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**The Economic Implications of Using HACCP as a Food Safety Regulatory Standard**

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## **The Economic Implications of Using HACCP as a Food Safety Regulatory Standard**

Several trends are bringing greater attention to food safety regulation in many countries. Science is identifying new foodborne pathogens and understanding their potential for serious consequences. Demand for safer food is growing as consumers become more affluent, live longer, and better understand the links between diet and health. The proportion of food obtained from food services is increasing, even in middle income countries, and this reduces consumer control over food handling and preparation. International trade in food products is a larger source of supply in many countries as both technical and trade barriers to food trade are reduced, and this can introduce new sources of risk into the food supply. These trends converge to create both public and private demand for greater food safety. At the same time, governments everywhere are trying to make more efficient use of public resources.

Private markets often fail to provide for adequate food safety because the safety is not readily apparent to consumers and it is often very costly to test for the safety of product. Furthermore, producers or retailers may not be able to ascertain or certify the safety of foods given the wide array of microbial agents and their potential for hazard. Without the ability to fully capture returns to costly control of product hazard, firms lack incentive to implement controls for food safety.

As a result, many governments are taking a new approach to ensuring the safety of the food supply: mandated use of the Hazard Analysis Critical Control Point (HACCP) system in food industries. Such a system focusses on verifiable control of the process. For example, the European Union Directive 93/43, effective in December 1995, requires food companies to implement HACCP (Grijspaardt-Vink, 1995). In the United States, HACCP was mandated

through regulation for seafood in 1994, for meat and poultry in 1996, and proposed for fresh fruit juice in 1998, with regulations for other food industries expected in the future (Morris, 1997). Australia, New Zealand, and Canada also have mandatory or voluntary public programmes to encourage adoption of HACCP (Peters, 1997; Dean, 1990). As an outcome of its use in most developed countries, HACCP is increasingly practiced in less developed countries that export food products into industrialized markets (Merican, 1996). The growing use of HACCP as a sanitary standard in international trade led the Codex Alimentarius to adopt guidelines for HACCP in 1993, and to incorporate HACCP into food hygiene codes starting in 1995 (Whitehead and Orriss, 1995).

Despite the widespread enthusiasm for HACCP among regulatory and international agencies, there are several controversies surrounding mandatory imposition of HACCP. First, there is disagreement regarding how effectively HACCP will control or eliminate some food safety hazards, and whether it must be combined with specific product standards (Hathaway, 1995). Second, there is controversy regarding whether it improves or reduces regulatory oversight (Smith-De Waal, 1996). Third, there is controversy regarding whether it allows firms to meet food safety objectives in the most efficient manner or whether it is overly prescriptive (Antle, 1998). Finally, there is disagreement regarding whether it can reasonably be used in place of sanitary performance standards in international trade (Hathaway and Cook, 1997).

This paper explores these controversies by examining the economic implications of using of HACCP in food safety regulation. We focus on the mandated imposition of HACCP, which differs from its use as a private process control method or as a private means of certification. We begin by reviewing the concept of HACCP, then discuss the rationale for public intervention to

improve food safety outcomes. Then, we review how the economics of regulation applies to the HACCP system. This includes three related issues:

- the economic efficiency implications of mandating HACCP to improve food safety;
- the public agency motivation for adoption of HACCP to reduce monitoring costs; and
- the difficulty of determining equivalence between HACCP standards for international trade.

### **What Is HACCP?**

HACCP is widely recognised in the food industry as an effective approach to establishing good production, sanitation, and manufacturing practices that produce safe foods (Pierson and Corlett, 1992). HACCP systems establish process control through identifying points in the production process that are most critical to monitor and control. HACCP's preventive focus is seen as more cost-effective than testing a product and then destroying or reworking it (ICMSF, 1988). The system can be applied to control any stage in the food system, and is designed to provide enough feedback to direct corrective activities.

Seven principles are involved in developing and operating a HACCP program (NACMCF):

1. assess the hazard, list the steps in the process where significant hazard can occur, and describe the prevention measures;
2. determine critical control points (CCPs) in the process;
3. establish critical limits for each CCP;
4. establish procedures to monitor each CCP;
5. establish corrective actions to be taken when monitoring indicates a deviation from the CCP limits;
6. establish record keeping for the HACCP system; and

7. establish procedures to verify that the HACCP system is working correctly.

By focussing inspection at CCPs, HACCP improves the scientific basis for safety and control processes. A CCP is “any point in the chain of food production from raw materials to finished product where the loss of control could result in unacceptable food safety risk” (Pierson and Corlett, 1992). Monitoring of CCPs is done best by using indicators that can be measured easily. This focus on measurable indicators provides a more cost-effective approach to control than product sampling and testing, which is more expensive and may not provide timely results. This is especially important for foodborne microbial pathogens, because their incidence is low and costs of testing are high.

It is important to recognise that HACCP is not designed to replace management decisions weighing potential benefits from product qualities against costs, or the value of improved safety versus the costs of achieving it. HACCP facilitates improved product safety, but management has discretion to determine what the final product quality will be. These issues enter into the firm’s deliberations in determining CCPs and tolerance limits at CCPs.

HACCP was originally developed as a quality control tool in food processing, where branded product liability creates industry incentives for hazard control. It was intended to be flexible enough to adapt to different firms, plants, or processes within plants. Its application as a regulatory standard to an entire industry or sector, or at different stages in the supply chain, is necessarily different. First, its mandate should be linked ideally to a system-wide risk assessment (NRC, 1985; Hathaway, 1995). This allows identification of the likely sources of hazards and the scientific basis for reducing them, so that regulation focusses on the most important sources of risk. Second, it may be explicitly linked with a particular regulated standard for food safety,

which has implications for setting critical limits at CCPs (Unnevehr and Jensen, 1996). Risk assessment and identification of the publicly desirable level of risk reduction have implications for the cost/benefit analysis of regulation and for recognition of HACCP in international trade, as will be discussed below.

### **Rationale for Food Safety Regulation**

Food safety regulation may be justified by the existence of a failure in the market for safety attributes. Because consumers cannot ascertain the safety of many food products, they are unable to express preferences for greater safety in the marketplace. Furthermore, producers or retailers may be unable to ascertain or to certify safety because foodborne pathogens are living organisms that can enter the food at any point and may grow over time. The lack or high cost of information about safety and the resulting consequences for public health are the fundamental justifications for public intervention to improve food safety.

Several studies have demonstrated the high costs to society of foodborne illness in different countries, including the United States (Buzby et al., 1996) and Canada (Dean, 1990). There is also a growing literature on the importance of reducing foodborne illness in developing countries (Motarjemi et al., 1996; Moy et al., 1997). These demonstrate that there may be large benefits to improving food safety, and that market mechanisms have not fully internalised these benefits to reward firms.

However, the market failure in food safety is not total, because there are private incentives to improving food safety. These arise most clearly when foodborne illness is easily traced to a particular source, or when food safety is jointly produced with other attributes that have market value, such as product shelf life. Traceability is more likely for branded products or when a single identifiable source (e.g., restaurant chain) serves a large number of customers.

Sometimes these private incentives are passed back through the supply chain. Several studies have shown that food producers adopt HACCP in order to satisfy downstream customers (Mazzocco, 1996; Henson, et al., 1998). In addition, firms have incentives for HACCP adoption to prevent losses of reputation and market share should an outbreak occur. Thus the challenge for regulators is to identify where intervention is justified to improve public health, i.e., where social benefits from reduced foodborne illness are not reflected in market incentives. This may be why the U.S. government has mandated HACCP for industries that sell raw, unbranded products to consumers (seafood, meat, and poultry; fresh fruit juices; and possibly fruits and vegetables in the future), because these are markets where producers cannot capture returns to improved safety.

### **Choice of Efficient Regulatory Intervention**

Government intervention can take many forms. We distinguish between direct command and control (CAC) interventions and information-based interventions that provide incentives for private market solutions (Litan and Nordhaus, 1983; Ippolito, 1984). Direct interventions include CAC standards for performance, e.g., pathogen counts for products at some stage of the marketing channel. An example would be the salmonella standard for powdered milk (Hathaway, 1995). Such standards require monitoring of the product's quality, usually based on sampling and testing. In contrast, CAC processing standards achieve improved final product by directly specifying procedures to be followed in production. Examples of contamination control procedures include milk pasteurisation, specific product washing solutions, or chill temperatures. These are sometimes specified as Good Manufacturing Practices (GMPs), such as those required under the food codes in many European countries. A third type of CAC approach is mandatory disclosure of information. While it may be difficult to enforce disclosure of information about microbial pathogens because producers do not always know product safety levels, producers



could be required to provide information on any pathogen reduction processes that they use, such as irradiation.

In contrast to CAC, incentive-based approaches are designed to induce either producers or consumers to identify and practice cost-effective methods that achieve improved food safety. Such interventions might include providing information to consumers to allow them to evaluate and avoid a hazard, lowering the costs of information through subsidizing development of new pathogen tests, or facilitating private contracting through public certification of products that meet a minimum safety standard. Establishing liability or the need for “due diligence” makes clear the rights and responsibilities of the two parties to the implicit contract in a private sale.

The environmental economics literature demonstrates that there is a hierarchy among regulatory approaches from an economic efficiency perspective (Cropper and Oates, 1992). The most desirable is an incentives-based approach that allows producers and consumers to choose the most efficient level of pollution. This is accomplished either by creating a market for the negative externality, e.g., tradeable pollution rights, or from the application of optimal pollution taxes. Incentives-based approaches are preferable to CAC, which reduces efficiency by constraining market choice. Among CAC approaches, process standards are less efficient than performance standards. They specify how firms should achieve pollution reduction goals rather than specifying a performance standard and allowing firms to choose the least expensive process for achieving it (Besanko, 1987). Setting performance standards and allowing choice of production methods and, over time, innovation to meet standards should allow greater efficiency in meeting a particular public health goal. Helfand (1991) demonstrated that setting a direct restriction on the level of pollution resulted in the highest level of profits and production efficiency among a set of five different performance and process standards.

However, there are many exceptions to these generalisations, and they may not apply to the market failure in food safety from microbial pathogens. Information-based approaches may not work simply because the main reason for the market failure is that information is very costly. Mandating the provision of information does not reduce its cost, and therefore may be a very expensive way to address the market failure in food safety. Ippolito (1984) argues that where quality information is costly or difficult to convey to consumers, and where there would be little informed demand for quality below a minimum standard, a CAC performance standard may be an appropriate choice. So if information interventions are impractical, then the choice is among CAC approaches. The difficulty for setting a CAC performance standard for microbial pathogens is again the high cost of testing for a hazard that often has a low incidence. Thus monitoring and enforcement of a performance standard can be costly.

### **What Kind of Intervention is HACCP?**

It is the difficulty of measuring and monitoring microbial pathogen standards that has led governments to mandate HACCP systems as part of food safety regulation. Although HACCP appears to be a process standard, it is not as prescriptive as specifying GMPs. In fact, it embodies elements of both performance and process standards. First, HACCP focusses on measurable indicators at CCPs, which are demonstrated to achieve an explicit or implicit performance standard during the process of verification. The purpose of HACCP is to provide a means of overcoming the cost of establishing the level of food safety for each product, by substituting easily monitored control measures for direct tests to detect hazards (e.g., temperature instead of pathogen cultures). Second, HACCP implementation focusses on reducing hazards where they are most likely to occur and most effectively controlled, and thus encourages efficient resource

use in hazard control. HACCP implementation can be linked to a system-wide risk assessment to identify likely sources of hazards and the scientific basis for reducing them (NRC, 1985; Hathaway, 1995). Such risk assessment directs regulation, and resulting industry actions, towards the most important sources of risk. Third, HACCP allows firms a great deal of flexibility in designing and implementing controls to fit specific circumstances. Thus it is inherently more flexible than mandating specific processes.

An important motivation for governments to adopt HACCP is that it also reduces the costs of regulatory enforcement. Monitoring costs are increasingly recognised as constraining regulatory options (Laffont and Tirole, 1993). Just as HACCP provides a cost-effective way of monitoring quality control for private industry, it also may reduce the cost to a regulatory agency. The agency can test product, but the costs of testing are quite high when the probability that a hazard will get into final product is relatively small (but not zero). The agency can inspect frequently to ensure that GMPs are followed, but this is also costly in terms of agency resources. With a HACCP based regulation, the regulatory agency can review records periodically to verify that a HACCP program is working. Such records include verification of processes and the effectiveness of controls. Although shirking and avoidance may occur under any regulatory system, the enforcement costs of improving food safety may well be lower under HACCP.

In practice, HACCP application in regulation has contained elements of process, performance, and information standards. In the European Union, it replaces more prescriptive regulation specifying GMPs, and thus gives firms greater flexibility. There is a general requirement now for food safety controls based on “HACCP principles” to be applied. However, there are no specifics on what these systems should include, and some flexibility remains with member countries in the implementation. In contrast, the U.S. has detailed requirements,

including both performance and process standards. The U.S. meat and poultry regulation combines the HACCP requirements with required specification of Standard Operating Procedures (SOPs) for sanitation, and a performance standard for the incidence of salmonella. Australia has provided public certification for exporting industries that use HACCP, thus facilitating information about safety procedures in the international marketplace.

To sum up, HACCP has become a popular regulatory tool because it overcomes the high information costs of setting and enforcing standards for microbial foodborne pathogens. These information costs contribute to the market failure in food safety provision and make design of effective interventions difficult. However, HACCP must be tied to verification that it is actually reducing food safety risks in order for it to be a useful substitute for a performance standard. This point relates to the difficulties of determining equivalence among HACCP standards in different countries.

### **HACCP as a Standard in International Trade**

Adoption of HACCP as a regulatory standard has been motivated first by food safety concerns, and only second by a desire to facilitate trade (Caswell and Hooker, 1996). The process of facilitating trade will require mutual recognition of HACCP regulations across national boundaries. One trend that may influence such recognition is the use of HACCP as a private standard for international trade. The ISO 9000 certification series for food companies is being adapted for certification of private HACCP programmes. Such private developments may facilitate eventual harmonization of HACCP regulation among countries.

Harmonization takes place within the framework established by the 1994 GATT agreement on sanitary and phytosanitary standards. This agreement seeks to reduce trade

conflicts and barriers for food products (Unnevehr, et al., 1994). It specifies that countries may set their own risk standards, but that these must be science-based, transparent, and applied equally to domestic and imported products. The agreement provides new mechanisms for dispute resolution and recognises the Codex Alimentarius as the mechanism for developing scientific consensus regarding sanitary standards. A key element in setting standards that will stand up in the dispute resolution process is carrying out a risk assessment of the hazard. Only then can a country defend that a particular sanitary standard is science-based and actually reduces risk.

The growing adoption of HACCP by many industrialised countries has led the Codex to consider guidelines for setting microbiological safety criteria and for establishing HACCP programmes. One difficulty in setting these criteria is that there is no internationally agreed upon procedure for carrying out a microbiological risk assessment (ICMSF, 1997). In the absence of such an agreement, the Codex has recommended the application of HACCP as the preferred method for ensuring microbiological safety. In fact, the ICMSF explicitly recognises HACCP or good practices as a substitute for explicit microbiological standards (ICMSF, 1997, p.120; ICMSF, 1998). Hathaway (1995) has challenged this view that HACCP requirements can substitute for explicit microbiological criteria. He argues that HACCP should provide some quantifiable risk reduction, not merely the assurance that hazards have been reduced by some unspecified amount.

These opposing views relate to a critical issue for international food trade: How will equivalence among HACCP regimes in different countries be determined? For example, can seafood produced under HACCP in Thailand be exported to the United States, where HACCP is mandated for domestic producers? Or, will it be necessary to specify microbiological criteria and actual risk levels that HACCP should achieve? In practice, both microbiological criteria and the

existence of process controls will likely be considered (Kvenberg, 1998). But the extent to which HACCP will substitute for imported product testing is likely to be an area of controversy in international food trade for the foreseeable future.

Such controversy may well be most contentious in trade between developing and industrialised countries. Developing countries that export to industrialised markets must meet their HACCP standards. The marginal costs of implementing HACCP may be higher in developing countries, where fewer basic sanitation services are available, and technical assistance may be required because there are few trained HACCP specialists (Cato and Dos Santos, 1998). But sanitary standards may also discourage production in countries unable to certify HACCP systems or encourage multinationals to invest in food processing in order to control quality and safety throughout the food chain. Thus, sanitary regulation is likely to influence the structure of international food trade, in the same way that it may influence the structure of food processing in industrialized nations, as we discuss below.

### **Measuring the Impacts of HACCP Regulation**

An important question is whether HACCP is a more cost-effective approach to achieving improved food safety than alternative approaches. The economic impacts of HACCP regulation have been studied in the United States, where an executive order mandates such cost benefit analysis for regulation. Presumably it is of interest to consider these effects wherever HACCP has been mandated, and thus some of the generalisations from the U.S. literature may provide guidance about the expected impacts in other countries and help to clarify the unanswered questions.

Cost estimates of HACCP implementation show that costs are significant, but usually modest in relation to total industry costs (e.g., Crutchfield et al., 1997; Jensen, Unnevehr, and Gomez, 1998). A key area of uncertainty is whether firms must modify their processes or adopt new processes to control microbial pathogens, which increases costs. However, the direct costs of HACCP are likely to be overshadowed by the implications of HACCP for long run industry structure. The large investments and technical skills needed for implementation have economies of scale that favor larger firms (MacDonald and Crutchfield, 1996). The fixed costs of adding control technologies and for HACCP training may be prohibitively large for small firms. Thus its mandate may pose a greater burden on small firms, and lead to further concentration in the processing industry. Some observers have suggested a need for public education directed towards small firms. Others have suggested that there are operating efficiencies to be gained once HACCP is in place, through better organisation of labour or processes (Mazzocco, 1996; Henson, et al., 1998), which small firms could capture if they overcome initial adoption costs. However, it is clear that there are economies of scale in the human capital needed to implement HACCP, and thus its imposition will favor larger firms.

In addition to greater food industry concentration, HACCP regulations may also create incentives for greater vertical coordination to control food safety throughout the production process. Rather than testing product as it is delivered, it may be less expensive to contract or control production processes upstream (Mazzocco, 1996). These incentives dovetail with other emerging forces favoring greater coordination, such as increased demand for uniformity of product or for specific quality characteristics to meet niche market demand (Hennessy, 1996). Thus HACCP regulations will reinforce these two structural trends for food industries in industrialized countries.

The benefits of mandating HACCP arise from reduced foodborne illness. These are more difficult to estimate for two reasons. First, there is controversy about the appropriate methodology for valuing suffering and loss of life (Buzby et al., 1996; Van Ravenswaay and Hoehn, 1997). Second, there is no evidence yet available regarding the actual reduction in risk from mandating HACCP for an entire industry or portion of the food production chain. Crutchfield et al. (1997) have argued that the potential benefits are so large in the United States that they offset the costs, but the question of how much HACCP really improves food safety remains to be answered. We need to know how HACCP ultimately affects foodborne illness risks, particularly when it is mandated at only one point in the food chain. The difficulties in measuring benefits means that it may not be possible to find a regulatory standard that equates marginal costs with marginal benefits.

## **Conclusions**

HACCP is a different kind of regulation or intervention from those previously examined by the economics literature. It was developed as a private management tool for specific processes. Now it is being mandated for entire industries, which requires more explicit risk assessment in order to link HACCP mandates to desired public health outcomes. Performance standards for food safety under mandatory HACCP may only be determined implicitly through the accompanying process of risk assessment. As a public policy tool, HACCP combines elements of process and performance standards.

HACCP is increasingly adopted as a regulatory standard because it provides a way to overcome high costs of monitoring safety outcomes and provides firms with some flexibility in approach. Whether it substitutes for, or must be supplemented by, a performance standard for



microbial risk is a current area of controversy. When it substitutes for a performance standard, there is a danger that its implementation may fall back upon specifying GMPs, and hence it will become a de facto process standard. Without an accompanying performance standard, equivalence of HACCP regulations in international trade may be difficult to establish.

Economists would like to measure the impact of HACCP regulations to evaluate whether this approach is more cost-effective than alternative regulatory approaches to improving food safety. In other words, does it promote the most efficient market solution to improving food safety? This evaluation will be difficult in practice, especially because risk assessment of microbial hazards is still in its infancy (Hathaway and Cook, 1997). As long as the cost of directly monitoring microbial pathogens remains high, HACCP will continue to be the standard of choice because it focusses resources where they will have greatest effect in controlling hazards.

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