Food Safety Regulation in the 1990's

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The focus of the nation's food safety regulatory scheme has evolved over the last 15 years in response to corresponding changes in consumer interests and concerns. Consumer concerns about foods have grown from the simple fear of food additives to a more sophisticated concern about the "hidden hazards," what agricultural commodity producers, food manufacturers and the government can and should do about them, and the consumer's own role in reducing the risk of foodborne disease. The nature and direction of congressional initiatives and inquiries as well as regulation by the Food and Drug Administration, the United States Department of Agriculture and other federal and state agencies have developed accordingly.

In order to survive – and indeed thrive – in an increasingly skeptical environment, food processors and all others involved in food production and distribution must respond as well through technology and education of the consumer, the media and food handlers. The educational process includes explaining and putting into perspective potential hazards, what the food production and processing industries do to reduce and control these hazards, and how consumers can help protect themselves. While the technology must start with the planting of the first agricultural seed, it becomes especially important in the processing establishment through application of a form of hazard analysis critical control point procedures. The quality control procedure must encompass production, packaging, storage, and handling considerations.

I shall address the changing focus in food regulation and suggest how the "key players" – consumers, the food industry, Congress, federal regulators, and the states – have responded and can be expected to respond in the future. The message that I hope to leave is that the food safety concerns that the regulators will be called upon to answer in the 1990's are serious, far more so than the additive phobias to which the food industry was subject to in the 1970's. Industry must be prepared to accept some responsibility for helping to reduce hazards where they truly exist while ensuring that regulatory policy is realistic and based upon sound science. Unless the industry plays an active part in this process, the regulators will naturally gravitate toward zero risk policies for any food hazard that is identified in the same way that Congress adopted a zero tolerance for carcinogenic food additives 30 years ago. If this happens, food product development will be stifled well into the 1990's.

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Historical Perspective

In the early 1970's, the principal food safety concerns among consumers focused on food additives. Consumers most frequently asked questions such as "What is an additive?" and "Which additives are in which foods?" Consumers especially feared (and still do) carcinogens and were taught to believe than any level of carcinogen in a food product ultimately will cause cancer in humans.

Food additives still remain of interest to consumers, but consumers today seem to have a better perspective about additives than did consumers in the 1970's. In my opinion, the saccharin controversy of the late 1970's gave consumers an appreciation of just how Draconian strict application of the Delaney Clause and similar statutory provisions can be. The unsuccessful effort of FDA and USDA to ban nitrites in meat and poultry on the basis of suspect science also caused consumers and Congress to begin questioning more carefully food additive regulation. As many of you know, the Delaney Clause is that provision in the Federal Food, Drug and Cosmetic Act that requires FDA to prohibit the use in foods of any substance found to cause cancer in man or animals. USDA relies upon FDA to evaluate the safety of food ingredients before permitting their use in meat and poultry.

As the mid-1970's arrived, consumer interest began leaning toward nutrition with a focus on the amounts of vitamins and nutrients in particular food products. The initial interest in micronutrients to some extent led to a "horse power" race in food product development. Through the latter part of the 1970's and even up to today, consumers have learned that certain macronutrients play a part in disease prevention, which explains the more recent interest in sodium, fats, cholesterol, fiber, calcium and other constituents. The food industry, of course, seized upon the marketing opportunities that nutrition presents and helped create the current controversy surrounding health claims.

For the late 1980's and undoubtedly into the 1990's, consumer concerns have moved away from that which can be addressed through labeling and are focusing on issues that go to the heart of food processing – "hidden hazards," including pesticide and chemical residues, unavoidable environmental contaminants, and especially microbiological contaminants (salmonella, listeria, campylobacter and who knows what else). Recent events have intensified product surveillance for excessive residues. Microbiological quality, while always on the regulatory agenda, has now hit the front

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pages and presents some very real problems that will have to be addressed in the coming years.

Regulatory Responses

Banning suspect substances and labeling traditionally have been the regulatory answers to consumer questions about food additives. For example, in the early to mid-1970's, a variety of color additives were banned and certain non-nutritive sweeteners became bait for the regulators. FDA, USDA and Federal Trade Commission even held hearings throughout the country to ask consumers what kind of information they wanted on food labels.

When FDA proposed to ban saccharin on the basis of evidence which demonstrated that consuming the equivalent of 800 cans of diet soft drinks per day might induce human cancer, consumers began to realize that their additive phobia might have gone overboard. Again, for the meat industry, the turning point came when USDA and FDA proposed to ban nitrites on the basis of a scientific study that could not stand up to peer review. Congress responded to the saccharin episode with a flurry of bills to amend the Delaney Clause and allow FDA to make risk/benefit analyses in food additive approvals. These bills also would have required peer review of any scientific data upon which regulatory decisions were to be made.

Although the bills to "modernize" the food safety laws never progressed very far (no one in Congress wants to be accused of promoting cancer), the legislative initiatives did encourage FDA to exercise administrative ingenuity. For example, the agency developed a policy providing in effect that a carcinogen is not a carcinogen if its amount or the risk it presents are insignificant or *de minimis*. Perhaps unfortunately, recent court decisions holding the *de minimis* doctrine unlawful as applied to certain color additives may well restrict FDA's administrative discretion in this area. These decisions may also force Congress to take another look at the food safety laws.

Finally, on the premise that the federal government has not sufficiently protected its citizens, several states over the years have mounted their own initiatives to ban or require labeling of suspect carcinogens and reproductive toxicants. California Proposition 65 and similar bills pending in a number of state legislatures today demonstrate how far the states are willing to go in taking the law into their own hands. The difficulties that the independent exercise of states rights in this area presents for national food marketers is something that both the federal agencies and Congress eventually will have to confront.

FDA has responded to consumer interest in nutrition primarily through labeling initiatives. In 1975, FDA adopted its regulations requiring that, if a food is fortified or if a nutrition claim is made in labeling or advertising, a laundry list of nutrients must be provided on the label in a prescribed format. Although no one has ever seemed to like this approach very much, until the agency determines which information is most useful and how best communicated, these regulations will remain on the books. USDA has been somewhat more flexible in the nutrition labeling of meat and poultry products. Because the labels of meat and poultry products must be approved by USDA before these products may be marketed, however, USDA is traditionally more restrictive than FDA in the kinds of claims that can be made.

With the increasing consumer interest in nutrients and the relationship of diet to health, food retailers have introduced point-of-purchase nutrition information programs. These programs have been generally well accepted and, while some may technically violate certain regulations, it is unlikely that they will be challenged. The meat and poultry "Nutrifacts" programs represent a legitimate and legally sound approach to providing a great deal of important nutrition information at the retail level.

More recently, controversy has surrounded broader health claims made for foods in labeling and advertising. The FTC tried to prevent this kind of product promotion through a failed effort to adopt a trade regulation rule in the late 1970's. FDA and USDA historically have taken the position that therapeutic claims made for foods in effect convert the products into drugs requiring new drug approval. In the face of the Kelloggs All-Bran campaign and other promotional programs, however, FDA was pressured to propose regulations to govern such claims. These regulations are still under review and, once published in final form, may well be challenged in court. Whatever guidelines ultimately survive are likely to be adopted by USDA to judge health claims made for meat and poultry products.

Responding to consumer concerns about sodium levels in foods and efforts by Congress to mandate sodium labeling, both FDA and USDA adopted regulations intended to foster voluntary sodium labeling. These regulations have been successful as the amount of sodium information voluntarily provided has grown. FDA has also proposed voluntary cholesterol labeling regulations modeled upon the sodium regulations. Of particular interest in that proposal is a requirement that a cholesterol claim include fat labeling with a breakdown of saturated and polyunsaturated fats. This, in and of itself, demonstrates the increasing sophistication of consumers and the information that at least the regulators think they want and will be able to use.

It is quite likely that USDA will follow FDA's lead in the area of fat and cholesterol labeling as well. In fact, consistent with the objective to accommodate consumer concerns about fat and the desire of meat companies to provide lower-fat products, USDA responded to an American Meat Institute petition by amending its regulations to allow for the development of lower-fat hot dogs. The agency also amended its policy governing lean labeling claims. Finally, and again in response to a meat industry recommendation with consumer endorsement, USDA recently changed its grading standards to foster the production of leaner beef.

Notwithstanding these initiatives, some members of Congress continue to seek more, especially in the way of saturated fat declaration. Representative Cooper (D-TN) has introduced a bill that would define quite narrowly terms such as "lite" and "lean," and Representative Glickman (D-KS) with Senator Harkin (D-IO) have pursued legislative measures to require saturated fat declarations for foods containing "tropical" oils such as coconut and palm oil. Senators Hatch (R-UT) and Metzenbaum (D-OH) continue to talk about an omnibus food labeling bill that, among other things, could lead to mandatory nutrition labeling generally and fat labeling specifically.

Legislative proposals have a way of encouraging regulatory action, even when the proposed legislation is not enacted into law. With the recent publication of a National Research Council report concluding that existing FDA and USDA policies promote the development of high-fat foods, it is likely that fat labeling will remain a matter of Congressional and regulatory attention.

The "Hidden Hazards"

As earlier indicated, the regulatory evolution has gone from the food additive focus of the 1970's, through nutrition to what food industry critics, the media, and others have come to call the "hidden hazards" of residues and microbiological contamination. These are the nation's leading food safety issues today and will remain such well into the next decade. The legislative and regulatory activity addressing these areas will affect production, processing, inspection and distribution of food and farm commodities.

While pesticide residues have always been of some concern, interest was heightened when the National Academy of Sciences issued a report suggesting that almost all foods have pesticide residues. The NAS report, which highlighted the different standards for regulating pesticide residues as compared to direct food additives – something the report called the Delaney Paradox – immediately became the subject of congressional hearings. A Government Accounting Office report on the issue was commissioned and House Commerce Committee Chairman Dingell (D-MI) and most recently House Commerce Health and Environment Subcommittee Chairman Waxman (D-CA) are pursuing proposed legislation to increase pesticide monitoring and control. In addition, FDA's fiscal year 1988 budget was increased with a directive from the Appropriations Committee that FDA intensify its monitoring of pesticides in foods, especially in imported foods.

In the meat industry, the residue issue has centered on the drug residues in meat products from animals that have been fed excessive doses of antibiotics and other drugs. The industry is aggressively working in cooperation with USDA to find ways to address this problem. USDA's Packers and Stockyards Administration, for example, has recently proposed a regulation that would have the effect of holding financially responsible producers whose animals are found to contain excessive residues.

While certainly important, the residue issue pales by comparison to the concerns that have been raised about microbiological contamination. Congress and the regulatory agencies began giving increased attention to this in the aftermath of outbreaks of listeria in dairy products. The issue became a top priority following several newspaper articles and a CBS *"60 Minutes"* segment in 1987 suggesting that salmonella in poultry had increased in recent years and that processing techniques and USDA inspection procedures were at fault.

Subsequent Senate hearings concentrated on USDA inspection procedures and the program's effectiveness in preventing bacterial contamination of meat and poultry. Consumer groups and organizations representing government inspectors claimed that processing techniques were increasing the risk of bacterial contamination and that inspection procedures were in need of revision.

A report from the National Academy of Sciences, however, pointed out that although bacterial contamination can be a problem for all raw foods, proper handling and cooking of meat and poultry products virtually can eliminate the hazard. The report recommended the adoption of risk-based processing and inspection procedures. Both USDA and the regulated industries endorsed that proposal.

Senator Leahy (D-VT), Chairman of the Senate Agriculture Committee, introduced a bill that, among other things, would mandate the establishment of standards or tolerances for pathogenic microorganisms in meat, poultry and other products. Animal feeds would be subject to tolerance levels as well. Companies whose products fail to comply with the standards would be subjected to regulatory and civil action.

A more moderate measure, and one that has received broad agricultural community support, was introduced in the Senate by Senators Bond (R-MO) and Pryor (D-AR), and in the House by Representative Stenholm (D-TX), who chairs the Agricultural Subcommittee on Livestock, Dairy, and Poultry. Their bill would fund research intended to identify where foodborne hazards exist in the production, processing and distribution chain and how best to control them. The research would encompass all food products and be used to develop new techniques for risk-based food processing and inspection. This bill was the subject of House hearings in March and could reach the House floor for a vote this year. Senate action is less likely, but the action so far at least appears to promise additional attention to this issue next Congress.

The regulatory agencies have become especially aggressive in the area of microbiological quality regulation. They are aware of the public attention to this subject and their legal responsibility to prevent the distribution of products that might be adulterated and do not want to be criticized for failing to act. Both USDA and FDA have intensified their listeria monitoring programs, for example, adopting policies that are intended to increase the testing of products for listeria at the plant level with regulatory action to follow to remove contaminated products from the market. Even though it has yet to be determined at what level listeria in a product renders the product unsafe and many other questions remain about the control of listeria, the agencies have predictably adopted zero tolerances for this contaminant.

USDA's listeria policy, at least as it stands today, presents a dilemma for a meat company that desires to act responsibly by testing the plant environment and finished products to ensure that they are not contaminated. If a company tests environment and not finished products, it cannot be completely confident that its controls are working. On the other hand, if a company tests finished product, it exposes itself to regulatory and product liability consequences. In this regard, even though USDA will not ask a company to recall products unless a positive listeria sample has been confirmed with later samples analyzed in a USDA-accredited laboratory, questions still exist as to the extent of a company's responsibility to recall suspect products from the standpoint of civil liability. Thus, "to test or not to test" has become a popular question among meat industry executives these days.

A microbiological criteria commission has been established by USDA and FDA with membership from government, private and consumer sectors to study issues relating

to microbiological quality. The commission, which has scheduled its second meeting, is expected to recommend regulatory and other approaches to food safety perhaps within the next two to three years.

There has also been a growing emphasis, both at the company levels and in terms of USDA and FDA policy, upon good manufacturing practices for specific product categories. In the growing area of refrigerated foods, for example, USDA has adopted a policy that sets forth specific quality control requirements that must be satisfied before USDA will approve a label for a refrigerated food containing meat or poultry. The goal of this policy is to reduce contamination by preventing cross-contamination between raw and cooked products and by ensuring proper cooking, handling and packaging conditions.

In short, the issue of microbiological safety is being addressed in many forums and will continue to be the subject of legislative and regulatory attention. It is troubling but also understandable that USDA and FDA have adopted regulatory policies necessarily based on less than complete information. The "Catch 22" that USDA's listeria policy has created for the meat industry is a consequence of regulatory policy preceding science. It is, therefore, in the industry's interest to support research and encourage the agencies to develop realistic policies that are based upon good science. One way to do this is to support legislative measures that help fund necessary research and then insist that government-funded research projects (whether they are conducted by private or public institutions or by USDA's own Agricultural Research Service) address immediate food safety problems.

Summary

The food safety regulatory evolution since the early 1970's has been obvious, moving from a relatively immature fear of food additives to a somewhat sophisticated skepticism about the microbiological quality and safety of all food products. Congress and the regulators have been quick to respond, sometimes in ways that have not been supported by sound science.

The issues facing food producers and marketers now, and it is predicted well into the 1990's, are difficult ones because the answers are not readily apparent. Yet the problems are real. Never has the responsible participation in the development of public policy by academicians, food industry scientists and quality control experts, and others knowledgeable about food processing and who have access to the research and technology necessary to ensure that regulatory policy is appropriate been so important.