



The World's Largest Open Access Agricultural & Applied Economics Digital Library

This document is discoverable and free to researchers across the globe due to the work of AgEcon Search.

Help ensure our sustainability.

Give to AgEcon Search

AgEcon Search

<http://ageconsearch.umn.edu>

aesearch@umn.edu

*Papers downloaded from **AgEcon Search** may be used for non-commercial purposes and personal study only. No other use, including posting to another Internet site, is permitted without permission from the copyright owner (not AgEcon Search), or as allowed under the provisions of Fair Use, U.S. Copyright Act, Title 17 U.S.C.*

No endorsement of AgEcon Search or its fundraising activities by the author(s) of the following work or their employer(s) is intended or implied.

Food Safety and Inspection

Breakout Session 1, Friday January 14th, 1994, 1:00 pm
Moderated by Gordon Rausser, University of California, Berkeley

Major papers:

Food Safety and Inspection: An Overview

Nancy Bockstael, Richard Just, and Mario F. Teisl, University of Maryland
Paper presented by Richard Just

Current Policy Environment for Food Safety and Inspection

Julie Caswell, University of Massachusetts

Discussants:

Stuart Hardy, Resources Policy Department, U.S. Chamber of Commerce

Dennis Henderson, Marketing Economics Branch, Economic Research Service, U.S.
Department of Agriculture

John Horowitz, University of Maryland

Andrew P. Manele, Environmental Protection Agency

Richard Williams, Economics Branch, Food and Drug Administration

The Policy Environment for Food Safety and Nutrition: Regulating Quality and Quality Signaling

Julie A. Caswell

The policy environment surrounding issues of the safety and nutritional quality of the U.S. food supply is in considerable, although not unusual, turmoil. Calls for reform touch on every aspect of the regulatory effort, including standards, methods of achieving standards, and the choice of agencies for regulatory responsibility. The turmoil itself is not unusual, for it often occurs in the wake of important food safety incidents. The most recent large scale incident was in Washington, Idaho, California, and Nevada in early 1993 where approximately 500 people suffered cases of hemorrhagic colitis associated with *E. coli* 0157:H7 and three children died from eating contaminated hamburgers served at a fast food restaurant chain (U. S. Department of Agriculture (USDA) 1993, Schneider 1993). Another significant incident was the 1985 Chicago outbreak of salmonellosis associated with tainted pasteurized milk (Ryan et al. 1987), while concerns mount about salmonella in chicken, Alar on apples.

Rausser: There's been an institutional failure. I refer to the journalistic community that is responsible for such alarming publicity, for example, with the Chilean grape incident which immediately followed the Alar scar. The events are presented, but without any mention of the tradeoffs. There's so much "money on the table" that there is considerable incentive for the media to misrepresent (exaggerate) the event.

It is possible that this episode of policy turmoil will bring sweeping (or significant) changes in the food safety regulatory system, based on congressional and Clinton administration initiatives. It is certainly the case that the system has a large backlog of issues and controversies with which to deal. Re-engineering it is a large

and complex task but not one likely to be discouraged by claims of "if it ain't broke, don't fix it." Broken or outmoded pieces of the machine have come to litter the field, and a general clean-up is called for.

Williams: The present administration issued a new executive order, but not that much has changed. Both political parties feel that economic analysis of food safety and other issues is important.

Food Quality— Safety and Nutritional Content

The quality of a food product is multidimensional, including taste, color, texture, safety, and nutritional content. For consumers, food safety and nutritional content are special quality characteristics or attributes for two reasons. First, they are in large part "credence attributes" of food that the consumer is not able to judge effectively even after purchase and consumption. For example, say I felt somewhat nauseous all day yesterday—was it something I ate? Or, is my Vitamin-D fortified milk really fortified but not over-fortified? In other words, consumers have a serious information problem when it comes to food safety and nutritional quality. This information problem occurs to a much smaller degree with quality characteristics such as color that can be judged before purchase (i.e., "search attributes") and other characteristics such as taste that can be judged after use (i.e., "experience attributes").

Williams: Nothing is settled about nutrition. For example, some sources say that fat consumption is going down, while others say it's increasing. It depends on whether it's disappearance data or survey data. Much better data are needed to make policy—how can we make good policy if we have no idea what the trends are?

Second, food safety and nutritional content have direct acute and chronic impacts on human health. Poor quality in this area can imply poor health or, in extreme cases, death. Poor quality in regard to other food quality characteristics has much less serious consequences, perhaps disappointment that the red tomato is mushy inside and has no particular taste. Thus in the United States food safety and nutritional content have been thought to merit extensive regulatory effort because of consumers' difficulties in assessing these quality attributes and their importance.

Other rationales also exist for food quality regulation (see Bockstael and Just in these proceedings, Caswell 1990, Zellner 1988) and play roles in the choice of policies. Not given much discussion yet, but ultimately important, are the costs external to consumers' food choices that are imposed (or not imposed) on the health care system. With health care risks and costs likely to be spread more broadly over more universally-insured individuals, the health cost consequences of diet and foodborne risks will be an important factor in regulatory choices.

Finally, food companies have a large stake in having an adequate food quality regulatory system in place. Such regulation underpins consumer confidence and insures that all companies have to meet similar minimum standards, preventing firms from underproducing safety and free riding on the responsible companies in a market. Recognition of food companies' interest in the positive benefits that the regulatory system provides them (along with the costs it imposes) is essential to understanding the policy environment, particularly since the regulatory relationship is sometimes seen as purely adversarial, when it is not.

The Role of Information in the Regulatory System

There are two major classes of information used in regulation of food safety and nutrition. The first is what I will call monitoring information—information on the production practices, manufacturing processes, and final quality of foods, generated up and down the production/distribution channel. Monitoring information is used to judge whether a product meets minimum quality standards and is suitable for sale. The second type of information used is consumer information. It may be provided by government in a generic form (safe handling guidelines, nutrition guidelines) or through product labeling requirements. Required label disclosures may take several forms, including stating whether a product meets a particular standard or contains a specific ingredient, or giving quantitative information on quality attributes (e.g., the product contains 4 grams of saturated fat per serving).

The design of regulatory programs dictates the extent and type of monitoring information required from food producers, processors, and distributors. Compared to price and quantity information, I would argue that companies do not seem to be as sensitive to the government access to private information needed for safety monitoring. This may be explained by the fact that the information is often not made public or is only made public in limited ways. It is also the case that government activity to assure safety appears to have more general acceptance than its actions to monitor other types of performance.

A key test of this acceptability and of changes in the types and uses of monitoring information will be the proposed adoption over the next few years of the Hazard Analysis Critical Control Point (HACCP) approach as the dominant regulatory framework for food safety assurance. HACCP requires companies to develop, put

in place, and monitor sophisticated process and performance quality control programs. In these systems, the regulatory role shifts from inspecting the process to approving and monitoring the company's HACCP program. This involves a change in the type of monitoring information needed by the regulatory system and, in some respects, will represent a more information-intensive regulatory scheme. There is also an interesting potential for HACCP regulation to interact with consumer information policies, depending on if and how regulatory monitoring information is made available to the public. Companies' reaction to this system may be expected to hinge on the private and public uses to which the data it generates are put.

Hazard Analysis and Critical Control Points—

Hardy: It must be noted that these issues—and many others—are now being addressed by policymakers in the United States and elsewhere in the context of a science-based set of quality assurance principles known as Hazard Analysis and Critical Control Points (HACCP). Both Health and Human Services Secretary, Donna Shalala, and Agriculture Secretary, Mike Espy, have stated their determination to reorganize food regulatory programs and functions around HACCP principles. Several of our most important trading partners—the European Union, Japan, Canada, and Australia—are in the process of implementing mandatory HACCP programs, and most other developed nations have already switched to HACCP or plan to do so. And the Codex Alimentarius Commission is assisting developing nations to develop and implement HACCP-based regulation. HACCP is the key to harmonizing global food safety standards and procedures and resolving food safety-related trade disputes which have mushroomed in recent years.

HACCP aims at preventing hazards before they occur, rather than attempting to

Williams: The first set of regulations from HACCP will be out very soon. It will be applied to seafood, for seafood has been under siege. However, we don't plan to give up risk analysis and go entirely to HACCP (a process-oriented strategy). For one thing, there are serious measurement problems. And, for another, there is a real cost burden on small operations; the fixed cost would have to be spread over too small a base.

detect problems through product inspection. It is based on the premise that if safe ingredients are used from the start, critical points where hazards may occur are identified, and those key points in the process are continuously monitored, then the final product will be safe (Pierson and Corlett 1992). The first step for a manager is to analyze all conceivable hazards that might occur in a particular facility. Next, preventive measures are designed to control or prevent hazards at critical points in the production, manufacturing or distribution process. These preventive measures, such as temperature control to assure sufficient heat to kill microorganisms, must be continuously monitored, for example by a thermometer that records any deviations. When a deviation occurs at a critical control point, the facility manager must put the product on hold until further testing indicates whether it can be returned to the process line or destroyed. The final step in a HACCP program is to verify that the system is working correctly. This is where regulators come into the picture to audit and verify the effectiveness of the HACCP program at each site or facility (Stevenson 1993).

HACCP programs are applicable at every link in the food chain from farm to supermarket/restaurant. Each HACCP program is modified and tailored to individual facilities, although federal agencies, working in collaboration with industry and academia (in such forums as the National Advisory Committee on Microbiological Criteria for Food), are developing generic HACCP programs for specific food sectors, such as shellfish vessels or poultry processing plants. All major food industry organizations, ranging from such grower groups as the National Cattlemen's Association and the United Fresh Fruit and Vegetable Association, to food manufacturers, such as the National Food Processors Association, to retailer groups, such as the Food Marketing Institute and the National Restaurant Association, offer HACCP training programs for their members.

The implications of HACCP for industry are profound. Implementing and maintaining a HACCP program is certain to be costly and difficult. For example, the average expected first year cost of putting a HACCP system into place in a seafood firm will be \$23,900, and \$15,000 in following years, according to the FDA (*Federal Register* 1994). In the case of a typical food processing plant, line workers must be brought into the process and given sufficient training to understand the system's rationale. Workers must be encouraged to report incidents, however minor, and managers must never bend safety rules in the interest of cost. New equipment will be needed at critical control points to enable uninterrupted monitoring of data, and a product coding system will be needed to enable traceback and recall. Multidisciplinary review teams must be assembled to monitor and enforce hazard control procedures. Plant managers must provide regulators with open access to all data needed to verify the effective operation of the system.

HACCP implementation is already well underway in the industry. A 1991 survey by the Grocery Manufacturers Association indicated that virtually all major U.S. food processing companies have adopted or are in the process of adopting HACCP systems. Moreover, HACCP systems are being written into the industry-wide codes of operation known as Good Manufacturing Practices and, most recently, into FDA's Food Code. The HACCP evolution is moving less rapidly at the regulatory agencies, where institutional constraints abound. Nevertheless, FDA has recently proposed (*Fed. Reg.* 1994) mandatory HACCP for seafood, which—according to Secretary Shalala—is to serve as “the model for future food safety in this country” (*Food Chemical News* 1994b). Meanwhile, at USDA's Food Safety Inspection Service (FSIS), a HACCP forum is planned for this spring at which participants will help develop a rule for implementing mandatory HACCP in all meat and poultry establishments (*Food Chemical News* 1994a).

The benefits to regulatory agencies of replacing traditional product inspection with HACCP are enormous. Budgetary constraints and a vastly larger and more complex food supply mean that agency resources are already stretched so thin that much of the food supply is *unpoliced* and escapes official surveillance altogether. Even at FSIS where continuous inspection of meat/poultry slaughter and processing are still the norm, the century-old organoleptic inspection methods (the use of sight, touch and smell to detect tumors, inflammation, bruises and other obvious problems) are wholly incapable of detecting invisible, odorless threats to the food supply, such as *E. coli*, and other pathogenic microorganisms. HACCP allows agencies to move away from the overwhelming (in fact, impossible) task of inspecting products, and into the business of auditing and monitoring the effective operation of HACCP programs

at regulated facilities. This is the key to "leveraging out resources much more efficiently," according to FDA Commissioner David Kessler (*Food Chemical News* 1994b).

The process of introducing HACCP into all sectors of the food industry and into the regulatory arena will be long and difficult, and HACCP will likely coexist with traditional inspection during a transition period. In fact, FSIS is currently operating under just such a "two track" policy. Specific HACCP criteria have not yet been developed for all links in the food chain, and

criteria will continue to evolve as wider application of HACCP provides greater practical experience. Finally, regulatory personnel will require time and training to adjust to an entirely new method of regulation in which adversarial enforcement is replaced with cooperation and problem-solving.

The widespread implementation of HACCP, here and abroad, is nothing less than the most important and promising initiative in food safety/quality assurance since the development of organoleptic inspection methods a century ago.

Federal Register. 1994. "Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products," January 28, pp. 4142-4214.

Food Chemical News. 1994a. "FSIS Publishes HACCP Meeting Notice: Industry Wants Action." January 17, pp. 21-3.

Food Chemical News. 1994b. "Seafood HACCP Release May Not Stop Legislative Action." Jan. 24, pp. 37-8.

Pierson, Merle D. and Donald A. Corlett, Jr., eds. 1992. *HACCP Principles and Applications*. New York.

Stevenson, Kenneth E. 1993. *HACCP: Establishing Hazard Analysis Critical Control Point Programs*. Washington, DC: The Food Processors Institute.

Caswell continued:

For consumers, provision of both generic and product-specific information is important (Ippolito and Mathios 1990). The federal government has programs to deliver generic information on food quality, food handling practices, and diet. An example in the diet area is USDA's *Eating Right* food pyramid, that highlights recommended dietary practices. In practice, product-specific information is probably more powerful in influencing consumers' decisions. A key case study is the implementation in 1994 of mandatory nutrition labeling, which will transform a great deal of once-private information into public information. Interestingly here, while there was much opposition to the new labeling regime due to its costs and questions about whether it would be effective, there was no really serious question as to whether the federal government had the authority to require the information disclosure. Another test case is USDA's effort to require consumer-level safe handling labels on fresh meat and

poultry. Here too the main industry opposition appears to be focused on the manner and cost of implementation, rather than on the government's authority to require the information. And many processors may see a benefit in the label requirement in that it may more firmly fix responsibility for a product's ultimate safety on the consumer.

The information issues concerning food safety and nutrition regulation differ in other important respects from those associated with so-called traditional food and agricultural marketing policies. Probably most noteworthy, the question of "preserving" public information or public access to private information, as is relevant in regard to price and quantity information, does not apply to food safety and nutrition information. In fact, the progression has been one of continually increasing public information, transforming private information into public information (e.g., mandatory nutrition labeling), and, often, creating and using new information (e.g., HACCP protocols and monitoring

information). In other words, progressively more regulation (and use of information) has characterized quality regulation, although the forms have changed over time.

The Current Policy Environment

What should be and is the context for and the scope of the policy discussion on re-engineering food safety and nutrition policy? The broadest context is human health risks from all sources.¹ Although very difficult to do, government policy, and private decisions as well, should make tradeoffs across all risk sources. Within this context, risks and risk management can be broken down into narrower, more manageable spheres such as foodborne risks, including those carried in drinking water. These risks include microbial contaminants, nutritional imbalances (e.g., too much fat in the diet), naturally occurring toxicants, environmental contaminants, pesticide and drug residues, and food additives. Note that I am arguing throughout for joint consideration of food safety and nutritional risks, particularly on the level of decisions about allocation of resources to their management. Joint consideration of interactions between risk sources, genetic endowment, diet, and personal health status is likely to become even more important with improvements in scientific understanding. Such improvements will also tend to continue to modify our perception of food's potential preventative or curative properties.

A central characteristic of today's policy environment is that the various food safety and nutritional risks have been treated in a fragmented manner. In truth, an unconscionable amount of time and effort in this area is devoted to duplication of effort and turf battles. A recent major example is

the parallel efforts by the Food and Drug Administration (FDA) and the USDA to write new regulations governing nutrition labeling. Another representative example is the turf uncertainties (and some battles) that occurred over who had responsibility for the safety of shell eggs, implicated in outbreaks of salmonella enteritidis food poisoning (U.S. General Accounting Office (GAO) 1992a).

Another prominent characteristic of the policy environment is disagreement over the overall performance of the regulatory system. The standard of food safety and nutrition in the United States is among the, if not *the*, "highest in the world." The important achievements associated with this claim are emphasized by many food system participants. However, for domestic policy, the claim has proven to be only of relative relevance. It is important in judging how close we have come to what is currently viewed as attainable quality (the equivalent of using the best available technology in pollution control). It is also important in judging whether more or rearranged resources should be devoted to this area relative to other risks and needs. But in itself "best in the world" has little meaning because, for consumers and policy makers alike, our current best may not be good enough. In other words, food quality is a moving target, and digging in to argue whether we currently have better quality than someone else is not very productive.

A third characteristic of the regulatory environment, linked to the preceding two, is that the risk management burden of the federal government is increasing. There are several sources of this increase, including higher safety standards, the discovery of new pathogens, the proposal and adoption of new food processing technologies (e.g., irradiation), the development of new food ingredients and products (e.g., those resulting from application of biotechnologies), and the increased internationalization of the food

¹While very broad, this may in some respects be too narrow a context. For example, policy concerns may encompass environmental impacts that are not known to have human health consequences.

trade. Finally, policy faces fundamental choices between quality-assurance strategies. Put simply, the choice is between direct quality regulation through setting process or performance standards and indirect regulation through setting information standards (regulating quality signaling).

The Regulatory Facts

The regulatory facts could not be put more succinctly than has been done by the U.S. GAO (1992b, p. 25):

Currently, 12 federal agencies spend about \$1 billion annually to administer about 35 laws governing food safety and quality. Fundamental differences in agencies' missions, responsibilities, and authorities have led to inconsistent oversight, inefficient use of resources, and poor interagency coordination.

Major jurisdictional responsibility over food safety and nutrition is split (and sometimes concurrent) between the FDA of the Department of Health and Human Services and the USDA, primarily its Food Safety and Inspection Service. The split is generally based on product type with FDA regulating all foods except meat and poultry, which are regulated by USDA. Seafood is under the jurisdiction of FDA and the National Marine Fisheries Service of the Department of Commerce. The picture becomes much more complicated beyond this simple commodity-based breakdown of regulatory responsibilities. For example, pesticide policy is set by the Environmental Protection Agency, which also sets pesticide residue tolerance levels for foods. However, in certain circumstances the food additive provisions of the Food Drug and Cosmetic Act (FDA jurisdiction) apply to pesticide residues as well (National Academy of Sciences 1987).

Split and concurrent jurisdiction takes many forms. One split, mentioned

above, is of responsibility for commodities between agencies. This results in similar (although by no means identical) activities taking place in two places. For example, inspections of food processing facilities are carried out by FDA or USDA, depending on what is being processed. This duplication is not in itself *prima facie* evidence of need for reorganization, since legitimate rationales for split jurisdiction could exist. However, it does call for close scrutiny of the activities and their consistency across agencies.

A second form of split jurisdiction occurs when different agencies have responsibility for regulating separate characteristics of a particular product. Again the question is how effectively the split works. Finally, agencies often find that jurisdiction over food quality issues has been made concurrent or is ill-defined by legislation. It should be noted that the Federal Trade Commission also plays an important role in regulating safety and nutrition because of its jurisdiction over food advertising.

Williams: But considering a single food agency instead of so many players, the public choice literature indicates that if there were only one, a lot of people would lose power because fewer committees would be needed. So, that will probably never happen.

Over the past few years, numerous reports detailing, and often criticizing, the operation of various aspects of the food quality regulatory system have appeared. They have given close scrutiny and found the current organization of activities wanting in several respects. Reports by the National Academy of Sciences and the U.S. GAO alone are a tour de force of weaknesses in the regulatory system. Among the most important of these reports are those on pesticide residue regulation (National Academy of Sciences 1987, U.S. GAO 1986a, 1986b); food inspection activity

(National Academy of Sciences 1985, U.S. GAO 1989, National Academy of Sciences 1990a); animal drug residues (U.S. GAO 1990); and diet and nutrition (National Academy of Sciences 1990b, 1991). These reports give a full flavor for the particulars of the various regulatory programs.

It is standard practice to note that consumer interest in food safety and nutrition has increased in the last decade (for evidence, see for example, van Ravenswaay 1992, McGuirk et al. 1990). The reasons for the interest vary, however. Food safety has gotten prominent attention because of "bad news" incidents and a perception that the quality of the regulatory system slipped during the 1980s under the Reagan administration. It also gained prominence through the concerted efforts of activist groups such as the National Resources Defense Council to bring safety issues to the public's attention (see, for example, Sewell and Whyatt 1989) and gains in scientific knowledge that underline the importance of food safety to human health. For consumers, food safety relates to negative, perhaps largely uncontrollable, risks. Nutrition, on the other hand, has gained attention because of what I characterize as "good news"; the consensus that Americans can improve their health by improving their diets (U.S. Department of Health and Human Services 1988, National Academy of Sciences 1989). With nutrition, consumers can gain positive results by changing controllable choices. (Of course the news is not good for those of us who enjoy super premium ice cream and French fries.) The difference between avoiding an evil and attaining a good is central to differences between the regulatory frameworks used for food safety and nutrition issues.

Another major difference between the policy environment for food safety and nutrition at this point in time is that we have just had a major overhaul of the key aspect of nutrition regulation, nutrition labeling, in

the form of the Nutrition Labeling and Education Act of 1990. No such action has taken place with regard to food safety regulation.

Finally, an important consideration in the policy environment for food safety and nutrition policy is growth in international trade, including the recent passage of the North American Free Trade Agreement and completion of the General Agreement on Tariffs and Trade. The regulation of food safety and nutrition is a sensitive trade issue and one where conflict easily arises, as witnessed by the U.S./European wars over hormones used in beef production. Increased internationalization of the food trade means quality regulations will have an additional criterion to pass. Specifically, they will have to pass muster that they are truly in the interest of safety or consumer protection and not simply hidden nontariff barriers to trade.

Re-Engineering Policy: The Questions to Be Answered.

The central difficulty in the policy discussion surrounding food safety and nutrition is its fragmented and jumbled nature (Kramer and Caswell 1994). Proposed legislation to change risk standards for pesticide residues in food, to reassign food inspection duties between agencies, to establish labeling standards for the products of biotechnology such as bovine somatotropin, and to do all manner of other things each take a turn on center stage. There is insufficient understanding of the bigger picture and how it fits together.

In a real sense, food quality regulation can legitimately be seen as a purview where the constraints imposed by humans' bounded rationality (and opportunism) are pinching. Consistent regulation is difficult to achieve. And I submit it is beyond our abilities to attain regulation across foodborne risks that is fully rational and consistent, especially when we consider the incomplete nature of

risk information and differences in individual assessments of the importance of risks. Another major barrier to better policy is the investment many parties have in the operation of the current system. However, policy could be much more rational, and a first step toward its becoming so is for the policy environment (people) to be more disciplined in recognizing (and respecting) the four different levels of policy questions to be answered (see Figure 1).

I. Risk Management and Reduction Goals

Clearly articulated and pursued policy is important to insuring consumers' confidence in the food supply and producers/processors' ability to operate effectively in the food system. Confidence in the regulatory system has been buffeted by some poor performance in the past decade or so. It is important to realize, however, that some buffeting of consumer confidence will occur anyway simply because scientific knowledge about foodborne risks is evolving; as it does so, it is widely reported in the popular press, but in a piecemeal fashion. Public policy has to be stable enough to accommodate new knowledge and also to smooth some of the churning feeling it creates among consumers.

At the first level, our society faces setting the broad outlines of our treatment of human health risks through use of public policy. A major input to this process, but

ultimately an additional matter of public choice, is reliable information on the relative risks to human health from all sources. Our knowledge is incomplete, will get better, but will never be comprehensive enough to be fully satisfactory. The most important need is for relative risk information to be complete enough so that policy is not simply aimed at squeaky wheels of one kind or another.

Within the overall risk spectrum, the first level policy question is risk management and reduction goals. As is happening with the discussion over health care reform, these overall goals are either explicitly or implicitly put in the context of a "risk reduction budget" and analysis of the most effective way to set and spend that budget. Thus the discussion cannot be far from risk/benefit or cost/benefit analysis. Based on relative risks, part of the overall budget will be allocated to management and reduction of foodborne risks. Of course, the final step is judgment of the relative importance of particular foodborne health risks.

In our current policy environment, this level of analysis has been rather painfully inadequate. Consistent risk analysis and standard setting across risk sources has not been generally done, despite efforts to rationalize the risk assessment activities of the federal government. This is particularly a problem in the arena of food

Figure 1: The Four Levels of Policy Questions

Question Level	Policy Question:
I	Risk Management and Reduction Goals
II	Responsibility for Risk Management/Reduction Goals
III	Choice of Regulatory Approach
IV	The Mechanics of the Regulatory Approach

safety and nutrition because the enabling legislation is so varied and agency responsibility so fragmented. This, combined with the fragmented committee structure and limited research capabilities of Congress, means that a detailed road map of risk management and reduction goals has not been drawn.

II. Responsibility for Risk Management/Reduction Goals

The second level policy questions are how risk management/reduction goals should be pursued and by whom (producers, processors, consumers, government). Again, this quickly turns to what is feasible, cost effective, and ultimately will be popular with the American people. This question of how and who should pursue the goals is complex in most regulatory areas, and is certainly so for food safety and nutrition. The ultimate safety or nutritional content of a food product is an ensemble production, with contributions from the input suppliers, producers, processors, distributors (including food service operators), and the consumer. Bad, or even sloppy, actors at any point in the chain of distribution can compromise a product's quality. Strong incentives for quality control exist for companies, even in the absence of regulation, because of potential liability or loss of business that may accompany incidents of poor food quality.

At which points and by whom will quality control efforts be most effective? The answer may indicate consumer, company, federal, state, or local responsibility for the management of a particular type of foodborne risk, but almost always it is some combination of these. Where regulatory action is desired, it is interesting to note that the consensus in the last five years or so has been generally strongly in favor of exclusive federal regulation, except in the case of food service operations. Everyone, including food companies, seems to have learned that the "new federalism" of the Reagan years

(in practice, federal deregulation and fragmentation of the national market as the states stepped into the regulatory vacuum) was a nightmare, rather than a dream.

III. Choice of Regulatory Approach

If regulatory intervention is believed to be called for, the third level policy question is the form of the intervention. The range of government policy choices essentially boils down to two: a standards (process/performance) approach or an information approach (Caswell 1990). The standards approach is direct quality regulation, involving setting minimum standards either in the form of required processes (e.g., good manufacturing practices, implementation of a HACCP program) or final product quality levels. The standards are a quality floor, and products that do not meet them are deemed illegal for sale. This can also be referred to as a banning approach since it prohibits products that do not meet standards.

The information approach to food quality regulation focuses on altering the flow of information on quality, often through mandatory disclosure requirements, rather than quality itself. In other words, it regulates companies' use of quality signaling to consumers through product claims made on labels or in advertising. This approach often includes regulation of the format of information disclosures. Information regulation is usually combined with publication of generic standards or guidelines that provide a context or metric to aid the consumer in making judgments. For example, nutritional guidelines have been published and food labels will now carry standardized nutrition information panels that provide detailed information on the important macro- and micronutrients discussed in the guidelines.

In the United States, the standards (process/performance) approach as applied to food producers, processors, distributors and food service operators has almost universally been used for food safety

regulation, while the information approach has nearly always been used for nutrition regulation. The information approach for nutrition has become even more firmly entrenched with the passage and implementation of the Nutrition Labeling and Education Act of 1990. The standards approach appears likely to remain dominant in food safety regulation (e.g., adoption of HACCP programs), but in some newer areas of activity the information approach is being employed as well. A recent example is the safe handling labels that USDA is attempting to introduce on consumer packages of fresh meat and poultry. A further example may be the development of voluntary labeling of food products that do *not* employ biotechnology or biotechnology-based inputs (e.g., "rbGH-free" cheese). A major policy question is the extent to which private markets and information policies can and should be relied on to deliver acceptable quality levels to consumers.

Interestingly, the second and third level policy questions seem to be those most firmly answered in the current policy environment. In other words, the parties that should be responsible for assuring food quality and the dominant regulatory mechanism to enforce that responsibility appear to be fairly well settled.

IV. The Mechanics of the Regulatory Approach

The fourth level of policy questions involves the actual mechanics of the regulatory system, including the organization of regulatory activities and the incentive and enforcement means used. A great deal of the policy discussion on food quality issues necessarily takes place at this level (Kramer and Caswell 1994). The list of particulars is very extensive. A major thrust of current discussions is whether food safety regulatory activities should be gathered under a single agency, eliminating much of the fragmentation that characterizes the current system.

A second major thrust is the design of regulatory standards. This involves the fine-tuning of broader risk management and reduction goals made at the first level of policy making. An example is the acceptable risk standard for pesticide residues in foods, which has been the focus of extensive activity for several years. The controversy involves whether the zero tolerance for cancer risk mandated by the Delaney Clause is a good standard or whether a negligible risk (defined as a one in one million risk of an additional cancer) standard would be preferable. While it is only one very small part of the food safety regulation picture, the Delaney Clause/negligible risk debate typifies the deadlock that has existed in many areas of food regulation where changes in standards are perceived very differently by different parties. Changes that are seen by some as being based on realistic, scientific risk assessment may be viewed by others as an unnecessary weakening of regulations. It seems that adjusting risk standards to achieve some consistency will probably need to be done as a kind of package deal, where give-and-take bargaining between the interested parties can take place. There is also likely to be a need for package deals that can internalize and settle tradeoffs on other quality issues.

A third major thrust is the reform of the standards (process/performance) regulatory approach. In fact, a major policy issue is the choice *between* process and performance approaches. In food inspection, for example, the current consensus is that FDA and particularly USDA have put too much emphasis on process inspection (e.g., visual inspection of foodstuffs) versus performance inspection (e.g., testing of the final product for microbial contamination). In reality, however, a combination of process and performance approaches is often most effective and is likely to be the direction of future inspection activity, for example under HACCP procedures.

The ultimate question is what types of programs (1) encourage and support firms and consumers in quality assurance activities they are already interested in and pursuing and (2) effectively insure that firms and consumers pursue those activities judged to be needed that they are not now pursuing. A final question that must be faced on this level is who pays and how for quality assurance activities. If government budgets remain tight and demand for government-led quality assurance programs grows, increased user fees of various types will have to be considered.

Ten Years From Now . . .

What will be the regulatory framework and policy environment for food safety and nutrition 10 years from now? The constant addition of new information will mean that the agenda of issues to be dealt with is unlikely to be shorter than it is today. Given that a new comprehensive approach to nutrition through nutrition labeling reform is just being implemented, we are unlikely to see much further change in that area. Hopefully, however, in the next 10 years we will see accomplished some of the difficult work needed to answer the four levels of questions posed above. The work is required in order to rationalize our regulatory approaches to food safety so the federal government's activities will be more effective in assuring the quality and safety of our food supply.

References

- Caswell, Julie A. 1990. "Food Safety Policy Fights: A U.S. Perspective." *Northeastern Journal of Agricultural and Resource Economics* 19: 59-66.
- Ippolito, Pauline M. and Alan D. Mathios. 1990. "Information, Advertising, and Health: A Study of the Cereal Market." *RAND Journal of Economics* 21: 459-480.
- Kramer, Carol R. and Julie A. Caswell. 1994. "Food Quality: Safety, Nutrition, and Labeling." In *Food and Agricultural Policy Issues and Choices for 1995*, M. C. Hallberg, D. Ray, and R. Spitze, eds. Boulder, CO: Westview Press. (Also published as Research Report No. 20, Food Marketing Policy Center, University of Connecticut.)
- McGuirk, A. M., W. P. Preston, and A. McCormick. 1990. "Toward the Development of Marketing Strategies for Food Safety Attributes." *Agribusiness* 6 (4): 297-308.
- National Academy of Sciences, Institute of Medicine. 1990a. *Cattle Inspection*. Report of the Committee on Evaluation of USDA Streamlined Inspection System for Cattle (SIS-C), Food and Nutrition Board, Institute of Medicine. Washington, DC: National Academy Press.
- National Academy of Sciences, Institute of Medicine. 1990b. *Nutrition Labeling: Issues and Directions for the 1990s*. Report of the Committee on Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine. Washington, DC: National Academy Press.
- National Academy of Sciences, Institute of Medicine. 1991. *Improving America's Diet and Health: From Recommendations to Action*. Report of the Committee on Dietary Guidelines Implementation, Food and Nutrition Board, Institute of Medicine. Washington, DC: National Academy Press.
- National Academy of Sciences, National Research Council, Board on Agriculture. 1987. *Regulating Pesticides in Food: The Delaney Paradox*. Washington, DC: National Academy Press.
- National Academy of Sciences, National Research Council. 1985. *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program*. Prepared by the Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program, Food and Nutrition Board. Washington, DC: National Academy Press.
- National Academy of Sciences, National Research Council. 1989. *Diet and Health: Implications for Reducing Chronic Disease Risk*. Report of the Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences. Washington, DC: National Academy Press.
- Ryan, Caroline A., Mary K. Nickels, Nancy T. Hargrett-Bean, Morris E. Potter, Tomy Endo, Leonard Mayer, Carl W. Langkop, Carol Gibson, Robert C. McDonald, Richard T. Kenney, Nancy D. Puhr, Paul J. McDonnell, Russell J. Martin, Mitchell L. Cohen, and Paul A. Blake. 1987. "Massive Outbreaks of

- Antimicrobial Resistant Salmonellosis Traced to Pasteurized Milk." *Journal of the American Medical Association* 258: 3269-74.
- Schneider, Keith. 1993. "White House Plans Overhaul of Meat Safety: Proposal Involves New Techniques for Monitoring for Bacteria." *San Francisco Chronicle*, March 17, p. 1.
- Sewell, Bradford H. and Robin M. Whyatt. 1989. *Intolerable Risk: Pesticides in Our Children's Food*. Washington, DC: Natural Resources Defense Council.
- U.S. Department of Agriculture. 1993. *Briefing Book*. AMI.
- U.S. Department of Health and Human Services, Food and Drug Administration. 1988. *The Surgeon General's Report on Nutrition and Health*. DHHS (PHS) Publ. No. 88-50210. Washington, DC: Government Printing Office.
- U.S. General Accounting Office. 1986a. *Pesticides. Better Sampling and Enforcement Needed on Imported Food*. GAO/RCED-86-219. Washington, DC, September.
- U.S. General Accounting Office. 1986b. *Pesticides. Need to Enhance FDA's Ability to Protect the Public From Illegal Residues*. GAO/RCED-87-7. Washington, DC, October.
- U.S. General Accounting Office. 1989. *Domestic Food Safety: FDA Could Improve Inspection Program to Make Better Use of Resources*. GAO/HRD-89-125, Washington, DC, September.
- U.S. General Accounting Office. 1990. *Food Safety and Quality: FDA Surveys Not Adequate to Demonstrate Safety of Milk Supply*. GAO/RCED-91-26, Washington, DC, November.
- U.S. General Accounting Office. 1992a. *Food Safety and Quality. Salmonella Control Efforts Show Need for More Coordination*. GAO/RCED-92-69. Washington, DC April.
- U.S. General Accounting Office. 1992b. *Transition Series. Food and Agriculture Issues*. GAO/OCG-93-15TR. Washington, DC, December.
- van Ravenswaay, Eileen O. 1992. "Public Perceptions of Food Safety: Implications for Emerging Agricultural Technologies." In *Volume 2: A New Technological Era for American Agriculture—OTA Commissioned Background Papers: Part E: Food Safety and Quality*. US. Congress, Office of Technology Assessment, National Technical Information Service, Springfield, VA.
- Zellner, James A. 1988. "Market Responses to Public Policies Affecting the Quality and Safety of Foods and Diets." *Consumer Demands in the Marketplace: Public Policies Related to Food Safety, Quality, and Human Health*, Katherine L. Clancy, ed., pp. 55-73. Washington, DC: Resources for the Future, National Center for Food and Agricultural Policy.
-

The issue is much broader than food—

Manele: I'm somewhat distressed both papers were rather narrowly focused on food. I'd like to broaden the whole subject to include considerations about *how* the food is produced. There is a clear connection between agriculture and the environment. If we are to maximize social welfare, then food safety simply must include considerations about environmental impacts from food production—and we must make this connection clear to consumers. For example, small dairy operators who are not sufficiently capitalized to handle waste safely are a major source of water pollution. Consumers should be given a complete picture—that the milk is safe *and* that it was produced without negative environmental impacts. We're exploring ways to identify broad categories of production methods to make this information available to consumers.

The dialogue following the Alar scare brought all the major players into the food safety arena. But there is no such thing as a safe pesticide; it's like the search for the Holy Grail. Clearly, some are more toxic than others, but safety relates to how they are used. For example the Aldicarb incident in watermelons happened because of a misuse of the material. Yet, we continue to focus on registration—on what is to be allowed—when the focus needs to be on how it is being used. And there are some pesticides that have very little consequence to consumers but are of great ecological risk. Would we want to use these? No, we simply need to broaden the framework of what is considered safe.

Boekstael to Manele: There are several studies looking at consumer willingness-to-pay not just for food safety, but for environmentally friendly products.

Sarahelen Thompson, University of Illinois: There seems to be a maintained hypothesis that the less technology is applied, the more neutral the environmental effects. This includes a real mistrust of purchased chemical inputs. But this hypothesis never seems to be tested.

Manele: Sustainable agriculture is certainly not less technical. Rather, it requires highly technical and more intensive management skills. It's not that we will be doing without chemicals; it's simply that we must learn to manage them better.

Comment: Agricultural chemical companies have seen the handwriting on the wall about pesticides and fertilizers. Given the liabilities they face, they'd also like to see usage reduced. Besides, they realize they can make far more selling their services about usage practices than they can selling the stuff.

Define the issues so that marketing economists can contribute their expertise—

Henderson: As marketing economists we need to define food safety and environmental issues so that we can apply the tools and concepts that we understand, thereby contributing a unique intelligence. For example, consider the due diligence principle used in the United Kingdom. There is a legal requirement on vendors that they exercise due diligence, assuring that products they receive from suppliers do not pose a threat to consumers. It is the legal responsibility of the downstream firm to document the risk and safety of all they acquire. Well, the obvious economic implication is that due diligence increases transactions costs. This leads to specific analytic concepts that we as economists can handle: Increased transactions costs in the presence of imperfect competition will lead to internalization of upstream supply and downstream vending through ownership. Vertical integration will consolidate liability

costs, simplify contract enforcement, reduce opportunistic behavior, and eliminate chance acquisitions from unknown sources. Thus, we need to do some innovative thinking to bring the analysis to familiar grounds where we can tackle the issues using tools we understand.

How do we conduct economic impact analysis of proposed regulations or standards? This brings us immediately to analyze the associated costs and benefits. On the cost side, we need to ask (1) what kinds of costs are involved in a proposed regulation, (2) how they are affected, and (3) how the impacts can be measured. These cost impacts vary dramatically across firms, across industries, and in vertical and horizontal directions. How do you design a system that can give you the needed information? Often the time frame for doing the analysis is very short—not long enough to do any reasonably complete analysis.

On the benefits side, things are even more complex. First, how can we conceptualize the benefits—e.g., as savings in health care cost, in avoiding food-borne disease, in eliminating lost work time and the values of living longer and maintaining physical and mental acuity. And there is a great variability among beneficiaries.

So, isn't there a way to appraise out of the proposals for regulations, implications that put us on ground where we can use our tools—some implications for industrial organization, for strategic behavior, for economic performance? For example, if we can get some pro-competitive implications, then we can use conventional welfare concepts.

Rausser to Henderson: You are saying that if we could draw some pro-competitive implications from a regulation, then we can use our conventional tools of analysis. Well, many regulations are *not* pro-competitive. For example, the California poultry industry got a standard passed that any chicken below 25°F was to be called frozen.

Promotion had convinced many consumers that fresh chicken was safer and healthier. The law meant that any out-of-state chicken must be labeled as frozen. This anti-competitive behavior caused harm to consumers who, when buying out-of-state, usually cheaper, chicken must now buy a "thawed" product.

Re: The Delaney Clause—

Manele: The descriptions you hear about the Delaney Clause are not the original interpretation. Rather, originally the intention was to prevent a carcinogen in a processed product if it concentrated *beyond* what was in the raw product. Now this is being understood to mean none at all—zero risk.

Rausser: I expect that the Delaney zero risk standard will, sooner or later, be modified—as soon as some other regulation can be substituted. We, as economists, ought to be doing some work on this to inform the debate.

A final note—

Hardy: Widespread public perception (and *misperception*) of the linkage between diet and health, as both papers note, is driving fundamental changes in quality assurance programs in industry and regulatory agencies. Industry is in the lead, while regulators struggle to keep pace with accelerating changes in food production, processing and marketing. Both papers identify several of the more pressing issues confronting policymakers today. Is the patchwork quilt of fragmented programs and policies up to the task of regulating a proliferating, increasingly complex, food supply? What is the proper balance between the public's right to know and the firm's right to privacy? How much risk should we tolerate, and who should take responsibility for managing/reducing food-borne hazards? The Caswell paper, in particular, underscores the need to modernize and harmonize the food regulatory system on the basis of the best available science and to target public resources at areas of greatest risk.