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ABSTRACT

The current system of meat inspection in the United States does not adequately address the problem of microbial food-borne pathogens. The application of Hazard Analysis Critical Control Point (HACCP) systems to control and reduce the incidence of pathogens is included in proposed regulations for safety in meat products. This type of regulatory intervention combines control of process and product, and offers a regulatory innovation when the costs of hazard detection are high and the exact benefits associated with any particular standard are uncertain but potentially large. Although command and control standards may be appropriate for control of food-borne pathogens, more consideration might be given to combining these standards with incentives to improve food safety in meats.

HACCP AS A REGULATORY INNOVATION TO IMPROVE FOOD SAFETY IN THE MEAT INDUSTRY

There is widespread consensus that the current system of meat inspection in the United States does not address the most important food safety hazard in meat products: microbial food-borne pathogens. The National Academy of Sciences has issued a series of reports outlining an alternative approach to ensuring the safety of meat and poultry products (National Research Council, 1985, 1987, 1990). In contrast to the current system of organoleptic carcass-by-carcass inspection, the new approach would rely on science-based risk assessment and *prevention* rather than on detection of hazards. The preventive approach is codified in a set of principles known as the Hazard Analysis Critical Control Point (HACCP) system, which was developed by industrial engineers in the food processing industry.

This new approach has been embraced by USDA's Food Safety and Inspection Service (FSIS) in the proposed regulation for pathogen reduction (USDA/FSIS). Meat packers and processors would be required to put HACCP plans in place, to conduct periodic tests for microbial pathogens, and to reduce the incidence of pathogens. Regulations must undergo a cost/benefit analysis to ensure that the costs they impose on industry are less than the benefits to society (EOP). The scope of the HACCP regulation is sweeping, and FSIS has conducted only a preliminary analysis of its impacts. Furthermore, analysis of the costs and benefits associated with HACCP poses some conceptual challenges because the system does not conform to textbook examples of regulatory intervention.

In this paper, we discuss the origins of HACCP as an engineering concept and then the economics of HACCP as a regulatory tool. It is our contention that the economics literature has not adequately explored the benefits from prevention, particularly when the costs of hazard detection are high and the exact benefits associated with any particular standard are uncertain but potentially large. We begin with an overview of regulatory alternatives for improving food safety, and then discuss HACCP and its evaluation.

Regulatory Alternatives for Improving Food Safety

Food safety regulation may be justified by failure in the market to provide safety. Because consumers cannot ascertain the safety of meat 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 food-borne 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. Due to the limited scope of this paper, we take this justification as given, and proceed with an analysis of regulatory alternatives.

Government interventions 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; Ippolito). Direct interventions include CAC standards for performance, such as pathogen counts for products at some stage of the marketing channel. Such standards require the product's quality to be monitored, 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 specific product washing solutions or chill temperatures. 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.

Because food-borne pathogens have their origins in farm animals, there are many possible points of control during the entire production process from farm to table. Regulatory interventions could therefore address a wide spectrum of production activities, many of which currently fall under different government jurisdictions. In the rest of this paper, we explore the concept that has been proposed by the National Academy of Sciences and will be implemented by FDA and USDA to reduce food safety hazards.

The HACCP Approach

HACCP is widely recognized in the food industry as an effective approach to establishing good production, sanitation, and manufacturing practices that produce safe foods (Pierson and Corlett). 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). 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 recordkeeping for the HACCP system; and
7. Establish procedures to verify that the HACCP system is working correctly.

By focusing 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). CCPs are very demanding in required resources and information. 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.

HACCP can be viewed as a disembodied technological change because it is the application of new information and organization to the production process. HACCP implementation enhances the productivity of existing inputs (labor, capital) in producing product safety. It is important to recognize 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 uses its discretion to determine what the

final product standard will be. These issues enter into the firm's deliberations in determining CCPs and tolerance limits at CCPs.

The explicit or implicit choice of a safety standard to be achieved through HACCP has important implications for its use as a regulatory tool. Although HACCP is a process standard, in practice HACCP implementation requires the choice of a performance standard that the CCPs are selected to achieve. Setting up a HACCP system involves verification (product testing) to ensure that the CCPs are working. Thus, requiring adoption of HACCP by firms also implies requiring a particular standard for food safety, and the selection of the performance standard will have important implications for the costs and benefits of regulation.

The current FSIS-proposed rule regarding pathogen reduction (USDA/FSIS) combines both the process and the performance elements of HACCP. The process standards include requirements that meat and poultry processors adopt at least one specific anti-microbial treatment immediately and that they develop and implement HACCP over a longer time frame. The performance standards require that slaughter plants meet targets for pathogen reduction specified as reduction of average pathogen counts to one-half of the current industry average. This performance standard would be verified by daily microbial testing by the plant. Thus, the required adoption of HACCP is tied to specific performance measured in pathogen reduction.

The proposed FSIS regulation would impose practices that currently are not widely adopted in the meat industry. HACCP was originally developed as a management tool in food processing, where product liability may create a greater industry need for hazard control than in production of unbranded raw products. Only 10 percent of meat and poultry plants in the Northeast currently use HACCP (Karr et al.). In the seafood industry, HACCP implementation has relatively small marginal costs for larger firms but higher costs for smaller firms that do not have automated information collection (Martin et al.). Since market incentives do not seem to exist for most firms in meat and poultry slaughter and processing to adopt HACCP, the regulation will impose costs and these are likely to fall more heavily on smaller firms.

Evaluating HACCP

The environmental economics literature demonstrates that there is a hierarchy among regulatory approaches from an economic efficiency perspective (Cropper and Oates). 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, such as

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). 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 demonstrated that setting a direct restriction on the pollution level resulted in the highest profit and production efficiency level among a set of five different performance and process standards.

What are the lessons for food safety regulation? Incentives-based approaches to the food safety market failure require provision of information, which differs from establishing taxes or pollution rights. The usefulness of this approach will be limited by consumers' abilities to make choices (Magat and Viscusi). Furthermore, 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, then a CAC performance standard may be an appropriate choice, even though it may have inherent inefficiencies (Ippolito).

Food safety information is costly and may be difficult for consumers to use. An increasing proportion of food is consumed away from home (46 percent of food expenditures in 1993), much of it in institutional settings (USDA/ERS). Consumers in nursing homes or day care centers have little choice or control over food safety, yet they are among those who are most vulnerable to food-borne disease. Emerging recognition of the serious nature of some food-borne hazards means that there would be little demand for hamburger contaminated with *E. coli* O157:H7, for example, among informed consumers. The current high costs of testing directly for the presence of microbial pathogens makes it costly for producers to convey reliable information to consumers. These features of food-borne pathogens support the imposition of a CAC minimum performance standard.

The uncertainty of potential benefits and costs from food safety improvement is another rationale for a CAC approach. Weitzman addressed the issue of setting standards when there is uncertainty about either the costs or benefits of the standard, and demonstrated that the choice of policy instrument depends on the relative steepness of the marginal benefit and cost curves. If the marginal benefits curve is quite steep, but the marginal cost curve is fairly flat over some range, then a quantity restriction is preferable to a pollution tax. This is because the benefits of reducing pollution are potentially large and an incentive-based approach might not capture those benefits. Only when the

marginal benefits are relatively constant and the marginal cost curve is steep does it make sense to apply a tax and allow firms the maximum flexibility to adjust pollution levels.

It can be argued that the marginal benefits curve is steep for reducing the incidence of food-borne pathogens. Buzby et al. estimate that food-borne illness from six major pathogens results in medical and lost productivity costs of \$9.2 to \$12.9 billion annually, of which approximately one-half are attributable to meat and poultry products. Furthermore, a scientific understanding of the long-term health consequences of food-borne pathogens is only now emerging (e.g., salmonella can lead to rheumatoid arthritis). Regulators and consumer advocates have argued that the costs of pathogen reduction regulation, while estimated to be substantial (about \$2 billion over 20 years), are small compared to the potential benefits (about \$6 to \$24 billion) (USDA/FSIS). If these benefits would be difficult to achieve through incentives-based approaches, then imposing of a CAC minimum performance standard on industry could be justified in economic terms.

How can HACCP be evaluated as a CAC standard? Helfand's analysis of alternative standards can be adapted to the proposed HACCP regulation. In her terminology, this regulation combines the mandated use of a pollution control technology (HACCP) with a standard on pollution per unit of output (percent of samples with pathogens). This combination will tend to maintain high levels of output but will reduce profits more than a direct restriction on the level of pollution (Helfand, p. 629). Thus it would be more efficient to specify an overall reduction in total numbers of pathogens in each firm's output as the performance standard than to mandate use of a contamination control technology. But this result depends on assumptions about the effect of the control technology on output and use of other inputs. For example, if HACCP does not contribute to production (marginal product is zero), then its imposition is equivalent to a direct restriction on the level of contamination. HACCP's impact on production is an empirical question that deserves further study to understand how mandating its use will affect producer and consumer welfare.

To this point, the analysis ignores the costs of testing and monitoring food safety outcomes. Monitoring costs are increasingly recognized as constraining regulatory options (Laffont and Tirole). Where adopted by private industry, HACCP provides an efficient control approach because it relies on prevention and identification of measurable CCPs rather than on ex post testing. HACCP offers similar advantages to the regulatory agency in monitoring compliance. Inspection and verification by regulators can be more efficient when focused on prevention. Checking CCPs and verifying an HACCP program may provide cheaper and more effective regulatory monitoring than extensive

product testing. Thus, HACCP could be an efficient regulatory tool in spite of its being a CAC process standard.

How could the costs and benefits of any particular HACCP proposal be evaluated? The benefits will depend on the accompanying performance standard for safety improvement and the resulting fewer cases of food-borne illness. The costs of these avoided illnesses would give a lower bound estimate of the benefits of an HACCP regulation. A true estimate would include the value of risk reduction to all consumers in addition to the costs imposed on those who happen to become ill. The costs of the regulation would be the firms' costs to set up and maintain a HACCP system. The challenging part of evaluating HACCP is in directly linking its adoption to specific reductions in pathogens and in food-borne illnesses. A recent study of HACCP implementation for the seafood industry showed that HACCP procedures significantly reduced the risk of microbial pathogens related to human health problems (Martin et al.). USDA's proposed rule is silent on this point, and the motivation for the regulation would be strengthened by drawing upon the scientific literature to link specific reductions with specific health outcomes.

In the past, industry has applied HACCP to control hazards where a zero-risk standard is appropriate (e.g., broken glass in canned food). The private sector has evaluated the expected benefits from avoiding product liability as very high relative to the costs of HACCP. For microbial pathogens in raw unbranded products, a zero-risk standard may or may not be appropriate. Regulators and consumer advocates have argued that marginal benefits of reducing food-borne illness are large, and thus have justified the imposition of HACCP through regulation. Establishing the critical limits that must be met at each CCP for microbial contamination, however, may require marginal cost-benefit analyses, where the value of reducing risk to very low levels is weighed against the additional costs. This type of analysis is not evident in the preliminary impact assessment of USDA's proposed rule, and exploration of these trade-offs would surely improve the design of regulation.

Conclusions

Scientists have advanced HACCP as an approach to improving food safety, and regulators are proposing to mandate its use to achieve safer food products. Although HACCP does not conform to the most efficient interventions suggested by the economic literature, it may have some unrecognized advantages in its focus on prevention. It represents a knowledge-based technology that increases productivity of existing inputs in the production of a safety attribute. The attraction of a preventive

approach stems from the uncertainty associated with food-borne health hazards and the costs of monitoring outcomes. When the potential benefits from hazard reduction are large but unknown, and the costs of monitoring performance are high, prevention may be preferred.

In considering how to evaluate HACCP as a regulatory intervention, we note two features of importance. First, while HACCP is a contamination control technology and hence a process standard, in practice, its application will be tied to a performance standard. Explicit consideration of what performance standard is being set will facilitate identification of the costs and benefits associated with HACCP. Second, HACCP implementation in private industry has not been married with marginal cost benefit analysis in setting critical control limits. Examining the costs and benefits of different levels of contamination control would be useful to inform policy making.

Although we have argued that CAC standards are appropriate for food-borne pathogens, more consideration might be given to combining standards with incentives in food safety. The environmental regulation literature suggests that combinations of standards and incentives are often the most practical and efficient approach (Cropper and Oates). In a food safety context this might mean setting a standard for a minimum level of safety that would capture most of the benefits and then providing incentives for some firms to exceed that standard—for example, by certifying safer products for consumers who have higher risks from food-borne illness. Exploring these combined approaches would facilitate finding a set of interventions that would provide the highest net benefit to society.

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