The Economics of HACCP

Costs and Benefits

Edited by
Laurian J. Unnevehr
Department of Agricultural and Consumer Economics
University of Illinois, Urbana

eagan® press
St. Paul, Minnesota, U.S.A.
2000

Chapter 7

HACCP Principles for Regulatory Analysis

Richard B. Belzer[1]

Introduction

The rapid expansion of food inspection based on the Hazard Analysis and Critical Control Points (HACCP) system has created a wealth of new research opportunities for applied economists. HACCP systems are so different from prior approaches to food technology that new analytical tools and methods must be developed to enable manufacturers to gain a better grasp of the cost-effectiveness of both production innovations and new products. Similarly, as government regulators proceed to extend HACCP to additional product lines and stages in the food production and distribution system, the benefits and costs of these new regulations must be reliably assessed.

This paper draws an analogy between HACCP as applied to food technology and long-established standards for analysis of the consequences of regulatory action. To get these analyses right, a foundation for quality analysis among regulatory agencies must be established that is as obedient to fundamental analytic principles as HACCP rules require industry to behave toward the food they make. Regulatory agencies imposing HACCP principles and rules to more sectors of the food business should apply these same principles to the way they analyze the consequences of alternative regulatory approaches and design regulations. Unless regulators set such an example, their credibility among those they regulate will wither, thereby undermining the moral legitimacy of their role.

To make these points clear I use as examples the seafood HACCP rule promulgated by the Food and Drug Administration in 1995 (FDA 1995a) and the meat and poultry HACCP rule promulgated by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS 1996). Both regulations were accompanied by regulatory analyses as required under Executive Order 12866 for "economically significant" rules (EOP 1993: Sec. 6). This Executive order (as well as its predecessor, Executive Order 12291 (EOP 1981)) could be thought of as a "Generic HACCP Plan for Regulatory Analysis." Both Plans were supplemented

with what may be called "Generic HACCP Implementation Guides for Regulatory Analysis" (OMB 1990, OMB 1996). However, neither analysis conformed to elementary principles in these Plans and Guides, despite the fact that the Guides have been in place for almost a decade and the Plans since 1981. Had these analyses been subjected to enforcement provisions analogous to those which FDA and FSIS use to ensure compliance by food producers with HACCP regulations, both agencies would have been subject to significant sanctions. One can only speculate as to whether the regulators' analyses as "products" would have been embargoed until made compliant, recalled as defective or adulterated, or destroyed as unwholesome and unfit for consumption.

Federal food safety agencies continue to expand mandatory HACCP requirements to additional food products, such as juice (e.g., FDA 1997b, 1997c, 1998b, 1998c, 1998d), and new sectors, such as retail (e.g., FSIS 1997b). To an impartial regulatory analyst, it is troubling that these decisions are proceeding based on both extremely high expectations for their effectiveness at reducing foodborne illness and a surprisingly weak analytical foundation for claims that they actually do. Analysis suggests that successes will be limited, unsatisfying, and achieved at enormous expense and frustration, thus imperiling public confidence in both HACCP as a risk-reducing tool and the agencies as effective guardians of public health. Better compliance with established HACCP Principles for Regulatory Analysis would reduce the likelihood of these undesirable outcomes and increase the odds that regulatory action cost-effectively reduces the social costs of foodborne illness.

Principles of HACCP

Over the last few years, HACCP seems to have become an all-encompassing food safety mantra, yet this is actually a relatively recent phenomenon. HACCP has been around for more than two decades and has been the subject of at least three supportive National Academy of Sciences reports (NAS 1985a, 1985b, 1991). However, HACCP received a cool reception from the regulatory bureaucracy throughout most of this period.

HACCP is, in fact, an adaptation of the more generalized concept of statistical process control. By identifying hazards to quality and critical steps in manufacturing, quality can be improved by reducing the variance at each step, thereby reducing the proportion of defective units. Process control is particularly attractive where a system of performance standards cannot be devised or implemented. For example, the use of performance standards obviously will not work in cases where there are no reliable instruments to measure performance objectively. Performance standards also may be inadequate if the anticipated failure rate is too small to permit inspection by sampling, if inspection itself is destructive, or if the final

good is sufficiently perishable that inspection testing cannot be obtained in a timely manner.

In simplified form, HACCP involves only a handful of steps: identify and analyze those things which pose a hazard to the final product; determine the control points in the production process where these hazards may arise; establish critical limits for each control point that should not be exceeded; and set out corrective action procedures to follow when (not if) these critical limits are exceeded. Of course, this simplified exposition does not do justice to the true level of complexity involved, but complexity arises in specific applications rather than in the general theory, and each specific application is likely to be different.

HACCP Principles for Regulatory Analysis

Something akin to HACCP could be devised for regulatory analysis, for the analogy is unmistakable and its principles self-evident. The final product is a document capturing all the relevant information necessary for rational decision making. For nearly two decades, there has been a "Generic HACCP Plan for Regulatory Analysis" (EOP 1981, 1993) and for almost half that time a "Generic HACCP Guide" to assist agency compliance (OMB 1990, 1996). "Hazards" to quality regulatory analysis are well known to those engaged in its production and consumption. They include the usual HACCP-like issues, such as the quality of raw material inputs; the ability and willingness of producers to devise and follow a comprehensive plan; and a host of places along the production process where both external and internal factors arise which, if left uncontrolled, may seriously compromise the quality of the product.

There are surely as many critical control points in the production of regulatory analysis as there are in the production of pork 'n' beans. Unlike the food business, however, there is no monitoring of critical limits. There are no corrective action plans in place that dictate how these violations should be dealt with by producers, and there is ample evidence that the regulator charged with enforcing HACCP for regulatory analysis lacks the capacity to levy significant sanctions no matter how egregious the violation. Producers cannot be fined, the product cannot be seized, embargoed, or recalled, and the "withdrawal of inspection services" is not a credible option.

The Generic HACCP Plan for Regulatory Analysis

Executive orders governing regulatory analysis have been in place for two decades. Most recently, Executive Order 12866 formalized a set of analytical requirements for agencies to meet in support of significant federal rulemaking (EOP 1993). The degree of effort expected depends on the scope and scale of the action. Thus, these principles apply to all

regulations but have particular import for "economically significant" rules.[2] These principles constitute a Generic HACCP Plan for Regulatory Analysis because they provide the framework for the analysis of each covered regulatory action ("product"), but rely on the expert knowledge of the agencies ("producers") to implement the framework in a sensible way given the particulars of the issue at hand ("plant-, process-, and product-specific concerns").

The Generic HACCP Guide for Regulatory Analysis

In January 1996 the Office of Management and Budget published more detailed performance standards for regulatory analysis (OMB 1996). This Generic HACCP Guide for Regulatory Analysis was prepared under the auspices of the President's Council of Economic Advisors. It reflected over two years of work by a team of regulatory economists from across the federal government, including economists from both the Food and Drug Administration and the Department of Agriculture. The contents of this document were substantially equivalent to a preceding document (OMB 1990) addressing an earlier vintage "Generic HACCP Plan" (EOP 1981). Thus, the fact that the current HACCP Guide was published in 1996 should not have posed any significant impediment to either agency's capacity to comply.

Both OMB guides provide a detailed framework for a structured, comprehensive examination of the benefits, costs, and other effects likely to arise due to the promulgation of an economically significant regulation. They also call for analysts to address several key issues critical to the development of a regulatory analysis and provide a policy-neutral interpretation of its implications. The guide states up front that regulatory analysis is intended to inform policy making rather than justify predetermined decisions.

> In particular, the [regulatory analysis] should provide information allowing decision makers to determine that:
>
> - There is adequate information indicating the need for and consequences of the proposed action.
> - The potential benefits to society justify the potential costs, recognizing that not all benefits and costs can be described in monetary or even in quantitative terms, unless a statute requires another regulatory approach.
> - The proposed action will maximize net benefits to society (including potential economic, environmental, public health and safety, and other advantages; distributional impacts; and equity),

unless a statute requires another regulatory approach.

- Where a statute requires a specific regulatory approach, the proposed action will be the most cost-effective, including reliance on performance objectives to the extent feasible.
- Agency decisions are based on the best reasonably obtainable scientific, technical, economic, and other information (OMB 1996).

Each of these fundamental principles is reflected in both general- and issue-specific directives and performance standards. In the next section the general principles are applied in the context of the two path-breaking efforts for the federal government to establish HACCP as the basis for controlling pathogenic food safety risks.[3]

Applying HACCP to the Seafood and Meat and Poultry HACCP Regulatory Analyses

The Generic HACCP Plan for Regulatory Analysis sets forth broad issues which should be addressed. These include a rigorous analysis of the problem to be solved; the underlying basis for government action to solve it; a clear statement of the government's objective; a rich analysis of an array of reasonable and innovative alternative approaches for achieving this objective; and uniformly applicable principles for how benefits and costs should be estimated.

Market or Institutional Failures as Bases for Intervention

The Generic HACCP Plan requires regulatory agencies to identify the fundamental basis for government intervention:

> Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem (EOP 1993: Sec. 1(b)(1)).

Typically, some form of externality is expected to be the culprit that results in a divergence between private and social marginal costs or benefits. Indeed, market failure is a necessary (but not sufficient) condition for regulation to yield net social benefits.[4] Less frequently, intervention is premised on the existence of a natural monopoly or unusual market power. The Plan also recognizes the possibility that inadequate or

(more likely) asymmetric information may be the underlying problem that government regulation is intended to overcome.

The form and type of market imperfection typically suggests the general outline of plausible solutions. For example, where an externality is present efficiency is restored when government intervention restores correct price signals. Monopoly and market power problems, in contrast, usually indicate the need for intervention to remove barriers to entry and competition. Finally, informational imperfections or asymmetries suggest the need for incentives to motivate the production and dissemination of information (where information in total is judged to be inadequate), or the alteration of rights and responsibilities with respect to disclosure (where asymmetries in information are believed to systematically disadvantage certain market actors).

Seafood HACCP. Based largely on work performed for the notice of proposed rulemaking (NPRM), the regulatory analysis claims that private markets have substantially failed. This market failure consists of three parts: (a) imperfections in common law which prevent injured consumers from recovering damages suffered from seafood-related foodborne illness, leading to excess risk; (b) suppressed consumer confidence in the safety of seafood resulting from inflated perceptions of the actual foodborne illness risks posed by seafood; and (c) an excess of consumer choice among products with differing degrees of safety as an identifiable product attribute.

(a) "Excess risk from imperfections in common law." Consumers who suffer seafood-related foodborne illness cannot recover damages in tort because the food responsible for transmitting it often cannot be positively identified:

> In most instances, consumers experiencing illness from food consumption are unable to link the illness to consumption of a particular food. This is because many symptoms do not occur immediately after consumption of the product. Delayed effects may vary from hours to months. To the extent that any illness is actually caused by man-made or natural contaminants in seafood, the lag may exceed ten years (FDA 1993: Sec. II).

Even where seafood can be identified as the vehicle of transmission, the specific firm responsible cannot be identified, making tort recovery impossible:

> The seafood industry differs from a large part of the food industry in that, except for certain branded fish products, almost all fresh and a large portion of frozen seafood is sold to the public unbranded or under brands that are not widely

advertised and not generally recognized. Often, when fish or shellfish is offered for sale by a supermarket or restaurant, that product has been sourced from several suppliers in order to obtain a large enough quantity to meet consumer demand. Each supplier, in turn, may source from several processors for much the same reason. Likewise, each processor may receive raw material from several harvesters and possibly import it from one or more countries. For these reasons, these products lose their source identity and are marketed generically (exceptions being canned, frozen, and branded seafood). This subsequently makes it difficult for a supermarket or restaurant to discern the source of the product involved in a consumer complaint. As a result, some firms may not be adequately motivated to provide sufficient levels of safety. Thus, it may be argued that, for the most part, the tort system does not adequately compensate consumers for illnesses derived from the consumption of seafood (FDA 1993: Sec. II).

(b) "Suppressed consumer confidence due to exaggerated risk perceptions." Consumers believe that seafood is much riskier than it actually is, thereby reducing demand for seafood below optimal levels:

> Because of the negative publicity concerning water pollution and seafood safety, consumer perception of seafood safety may not be consistent with actual risk. Contamination scares cause drastic short-term drops in consumer demand for seafood products, and undoubtedly contribute to the chronic level of consumer concern about seafood safety. Thus, safety concerns about seafood are a likely factor preventing wider consumer acceptance of seafood as part of the U.S. diet.
>
> The 1993 FDA Food Safety Survey confirms much of the previous research on consumers perception of seafood safety. Consumers in this study report that they are more careful when handling seafood than when handling meat and poultry. Given that consumption levels of fish are much lower than for meat and poultry, a disproportionately larger percentage of self-reported food illness episodes in the survey are attributed by the respondents to seafood. Although by weight, seafood consumption is only eight percent of the consumption of meat, poultry and seafood combined, consumers attributed 36 percent of their foodborne illnesses to seafood. The fact that consumers handle seafood more carefully and are more likely to attribute a food related illness to seafood than other flesh

> proteins suggests that consumers believe that seafood is less safe than meat and poultry (FDA 1993: Sec. VI.B, references omitted).

(c) "Excess consumer choice of alternative levels of safety." According to FDA, consumers may be better off without the freedom to choose different levels of quality. The regulatory analysis acknowledges that some processors made products safer than the minimum standard required under then-existing federal, state, and local laws and regulations, and that they charged consumers higher prices based on consumer demand for safety as a product attribute. But, the freedom to choose

> may place some consumers in a dilemma which they wish to avoid. In making their seafood purchases, some consumers may not want to be faced with the choice of a spectrum of differently priced products with different probabilities of illness. Instead, they may prefer that regulatory bodies set a minimum standard of safety that is high enough such that consumers no longer consider the risk relevant to their purchase decisions. Consumers may then take safety as given and base their purchases on other product characteristics such as price and taste (FDA 1993: Sec. II).

The first and second of these market failure arguments are inconsistent with each other, and the third is inconsistent with market failure. Even without any expectation of supporting empirical evidence, the entire market failure argument must be rejected on theoretical grounds alone.

First, imperfections in the administration of tort law do not imply the existence of a significant market failure, nor is it obvious that any material imperfections exist. Approximately 90 percent of all losses from seafood-related illness are attributed to the consumption of raw shellfish. Half of all losses consist of about 60 deaths per year from *Vibrio vulnificus* infection transmitted by raw oysters from the Gulf of Mexico. Because raw shellfish are understood to pose greater hazards than cooked seafood, it would be surprising to discover that the common law regularly assigned liability for these harms to producers. Only a handful of the remaining cases of seafood illness are severe enough to warrant bearing the cost of litigation even if the identity of the producer were known.

Risk is an inherent attribute of food, and one that, as the regulatory analysis repeatedly points out, consumers are quite capable of valuing. Its presence per se does not indicate a market failure. In any event, the regulatory analysis did not provide empirical evidence supporting the claim of *excess* risk. Rather, the analysis proceeds as if the mere existence

of foodborne illness constitutes evidence of excess risk. This can only be true, of course, if the optimal level of risk is zero.

Second, suppressed consumer confidence implies that consumers *overstate* the risks posed by seafood. This contradicts the first market failure argument, which requires that consumers believe seafood to be safer than it really is. Both types of market failure cannot coexist in the same mind, however. Excess seafood-related foodborne illness implies that consumers *underestimate* the true risk, whereas insufficient consumer confidence implies that consumers *overestimate* the true risk.

FDA claimed billions of dollars per year in "consumer confidence benefits" in the preliminary regulatory analysis. These benefits, which consisted largely of reduced coronary heart disease, were presumed to result from improved nutrition attributable to the substitution of seafood for higher-fat flesh foods such as meat and poultry. FDA abandoned these quantified benefits in the final regulatory analysis in response to criticism of the asserted linkage between increased consumer confidence and improved diets. Greater consumer confidence in the *pathogenic* safety of seafood may cause consumers to substitute seafood for meat and poultry, but there is little evidence that they simultaneously choose lower-fat recipes.

Note that FDA did not abandon these "consumer confidence benefits" because they were inconsistent with the assumption that seafood is riskier than consumers expect. Rather, FDA merely left them unquantified because public commenters eviscerated the credibility of its quantitative model (FDA 1995b).[5] The final analysis continues to posit the simultaneous existence of mutually exclusive forms of market failure.

Third, the argument that consumers have too much choice with respect to the safety of seafood may be the most bizarre manifestation of market failure of all. An expansive array of choices reflects efficient markets in their most vibrant form. Any restriction on consumer choice will generally cause economic inefficiency and excess burdens. Efficiency may be enhanced through restrictions on free choice only where the exercise of choice imposes significant external costs on others. Absent any basis for or evidence of such external costs, the claim that excess consumer choice constitutes a market failure can only be regarded as specious.

Meat and Poultry HACCP. Like seafood HACCP, this regulatory analysis also asserted that private markets had failed in fundamentally inconsistent ways. In fact, the regulatory analysis for the meat and poultry HACCP rule appears to have used the arguments in the seafood HACCP rule as a starting point for a much more expansive set of claims (FSIS 1996: 38949-38951):

a) Consumers have imperfect information concerning the risks posed by pathogens in meat and poultry, resulting in a divergence between private and social marginal costs.

b) Producers rather than consumers are generally responsible for foodborne illnesses when it occurs.
c) Producers lack accountability for the foodborne illnesses they cause because they experience no reduction in either quantities demanded or profits.
d) Many firms in the food business do not use the best available pathogen reduction technologies because:
    i) entry is easy into the food business;
    ii) the industry is highly competitive; and
    iii) managers of these businesses are indifferent to the social benefits of such technology.

As the discussion below shows, these market failure arguments violate more "critical control points" for quality regulatory analysis than did FDA's analysis.

(a) "Imperfect information concerning pathogenic risks results in divergence between private and social marginal costs." FSIS' fundamental error is that all markets display imperfect information, so the absence of perfect information alone cannot justify government intervention. Otherwise, there would be no aspect of life in which regulation would not be superior per se to individual decision making founded on consumer sovereignty. Further, because regulatory agencies never possess perfect information, the same argument could be used against regulators to justify the equally valid principle that they should never act to supplant private markets. Indeed, if some standard of comparative informational richness were used as the determinative criterion, regulators could routinely come up short, for with rare exception they possess less useful information than the parties they propose to regulate.

For imperfect information about pathogenic risks to imply a significant market failure, one must show that consumers' actual willingness-to-pay (WTP) for meat and poultry products is substantially inconsistent with their knowledge or beliefs concerning such risks. If consumers expect microbial hazards to be present in raw flesh foods, WTP is diminished to account for this potential risk. Conversely, if they expect raw flesh foods to be free of pathogens, WTP is increased to account for greater safety. That is, the level of risk is simply an attribute of the commodity. The mere presence of risk is not evidence of a market failure at all. Consumers must misperceive the level of risk -- in either direction -- so egregiously that correct information dramatically alters their choices.

Even more stridently than in the seafood HACCP rule, this analysis proceeds to assume that opposite forms of market failure exist simultaneously. Consumers are said to *underestimate* the risk of foodborne illness posed by the consumption of meat and poultry products, thereby purchasing more meat and poultry products and paying higher prices for them than they would if they had proper risk information. This implies

that the market-clearing price and quantity are both *above* optimal levels, and government intervention is needed to better inform consumers concerning these risks. At the same time, however, consumers are said to *overestimate* the risk of foodborne illness posed by the consumption of meat and poultry products, as evidenced by their lack of confidence in the safety of these foods. This implies that the market-clearing price and quantity are both *below* optimal levels, and government intervention is needed to restore consumer confidence in the safety of meat and poultry products.

Clearly both forms of market failure cannot coexist. The first form implies that the actual market demand curve is located upward and to the right of the efficient market demand curve. But the second form implies that the actual market demand curve is located downward and to the left. How the true demand curve can be located both above and below the observed demand curve is nowhere explained.

(b) "Producers rather than consumers are generally responsible for foodborne illnesses when it occurs." There is neither a theoretical nor an empirical basis for assuming that producers rather than consumers are always (or even mostly) "responsible" for foodborne illness. Most foodborne illness from meat and poultry results from temperature abuse, undercooking, or cross-contamination, all three of which occur under the watch of the food *preparer*. A case could be made that food *preparers* are generally responsible for foodborne illness, but producers and consumers would share responsibility in proportion to the extent of their roles as food preparers.

Under these circumstances, assigning liability to producers is efficient only if one of two conditions applies. The first condition is that producers are able to control the behavior of food preparers. The second condition has two parts: (i) producers are able to mitigate pathogenic risks more cheaply than can distributors, retailers, consumers and others in the roles as food preparers; and (ii) holding producers (strictly) liable does not create a significant moral hazard among these other actors. The first condition clearly does not hold, for producers cannot monitor -- much less control -- the actions of consumers and other food preparers. For the second condition to hold, the cost of preventative actions must be greater for consumers and other food preparers than for food producers, net of the costs of moral hazard. There is no evidence that this condition holds, either.

(c) "Producers lack accountability for the foodborne illnesses they cause." The notion that producers generally "cause" foodborne illness already has been debunked, so "causation" is assumed here to be limited to foods prepared by regulated producers and ready-to-eat at the point of sale. Even in this limited context, however, producers as a class do experience lost sales when foodborne illness occurs. All other things

equal, consumers purchase smaller quantities and pay lower prices for ready-to-eat products that they believe pose health risks. All producers of such products lose sales, and no producer can recoup these losses unless it can convince consumers that its products are safer than average. This potential price premium creates an incentive for some firms to offer safer products, provided that they can successfully market this safety attribute. But competition in pathogenic risk reduction is inhibited by FSIS regulations prohibiting producers from making valid product claims involving risk. Thus, there may be an informational defect in the market, but it is largely one of the government's own making rather than the result of deficient market processes.

Given government restrictions against truthful promotion of reduced-risk products, one logical market response would be to cultivate brand names as implicit proxies for the prohibited claim. Interestingly, FSIS' analysis acknowledges that this may have occurred. The analysis then asserts, however, that brand names are in fact ineffective proxies for reduced risk because *all branded* products are not produced utilizing the best available pathogen reduction technology. This rebuttal is merely a *non sequitur.* Use of the best available pathogen reduction technology is not a necessary condition for a brand name to truthfully transmit a message of reduced risk. A name brand performs this function if it poses lower risks on average and consumers recognize it. It need not transmit a message of zero risk, nor must it transmit a message of the lowest technically feasible level of risk.

(d) "Many firms in the food business do not use the best available pathogen reduction technologies because (i) entry is easy, (ii) the industry is highly competitive, and (iii) managers of these businesses are indifferent to the social benefits of such technology." As noted above, there is no reason to expect all firms to use the best pathogen reduction technology in perfectly competitive markets. The fact that many do not offers neither evidence of market failure nor any efficiency basis for government intervention. Technology can be expected to vary simply because pathogenic risks vary by species, product, type and size of establishment, extent of market, and a host of other factors. Further, the extensive (though not universal) use of best available pathogen reduction technology absent a government mandate indicates that safety is a quality attribute upon which producers would like to compete.[6] Similarly, easy entry and competitive behavior in the food business both argue against a diagnosis of market failure, particularly in the form of market power. Competition creates incentives to improve safety as long as firms are permitted to market validated safety claims and consumers value such safety improvements more than the cost of providing them.[7]

The analysis offers no evidence supporting the rather startling assertion that food company managers are indifferent to food safety. If indifference

actually ruled, then few, if any, producers would use best available pathogen reduction technology without both a government mandate and an oppressive enforcement regime. A fair reading is that the analysis is bereft of logic, and on this point it stoops to careless slander of even the best actors in the food business.

In sum, the regulatory analysis provides a most unusual examination of market failure. It is replete with internally conflicting representations of the direction by which efficient markets are said to be distorted, and other specious arguments. If the demonstration of a market failure matters as a critical control point for a regulatory analysis for a regulation purporting to yield billions of dollars in net social benefits, then this one has substantially violated the critical level. Deafening alarms should be clanging already.

Analysis of Reasonable Regulatory and Non-Regulatory Alternatives

The Generic HACCP Plan for Regulatory Analysis requires an assessment of the benefits, costs and other effects for a reasonable range of regulatory and non-regulatory alternatives:

> Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public (EOP 1993: Sec. 1(b)(3)).

The Generic HACCP Guide for Regulatory Analysis offers an extensive elaboration on this simple principle. It calls for regulatory analyses to examine an array of both regulatory and non-regulatory alternatives, including performance standards, differential requirements and/or effective dates, alternative levels of stringency and methods of ensuring compliance, informational measures, and market-based incentives (OMB 1996). As indicated earlier, these requirements are not new; they reiterate substantially identical principles that have been in place since at least 1990 (OMB 1990).

In addition, the Generic HACCP Plan also directs agencies to analyze the incremental effects of exceeding minimum statutory requirements. Where agencies have the discretion to exceed minimum statutory requirements,

> agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach (EOP 1993: Sec. 1(a)).

Seafood HACCP. The regulatory analysis considers only two options besides the one selected: (a) an approach focusing on high-risk seafood products only, and (b) the establishment of differential standards for small businesses. The first option was rejected without analysis because it was imperfect, a standard to which the agency's preferred approach was not also subjected:

> The first option is inconsistent with the objective of this regulation, to control all physical, chemical or microbiological hazards reasonably likely to be found in seafood products (FDA 1995a: 65179).

The second option was indirectly rejected, for all seafood processors were given two years to come into compliance. The preamble to the final rule implies that the absence of any serious consideration of alternatives reflected a conscious FDA policy:

> FDA confirms its tentative view, reflected in the proposal, that HACCP should be the norm, rather than the exception, for controlling safety related hazards in the seafood industry. Existing standards for such contaminants as drug residues, pesticides, and industrial contaminants, are established to ensure that their presence in foods does not render the food unsafe. Processors of fish and fishery products are obliged to produce foods that meet these standards (FDA 1995a: 65118).

A number of reasonable alternatives could have been analyzed, such as a program targeted on raw shellfish where 90 percent of the risks reside. Alternatively, FDA could have considered a voluntary HACCP regime in which participation in the program allowed preferential labeling options. But the absence of any credible analysis of reasonable regulatory alternatives constitutes an obvious and severe violation of this critical control point in the production of quality regulatory analysis.

Meat and Poultry HACCP. Unlike the seafood HACCP analysis, the regulatory analysis for meat and poultry HACCP includes no substantive examination of alternatives at all. Several "strawman" alternatives are described and evaluated based on subjective criteria against which only the agency's preferred alternative could possibly succeed. These alternatives also appeared in the NPRM. At least one commenter on the NPRM called this a "sham" analysis, a charge that the agency duly reported but did not rebut (FSIS 1996: 38988).

FSIS identified four approaches in the regulatory analysis, but analyzed only one of them. These alternatives were: (a) market incentives, (b)

education programs, (c) voluntary industry standards, and (d) uniform mandatory government standards. FSIS summarily rejected each of the first three alternatives. Only the option of mandatory government standards was left standing after FSIS dispatched the others.

Market incentives. The regulatory analysis rejected market incentives on the ground that existing markets were imperfect. Of course, how well existing markets function has nothing whatsoever to do with the merits of market incentives. A prominent example of a potential market-based incentive is the establishment of a special labeling program open only to those establishments that adopted HACCP (or some other pathogen-reducing production system). If HACCP is indeed a lower-risk food production process and consumers are willing to pay price premiums for reduced risk, then differential labeling offers a reasonable alternative to a one-size-fits-all federal mandate.

Education programs. The analysis rejected education programs because

> experience has shown that education alone has limited effectiveness in reducing foodborne illness. The effectiveness of education for food safety, and, indeed, for improving diets and other food related behavior, has not been demonstrated (FSIS 1996: 38950).

The implications of the rejection of education programs is itself revealing. First, it betrays a desire to reform consumers' behavior rather than merely overcome an alleged failure of private markets. In effect, the agency disapproves the preferences of the people it has been hired to serve. Second, consumer education remains a significant element of the agency's activities, one that the agency aggressively defends in budget debates. If education is in fact as ineffective as the agency now claims, then funding for these programs could be cut or eliminated without significant adverse effect.

Voluntary industry standards. The agency rejected voluntary industry standards on the ground that such standards would be more expensive than government standards and they would not be readily enforceable by the government. However, the analysis provided no empirical evidence of this greater expense, nor did it offer a logical argument to support the claim that FSIS enforcement is necessary. Limitations on the agency's capacity to enforce such standards is only a problem if non-regulatory enforcement mechanisms fail. Yet, the widespread use of voluntary industry standards elsewhere suggests that non-regulatory enforcement mechanisms exist and work reasonably well.

Uniform mandatory government standards. According to the analysis, a preference for uniform mandatory government standards is the inevitable result of having rejected each of the other three approaches. But the

analysis did not subject the uniform mandatory government standards alternative to the same criteria that were used to reject the others. For example, if the same standard used to reject market-based incentives were applied to uniform mandatory government standards, the latter would have to be rejected as well. FSIS currently operates a comprehensive inspection system that, by the agency's own acknowledgment, has completely failed to address pathogenic risks. Unlike the unsupported claim that private markets have failed and thus cannot be relied upon to solve the problem of pathogenic risks, the agency's acknowledgment that its existing inspection regime has failed amounts to a signed confession that government regulation does not work.

Similarly, the criticism that education programs are less than fully effective applies with at least as much force to uniform mandatory government standards. Thus, holding the agency's preferred solution to the same standard used to reject the consumer education alternative would cause uniform mandatory government standards to be rejected as well.

Process control. Separate from the HACCP-related provisions of the regulation are additional requirements for microbiological testing of outputs, ostensibly to verify process control. These requirements are fundamentally inconsistent with the theory behind HACCP, which is that performance standards verified through end-product testing are either infeasible or undesirable. If performance standards (such as *Salmonella* tests) capture the essence of pathogenic risk reduction, then the entire HACCP program is largely superfluous. Establishments would choose to adopt HACCP if it offered the least-cost method of compliance with these performance standards. Similarly, if other performance standards (such as the generic *E. coli* criteria) properly measure the effectiveness of an establishment's sanitation program, then the requirement for sanitary standard operating procedures (SSOPs) is redundant as well. However, if performance standards for either sanitation or pathogen loads in final products cannot be devised or effectively implemented, thus arguing for HACCP instead, then microbiological testing will be incorporated into HACCP plans only when it makes sense as a method for verifying compliance with such plans. By imposing these testing requirements, FSIS conveys a preference for redundancy or an implicit distrust of the HACCP model.

Benefit and Cost Assessment

For each alternative, the Generic HACCP Plan for Regulatory Analysis requires a full assessment of its likely benefits and costs:

> Each agency shall assess the benefits and costs of the intended regulation (EOP 1993: Sec. 1(b)(6)).

Again, much more detail can be found in the companion Generic HACCP Guide for Regulatory Analysis (OMB 1996: Sec. III(A)). In fact, the Guide can be thought of as providing a long list of "generic critical control points for regulatory analysis," including:

a) Counting benefits and costs correctly, including non-monetized benefits and costs.
b) Identifying and using an appropriate baseline to estimate incremental benefits and costs.
c) Evaluating each alternative fairly according to identical, appropriate criteria.
d) Discounting future benefits and costs.
e) Analyzing and presenting uncertainty and variability in estimates of benefits, costs, and other effects.
f) Assessing and valuing variable and uncertain risks.
g) Revealing all assumptions.
h) Accounting for international trade effects.
i) Explicitly and separately describing or quantifying equity considerations.

Clearly, each of these critical points is not equally critical across all regulatory analyses. The same can be said for critical points in food production, of course. Just as food safety regulators desire evidence that producers have carefully thought about each possible control point to determine, based on both theory and empirical data, which of them should be critical and which should not, an analogous process ought to be followed by regulatory analysts.

Seafood HACCP. FDA's analysis of benefits and costs violates a wide array of critical control points for regulatory analysis. Many of these violations are so severe that the document should be considered wholly unreliable as a summary of the rule's likely effects. The following discussion highlights but a handful of these problems.

Benefit assessment. FDA builds its estimate of the expected safety benefits in three parts: (a) estimates of the baseline incidence of foodborne illness from seafood; (b) estimates of the costs of morbidity and mortality associated with various pathogenic infections; and (c) estimates of the proportion of cases of foodborne illness that would be averted because of the regulation. The analysis reports safety benefits to the nearest dollar (FDA 1995a: 65187, Table 10) despite uncertainties in the estimation methodology that, at best, suggest confidence to the nearest $10 million.

The analysis also claims substantial benefits other than enhanced safety, including $20 million per year in cost savings to U.S. exporters needing HACCP certification, another $20 million per year in reduced enforcement costs, plus the unquantified benefits of reduced rent-seeking and increased consumer confidence (FDA 1995a: 65187-8, 1995b).[8] As indicated earlier, benefits from increased consumer confidence (resulting

from consumers' risk perceptions exceeding actual risk) are incompatible with benefits from increased safety (resulting from actual risk exceeding consumers' risk perceptions). Rent-seeking might decline under the rule, but only if prospective rent-seekers believed this rule was the "last word" in federal regulation of seafood. The estimate of cost savings to U.S. exporters appears to be based on the assumption that the Department of Commerce's existing certification program was inadequate (despite the fact that it also addressed non-safety concerns excluded from FDA's seafood HACCP program) combined with a "strawman" program of entry-by-entry inspection in EU ports (FDA 1995a: 65188).[9] Finally, enforcement costs seem likely to increase rather than decline, for without aggressive enforcement, the seafood HACCP rule stands to experience widespread noncompliance.

The use of an expert panel of four agency scientists to estimate (c) -- the proportion of cases of foodborne illness likely to be averted due to the seafood HACCP regulation -- is an innovative analytical approach to dealing with what is clearly significant scientific uncertainty.[10] Unfortunately, the procedures used by this panel were not documented. Without such documentation, the validity and reliability of the resulting predictions cannot be evaluated (although they can be tested *ex post*).

A necessary condition for expert judgment to be valid and reliable as a critical input into regulatory analysis is that the experts must make fully transparent their procedures, assumptions, models, and data. Especially important is a clear delineation of the precise mechanisms by which specific regulatory provisions result in the effects predicted. Transparency enhances accountability because experts have professional reputations that they value and seek to protect. Conversely, accountability is lost when experts make compromise or "consensus" predictions, for errors can be disavowed as the product of others' input.

Special problems arise where experts are subject to conflicts of interest, and conflicts were clearly present here because the experts were employed by the regulatory agency. Where internal experts are used, special procedures must be devised to insulate them from a host of political, bureaucratic, and professional pressures leading them to shade their judgments in ways beneficial to the agency. But the act of insulating them from these pressures sacrifices transparency, for the ability to persuasively deny responsibility for the resulting prediction is an essential feature of insulation.

Having followed the internal-expert judgment approach, the analysis claims that the regulation will avert between 18 and 52 percent of approximately 114,000 seafood-related cases of foodborne illness per year, and between 18 and 47 percent of the $245 million in associated costs. Approximately 90 percent of all cases of seafood-related foodborne illness are attributable to the consumption of raw shellfish, and a similar fraction

of safety benefits derive from reduced risks from raw shellfish consumption. More than half of all safety benefits are attributed to the prevention of between 20 and 50 percent of the 60 annual deaths from *V. vulnificus* infection, deaths which occur only in persons with severe liver disease who consume infected raw molluscan shellfish harvested from the Gulf of Mexico (FDA 1995a: 65185-6). Perhaps unwittingly, the analysis hints that these benefits may in fact be illusory because no proven technology existed to control this pathogen:

> *Vibrio vulnificus* is a naturally occurring, ubiquitous, marine organism. The lower and upper bound numbers reflect the fact that controls are newly emerging for this organism and still have uncertainties associated with them.

The analysis implies that its estimates are merely suggestive: "FDA has made *a preliminary attempt* in this analysis to *explore costs and benefits of future actions* which may occur to control this hazard" (FDA 1995b, emphasis added). Thus, half of the claimed benefits of the seafood HACCP rule are speculative. FDA's benefits assessment thus violates numerous critical control points for regulatory analysis, for there is simply no documented linkage between the provisions of the seafood HACCP rule and the benefits claimed.

Cost assessment. Given the magnitude of safety benefits attributed to this regulation, one might expect dramatic changes in seafood processing technology. Such changes might indeed be necessary to comply with the seafood HACCP regulation, but the costs of implementing them are largely ignored in the regulatory analysis. In effect, the regulatory analysis uses fundamentally inconsistent baselines for estimating benefits and costs. Benefits are estimated from a baseline that roughly corresponds to current practices and incidence of seafood-related foodborne disease. However, costs are estimated from a very different baseline in which the vast majority of seafood processors need only write HACCP plans, make minor expenditures to actually comply with these plans, and keep better records.[11]

The analysis used two alternative methodologies for estimating costs, one based on a survey conducted for the National Marine Fisheries Service (NMFS) and another model derived from unspecified FDA inputs and "agency expertise." This latter approach yielded estimates one-fourth as large and reflected the likely costs of operating a HACCP plan for a pair of small seafood processors. FDA assumed that one of these "model plants" substantially complied with current good manufacturing practices (CGMPs) and assumed that the other had "some CGMP deficiencies ... typical of those displayed by seafood processors." Cost estimates for the latter firm included some costs for improved CGMP compliance but no

costs for any operational changes necessary to comply with a HACCP plan. Estimates for the first firm included none of these costs.

The analysis states that the most important difference between the two cost models is that in the NMFS-based model, 80 percent of plants must make operational changes to comply with the CGMPs, whereas only 20 percent must do so in the FDA-based model. This four-fold difference highlights the importance of identifying the most appropriate baseline for analysis, for the larger the baseline compliance rate, the lower the expected costs of the regulation.[12] Indeed, the analysis asserts that any costs attributable to compliance with the sanitation requirements in the seafood HACCP rule are properly attributed to existing regulatory requirements:

> Because FDA holds that [the existence of sanitation deficiencies] must be corrected under existing requirements, the costs associated with these corrections will be borne by processors regardless of whether sanitation provisions are included in the seafood HACCP regulations or somewhere else (FDA 1995a: 65183).

If this were true, of course, then the sanitation provisions in the seafood HACCP rule would be superfluous, imposing no costs and yielding no benefits.

Another noticeable aspect of these models is that they assume a negligible number of critical control points. The FDA-based model, for example, assumes a single critical control point for a production line involving frozen tuna steaks and zero critical control points for one processing imported frozen orange roughy filets.[13] Thus, this cost model assumes away the very problem that the seafood HACCP rule must address in order to generate public health benefits -- the risks posed by raw shellfish. According to FDA's most recent HACCP Guide, producers engaged in marketing raw shellfish must deal with a long list of hazards and critical control points (FDA 1998a). Thus, any cost estimate based on low-risk seafood products rather than raw shellfish is simply disingenuous.

Meat and Poultry HACCP. Like the seafood HACCP analysis, FSIS' analysis of benefits and costs violates a wide array of critical control points for regulatory analysis.

Benefit assessment. FSIS' analysis includes several material errors that severely overstate the likely benefits of the rule. The most obvious of these errors is that the analysis simply assumed that the rule would reduce both the incidence of foodborne illness and losses which result from these illnesses by as much as 90 percent. The agency provided no risk assessment or other scientific basis for this assumption and quite readily acknowledged the absence of any credible basis for it:

> The link between regulatory effectiveness and health benefits is the assumption that a reduction in pathogens leads to a proportional reduction in foodborne illness. [The Food Safety and Inspection Service] has presented the proportional reduction calculation as a mathematical expression that facilitates the calculation of a quantified benefit estimate for the purposes of this final [regulatory impact analysis]. FSIS has not viewed proportional reduction as a risk model that would have important underlying assumptions that merit discussion or explanation, *For a mathematical expression to be a risk model, it must have some basis or credence in the scientific community. That is not the case here.* FSIS has acknowledged that very little is known about the relationship between pathogen levels at the manufacturing stage and dose, i.e., the level of pathogens consumed (FSIS 1996: 38945-38946, emphasis added).

Obviously, this is inappropriate for any regulatory analysis. It makes a laughingstock of the entire analytic enterprise. If it is acceptable to simply assume the existence of billions of dollars worth of benefits, no one should expect analysis to be useful for decision makers. A defensible scientific basis for estimates of risk reduction legitimately attributable to the rule constitutes an obvious critical control point for any credible regulatory analysis.

Cost assessment. FSIS' analysis contains several material errors in its cost assessment that severely understate the likely costs of the rule. First, the estimated cost of required SSOPs, HACCP plans, and generic *E. coli* testing includes only the cost of writing the plans themselves, training current employees, and performing the microbiological tests. The costs associated with the operational changes necessary to comply with SSOPs and HACCP plans are not included. However, if no operational changes are in fact required, then the requirement to develop these plans becomes superfluous. All benefits attributable to both SSOPs and HACCP must be related to specific operational changes that reduce the variance (and possibly the mean) in the level of pathogens in meat and poultry products. If no such changes are actually necessary, then the maximum value of benefits legitimately attributable to both SSOPs and HACCP plans is zero.

Second, the analysis excludes the cost of training new employees in SSOPs, HACCP, and other regulatory provisions. Many parts of the food industry experience high turnover, which will require recurring expenditures on new employee training. Third, productivity losses associated with diverting employees from production to training were not estimated. Again, both SSOPs and HACCP plans require extensive

training if they actually change the way food is made. But every hour spent in training represents an hour not engaged in the production of food, which is regrettably a real cost. Fourth, the estimated cost of preparing HACCP plans in the analysis is unreliable on its face. This estimate was based on a sample of nine establishments that volunteered to participate in an agency study and are not representative of the several thousand establishments regulated under this rule. Statistical inferences from even a random sample of nine are problematic, but they are obviously illegitimate from a convenience sample of nine volunteers.[14]

Identifying the Hazards to Quality Regulatory Analysis

So far this discussion of the regulatory analyses of the seafood HACCP and meat and poultry HACCP rules has focused on what could be called critical control points for quality regulatory analysis and the myriad ways in which FDA and FSIS violated these critical control points. But it would be incomplete if it did not address the underlying hazards to quality analysis for which critical control points for regulatory analysis stand as sentinels. Analysts, perhaps especially government analysts, experience numerous pressures to shade their work in service of what their bosses present as higher purposes. These blandishments fool only a few competent analysts, but even they lack the political and institutional support to resist. Quality analysis is the neglected stepsister of government rulemaking; agencies tolerate it only so long as it does not interfere with their agendas and welcome it only when it can be used to advance these agendas. Frequently they manipulate analysis instead.

Analytical Capacity

Agencies vary in their capacity to perform quality analysis because not all analysts are equally competent. This is particularly true in government agencies where getting rules issued is more highly valued than getting them right. Some agencies simply lack personnel with the ability to perform quality regulatory analysis, and the staff they do have may not be capable of adequately supervising contractors. These agencies also have serious problems retaining good analysts, who will tend to migrate to organizations where competence is rewarded.

Thus, an obvious hazard to quality regulatory analysis occurs when those entrusted with the job are not capable of performing it well. Where competence is a necessary (but not sufficient) condition for the production of a credible work product, a lack of competence is undoubtedly sufficient to ensure failure. Incompetence is as likely to succeed in producing high quality regulatory analysis as it is in producing wholesome and unadulterated food.

Non-Economic Inputs

Both HACCP analyses illustrate the limitations that arise when scientific information is either limited or completely absent. Both analyses required competently performed risk assessments as inputs but did not have any available. Frequently, risk assessments are available but have been produced under conditions that make them inappropriate for economic analysis. Common examples include chemical risk assessments, which focus only on upper-bound expressions of hazard or exposure (or both). Where scientific information is not available, particularly information defining a credible link between specific regulatory provisions and risk reductions, quality regulatory analysis may be simply impossible. This does not argue for forsaking regulatory analysis, however, for without it agencies can be assured that the worthy objectives they seek to accomplish will materialize only by chance. Like inputs to a food production process, bad inputs lead to bad outputs -- there is no "reworking process" that will convert contaminated inputs into a wholesome product.

The approach taken in the seafood HACCP analysis to utilize expert judgment to estimate the likely effectiveness of the regulation represents a welcome innovation. There were problems with the implementation of this approach, however, insofar as the process relied on internal FDA personnel, lacked documentation, and could not be independently audited. Improvements in the design of expert panel processes must be made so that they are transparent and imbued with incentives deterring strategic behavior.[15]

General Counsel Office Objectives

The role of agency lawyers cannot be readily discerned from either analysis, but experience teaches that the effects of legal inputs can be easily underestimated. In general, agency lawyers take policy objectives as given, strive to deter aggrieved parties from litigating, and maximize agency enforcement discretion. Because the nature of legal risks varies across regulations and cannot be readily generalized, specific hazards to quality regulatory analysis associated with agency counsels will depend on the case at hand.

Obviously, agency lawyers pose a hazard to quality regulatory analysis whenever it could conflict with the lawyers' mission. Regulations are easier to defend when they have more benefits than costs, so analysts face pressure to manufacture such results in the service of litigation strategy. Regulations also may be difficult to defend where there are well-documented uncertainties or broad areas of scientific ignorance. Where a convincing case can be made that an agency lacks a solid scientific,

analytical, or empirical basis for its actions, an aggrieved party will be better able to prove to a court's satisfaction that the agency's actions are arbitrary and capricious. In some cases, competent regulatory analysis may pose a clear and present danger to the achievement of agency objectives. In such cases, agency lawyers will strongly prefer that no analysis be performed at all.

Political Level Objectives

The political managers of FDA and FSIS were determined to press forward with these rulemakings despite lacking competent risk assessments or any analytic bases for expecting net social benefits to accrue from these regulations. One can only speculate about their motives. One possibility is that they found themselves "ahead of the curve," perhaps having publicly committed to take these actions long before the analyses had been conceived, much less completed, and could not bring themselves to abandon such ill-considered promises. Whatever the explanation in the case of these two rules, it seems clear that where political-level objectives conflict with those set forth in the Generic HACCP Plan for Regulatory Analysis, this conflict poses a lethal hazard to the analysis and not to political-level objectives. Notice and comment and a variety of review procedures have been devised over the years, but none has provided an effective antidote.

Conclusion

HACCP remains a promising model for improving the safety of the nation's food supply. It is based on the belief that process control represents a superior approach than performance standards because defects are rare, unobservable through reasonable sampling protocols, and impossible to detect in a timely manner. The HACCP model also can be applied to regulatory analyses, such as those prepared in support of major HACCP regulations. When HACCP principles are applied, however, it becomes readily apparent that these regulatory analyses would not pass muster. They would be rejected as adulterated products unfit for human consumption, and it is an open question whether the agencies that produce these products would be allowed to remain in business.

The analogy to HACCP is legitimate because both rules were advertised as solutions to significant real-world problems. If government risk estimates are true, thousands of people lose their lives each year due to foodborne illness and countless others suffer preventable illness. Yet, based on the regulatory analyses prepared in support of these actions, one should expect that neither regulation will achieve but a fraction of the promised public health benefits and at substantially greater than promised costs. There is no moral argument in support of wasting scarce resources,

nor can there be an ethical justification for promising effective regulatory solutions that cannot be delivered or resorting to misleading or incompetent analyses to support them.

Regulators have an ethical obligation to follow the rules. Because of their awesome power, this obligation exceeds that of any citizen or firm they regulate. For almost 20 years, the rules have required regulatory agencies to perform credible analyses of the likely consequences of the exercise of regulatory power. When regulators flagrantly break these rules, as FDA and FSIS did in the two HACCP rules described above, they undermine their own moral legitimacy and render suspect everything else they do.

Notes

[1]Visiting Professor of Public Policy and Regulatory Program Manager, Center for the Study of American Business, Washington University in St. Louis. The author reviewed both of the regulations discussed in this chapter in his previous position as staff economist in the Office of Information and Regulatory Affairs, Office of Management and Budget.

[2]See OMB 1996. An *economically significant rule* is defined as one that has an annual effect on the economy of $100 million or more or adversely affects in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. See EOP 1993: Sec. 6(a)(3)(C). Both FSIS' meat and poultry HACCP rule and FDA's seafood HACCP rule were determined to be economically significant.

[3]A comprehensive analysis based on the issue-specific principles set forth in the guide would add considerable richness to the discussion, but it would only reinforce the conclusions reached here based on an examination of only the general principles.

[4]Conversely, the presence of net social benefits implies the existence of a significant market failure. The greater the estimate of net social benefits, the larger must be the market failure. Market failure is not a sufficient condition for government intervention, however, because poorly crafted government action may not remedy the problem, and in some cases it may exacerbate it instead.

[5]This health benefit claim skirted extremely close to (and possibly beyond) one that would be prohibited if made by a seafood producer. 21 CFR 101.71(e) prohibits any health claim with respect to omega-3 fatty acids and coronary heart disease. 21 CFR 101.75 permits similar health claims with respect to dietary saturated fat and cholesterol, but only after successfully leaping a long succession of procedural and substantive hurdles. The preliminary regulatory analysis only alluded to this evidentiary burden and did not attempt to actually meet it.

[6]Some firms using best available pathogen reduction technology may prefer not to compete based on reduced risks, but instead use advanced technology as a weapon against competitors in a regulatory environment. Such firms are better off

competitively if regulations mandating such technology increase competitors' costs by a larger amount.

[7]Ironically, a much stronger case for market failure would be possible if in fact all firms used identical food production technology. Uniformity could be explained as a natural monopoly phenomenon or market power.

[8]The regulatory analysis supporting the notice of proposed rulemaking claimed benefits of $3 billion to $14 billion per year in improved health resulting from increased consumer confidence in seafood safety, leading to greater seafood consumption. As indicated earlier, these benefits were deleted from the final regulatory analysis in the face of critical public comment. The final regulatory analysis continues to assert that increased consumer confidence will result from the seafood HACCP rule, but does not quantify these benefits.

[9]The alternative of voluntary HACCP for firms exporting seafood to the EU was not examined.

[10]The experts were Dr. George P. Hoskin, Dr. Karl C. Klontz, Dr. Kaye 1. Wachsmuth and Dr. Thomas C. Wilcox. See FDA 1995a: 65185.

[11]In the preliminary regulatory analysis, FDA estimated the cost of corrective actions taken in response to violations of critical control limits at $1,000 per year per plant. This estimate was severely criticized as low by many public commenters. Only one commenter is noted as believing that this estimate was reasonable, a fact which was used to justify raising the estimate to just $2,000 per plant per year in the final analysis (FDA 1995b). In a similar vein, the cost of HACCP plan verification was assumed to be $1,000 per year per plant (FDA 1995b).

[12]Benefits should decline as well, of course. However, as the previous subsection shows, no similar adjustment was made in the estimate of benefits because of uncertainty about the appropriate baseline.

[13]The number of critical control points assumed in the NMFS-based model is not reported in the regulatory analysis, but appears to be similarly low based on the magnitude of the cost estimates.

[14]A sample of nine is the largest sample exempt from public notice, comment, and oversight by the Office of Management and Budget under the Paperwork Reduction Act. A fair conclusion is that this sample was chosen for the express purpose of avoiding OMB and its attendant public oversight.

[15]In contrast, FDA's "alternative" cost analysis was developed using precisely the wrong form of expert judgment. The critical assumptions, data, and inferences which went into the model were not disclosed, and the identities of the seafood experts on whose judgment the model rested were kept secret.

References

Executive Office of the President (EOP) 1981. Executive Order No.12291 ("Federal Regulation"). *Federal Register* 46:13193 (February 17, 1981).

Executive Office of the President (EOP) 1993. Executive Order No.12866 ("Regulatory Planning and Review"). *Federal Register* 58:51735-51744 (October 4, 1993).

Food and Drug Administration (FDA) 1993a. Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products; Proposed Rule. *Federal Register* 58:4142.

National Academy of Sciences (NAS) 1985a. Meat and Poultry Inspection: The Scientific Basis of the Nation's Program. Washington, D.C.: National Academy Press.

National Academy of Sciences (NAS) 1985b. An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients. Washington, D.C.: National Academy Press.

National Academy of Sciences (NAS) 1991. Seafood Safety: Committee on Evaluation of the Safety of Fishery Products. Washington, D.C.: National Academy Press.

Office of Management and Budget (OMB) 1990. "RIA Guidance." In: Regulatory Program of the United States Government, April 1, 1990 -- March 31, 1991. Washington, D.C.: Office of Management and Budget.

Office of Management and Budget (OMB) 1996. *Economic Analysis of Federal Regulations Under Executive Order 12886.* Washington, D.C.: Office of Management and Budget.

U.S. Food Safety and Inspection Service (FSIS) 1996. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule. *Federal Register* 61:38805-38989 (July 25, 1997).

U.S. Food Safety and Inspection Service (FSIS) 1997a. Generic HACCP Models and Guidance Materials Available for Review and Comment. *Federal Register* 52:32053-32054 (June 12, 1997).

U.S. Food Safety and Inspection Service (FSIS) 1997b. HACCP-Based Meat and Poultry Inspection Concepts. *Federal Register* 62:31553-31562 (June 10, 1997).

U.S. Food and Drug Administration (FDA) 1993. Preliminary Regulatory Impact Analysis of the Proposed Regulations to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products. Washington, D.C.: Food and Drug Administration (Docket Nos. 90N-0199 and 93N-0195, http://vm.cfsan.fda.gov/~djz/lcfudpria.txt).

U.S. Food and Drug Administration (FDA) 1994. Fish and Fishery Products Hazards and Controls Guide; Availability. *Federal Register* 59:12949.

U.S. Food and Drug Administration (FDA) 1995a. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products. *Federal Register* 60:65096-65202.

U.S. Food and Drug Administration (FDA) 1995b. Final Regulatory Impact Analysis: Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products. Washington D.C.: Food and Drug Administration (Docket No. 93N-0195, http://vm.cfsan.fda.gov/~lrd/haccpria.txt).

U.S. Food and Drug Administration (FDA) 1997a. Fish and Fishery Products Hazards and Controls Guide; Availability. *Federal Register* 62:7465-7467.

U.S. Food and Drug Administration (FDA) 1997b. Retail Food Program Standards; Notice of Grassroots Meetings. *Federal Register* 62:31611-31612 (June 10, 1997).

U.S. Food and Drug Administration (FDA) 1997c. Fruit and Vegetable Juice Beverages: Notice of Intent to Develop a HACCP Program, Interim Warning Statement, and Educational Program. *Federal Register* 62:45593-45596 (August 28, 1997).

U.S. Food and Drug Administration (FDA) 1998a. Fish and Fishery Products Hazards and Controls Guide. http://vm.cfsan.fda.gov/~dms/HACCP-2.html.

U.S. Food and Drug Administration (FDA) 1998b. Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Food Labeling: Warning Notice Statements; Labeling of Juice Products; Proposed Rules. *Federal Register* 63:20449-20486 (April 24, 1998).

U.S. Food and Drug Administration (FDA) 1998c. Food Labeling: Warning and Notice Statements; Labeling of Juice Products. *Federal Register* 63:20486-20493 (April 24, 1998).

U.S. Food and Drug Administration (FDA) 1998d. Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products; Proposed Rule. *Federal Register* 63:24253-24302 (May 1, 1998).