulatory requirements are either in the proposal or very early implementation stages. In this transitional phase at least, HACCP is frequently implemented as an additional layer of regulation, with existing process and performance standards still in place. This may satisfy regulators' goals of improving food safety, but it complicates compliance.

The larger regulatory systems in which HACCP is embedded seek to control the environment in which food is processed and sold. For example, the current draft of the revised Codex General Principles of Food Hygiene classifies eight broad programs that define minimal conditions for the production of safe food. These cover, often in extensive detail, primary production, plant design and facilities, operation control, establishment maintenance and sanitation, personal hygiene, transportation, product information and consumer awareness, and training. For food processing operations, national-level regulatory programs covering these program areas are in place in addition to any HACCP requirements. Called prerequisites or Good Manufacturing Practices (GMPs), these requirements are intended to be a base on which HACCP plans are built, allowing them to be more concise and focused on truly critical control points. Codex's intent to link these methods of ensuring food safety is evident in its inclusion of its HACCP guidelines as an appendix to the more general food hygiene documentation.

Both regulators and industry appear eager to keep some separation between prerequisite and HACCP requirements for safe food production. For example, John Cady of the National Food Processors Association voiced an industry position that U.S. HACCP requirements should be applied only to specific food safety hazards and not to (other) quality and financial concerns such as economic adulteration. He went on to advocate that "GMPs and detailed sanitation practices should not be included in HACCP plans unless they directly impact food safety" (Cady, p. 4). In practice, any company that enforces comprehensive prerequisites or GMPs that address the significant hazards found in food processing plants will find the transition to HACCP easier. But these practices have not necessarily considered chemical or microbiological hazards, the food safety concerns that have fueled the increased use of HACCP-based regimes.

The clear lesson from this is that for HACCP to operate as an effective international trade stan-
standard that facilitates food trade, both HACCP and prerequisite requirements must be coordinated. Prerequisite requirements can pose nontariff barriers to trade even when HACCP regimes are coordinated. For example, potential problems with prerequisites are evident in the U.S. and Canadian programs now being developed.

As proposed, the USDA Food Safety and Inspection Service's (FSIS) HACCP system for meat and poultry would work in conjunction with several other regulatory requirements. In addition to GMPs that FSIS considers to be a minimum basis for the production of safe food, it would require companies to have in place written Standard Operating Procedures (SOPs) for sanitation programs, at least one antimicrobial treatment process that targets levels of microorganisms at key processing steps, and measures to maintain specific time and temperature requirements for cooling carcasses post-slaughter. FSIS notes that some of these new requirements may be subsumed under a company's HACCP plan once it is adopted but envisions the maintenance of many GMPs and other regulatory requirements in addition to HACCP. Final rule-making and implementation will determine whether the FSIS HACCP plan is a performance or process standard. The specific process standards now included in the plan mandate particular CCPs, critical limits, and preventative measures.

Most important for international trade, the U.S. system does not directly adopt the exact Codex hygiene code making coordination of prerequisites or GMPs more difficult. In contrast, Agriculture and Agri-Food Canada in its Food Safety Enhancement Program (FSEP) HACCP implementation manual adopts the Codex hygiene code as its source of prerequisite requirements. The Canadian approach goes further toward promoting food trade.

HACCP's Future Internationally

HACCP has a bright future internationally as more countries adopt it as a regulatory standard for improving food safety. Widespread HACCP adoption is likely to facilitate trade as countries adopt similar regulatory approaches. Whether HACCP becomes a really effective international trade standard that significantly lowers nontariff barriers to trade in food products depends on the degree of regulatory rapprochement achieved by countries in its adoption. Its impact also depends on how effectively other elements of the regulatory systems, especially prerequisite requirements, are coordinated. An interesting sidebar to this discussion is the interaction and possible interdependency of the use of HACCP as an international regulatory standard and as a private standard in industry quality assurance programs. For example, the ISO 9000 certification series for food companies incorporates HACCP principles and is becoming a forum for private and public (Article 6, EEC 1993) harmonization of standards across boundaries. HACCP's private and public efficacy in trade facilitation ultimately will depend on the ability and willingness of governments to engage in regulatory rapprochement.

References


