



Too Many Cooks

A fragmented regulatory system has sliced the food-safety pie into too many pieces to nourish the confidence of the U.S. consumer.

BY JULIE A. CASWELL

For decades, U.S. consumers took safe food for granted. That changed recently with outbreaks associated with *E. coli* and *Listeria* in the United States and reports of mad-cow disease in Europe. These outbreaks have focused attention on an issue that is extraordinarily complex. Indeed, food safety encompasses everything from food-borne pathogens to residue levels for pesticides and animal drugs, naturally occurring toxins, and additives. For some, it even includes whether the food was produced with the aid of biotechnology.

Adding to the complexity, food safety is a responsibility shared among local, state, and federal governments; food producers and distributors; and consumers. Defining appropriate roles for each of these

players represents a central policy question. When it comes to imported food products, an even bigger cast of players takes the stage. The report cards of most of those players show reasonably good performance but definite room for improvement.

Food Supply: How Safe?

Food safety has improved over time, often dramatically, but demand for food safety has also been increasing as incomes rise and we learn more about links between diet and health. Currently, there are some clear causes for concern. For instance, we may in some cases be investing too many resources in food safety—resources that might be better spent improving car safety or health care for children or any of a dozen other concerns. Within the food area, poor nutrition and an increasing

trend toward obesity might represent more appropriate targets for public monies than curbing the incidence of food-borne diseases associated with *E. coli* and *Listeria*.

The federal government has improved its ability to measure the impact of food-borne illness on U.S. consumers, and data are best in regard to illness and deaths from exposure to food-borne pathogens. According to the best estimate, food-borne diseases cause 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.¹

The societal costs of five bacterial food-borne pathogens² alone are estimated at about \$7 billion per year, but the overall incidence of food-borne illness may have declined in recent years. Indeed, the Centers for Disease Control and Prevention reports that cases of food-borne illness per 100,000 people for specific bacterial food-borne pathogens decreased 22.4 percent from 1996 to 1999, with a 14 percent decrease from 1998 to 1999.³

Part of the challenge of ensuring a safe food supply arises from a fragmented roster of federal regulations that empower 12 separate agencies to oversee various components of the program. Primary responsibility lies with the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the U.S. Environmental Protection Agency (EPA). Meanwhile, state and local governments provide most oversight for food service operators. Food producers, processors, and distributors have a strong interest in providing safe products. Apart from simply protecting consumers, they need to attract consumers, avoid liability, protect themselves or workers from hazards, and comply with government regulations.

Big Pie, Too Many Slices

Rationalization of the food safety regulatory system is a perennial topic in Washington. Most recently, a National Academy of Sciences report pointed to problems with the current fragmented system but stopped short of recommending a move to a single agency.⁴ Recent General Accounting Office (GAO) reports have identified problems with the current system, but the policy response has been to maintain the current regulatory structure while adding increased coordination across agencies.

Meanwhile, the agencies remain entrenched in their spheres of influence. Perhaps the current level of performance, which looks good compared with that of some of our trading partners, leads to reluctance to take a chance on change. In contrast, the European Union, spurred on by recent failures in its systems, is moving to set up a single food agency.

A key concern with our fragmented regulatory approach is whether different levels of risk are treated in a consistent manner across agencies. But this concern is really a subset of the larger question of determining how safe is safe enough when it comes to food. In the language of the World Trade Organization, safe enough means foods that pose an “appropriate level of risk” to consumers. Defining that level of risk is a scientific, political, economic, and social endeavor.⁵ Americans expect the food they buy at the supermarket or order in restaurants and fast-food outlets to be safe. But absolute safety is very expensive, even if it *were* attainable. So where do we stop in the quest to attain a safe food supply?

Countries and bodies that establish international standards, such as the Codex Alimentarius Commis-

sion—a joint endeavor of the United Nations Food and Agriculture Organization and World Health Organization that sets food standards—have been struggling to develop a more standardized approach to food-related risk. In its most ambitious form, the idea is to reach consensus on which risks are serious and what level of protection should be provided against them. In practice, this type of consensus has proven elusive, as countries differ in their risk preferences based on income, culture, politics, and other factors. What has been accomplished is to articulate a common approach to risk, which has been formalized as the risk analysis framework.

Take, for example, the presence in processed meat products of *Listeria monocytogenes*, a commonly occurring bacterium that is hard to control because it can be ubiquitous in processing environments and grows at refrigerator temperatures. Its presence can cause listeriosis in humans, with an estimated 2,500 serious illnesses and 500 deaths each year in the United States. Listeriosis poses particular risks for pregnant women—where it can result in miscarriage, fetal death, and severe illness or death of a newborn infant—older adults, and those with weakened immune systems.

Relative Risk

Risk analysis begins with a risk assessment to gauge the likelihood of a particular food being contaminated with *Listeria monocytogenes* when it leaves the plant, of the food-borne pathogen load increasing while the product is refrigerated before eating, the likely ways in which the food may be prepared that would decrease or exacerbate the risk, the likely quantity ingested by a consumer, the likelihood of the

consumer becoming ill, and, finally, the likely severity of the illness.⁶

The risk management phase uses the risk assessment information to judge what level of safety should be targeted and what, if any, actions should be taken to achieve that level of safety.⁷ For example, an agency could target a reduction in the incidence of listeriosis and put in place *Listeria* control programs in processing plants and apply safe handling labels on consumer packages. Finally, risk communication includes constant discussion among all the parties to the problem about risk levels, perceptions of those risks, and actions to address them.

The ideal is that all food safety risks—and all risks from any source for that matter—be given a full risk analysis, with priorities for action based on the relative importance of different risks and benefit/cost analysis of potential actions. We are nowhere near achieving this ideal.

Risk analysis itself takes a considerable amount of resources. Risk assessments have so far been completed for only a handful of the most important food-borne pathogens, for instance, and benefit/cost analyses are done only for regulatory approaches that have already been chosen for use. Particular risks can jump up the queue if they gain widespread public awareness and political pressure builds to address them.

How safe is safe enough is a societal and political decision, but one that needs to be grounded in scientific assessment and benefit/cost analysis. The U.S. regulatory system provides that grounding and couples it with impressive expertise in addressing food safety issues. It has made progress toward taking a systematic approach to risk across different food-borne sources, but the fragmented system limits that progress.

Consumer Beware?

While the regulatory system has to gauge how safe is safe enough, it also has to assign responsibility for attaining a safe food supply. It has always been recognized in the U.S. regulatory system that the consumer is the final line of defense against some risks, particularly microbial food-safety risks. Many products are sold in a form that is hazardous without further action by the consumer—raw meat products, for example. The federal government has been fairly paternalistic, however, regarding its role in assuring food safety for microbial as well as other food-safety risks. In other words, where possible, it has regulated by means that minimize the need for self-protection by consumers. Labeling has been used in an array of other areas, including for nutrition and some process attributes—for example, organic production.⁸

There has been some fraying along the edges of this strategy, with labeling being looked upon more favorably as an option for further assuring food safety. An example is processed meat products, where risks associated with *Listeria* have come to the forefront. The USDA Food Safety and Inspection Service is looking closely at terms such as ready-to-eat or not ready-to-eat and cooking instructions that could be consistently placed on labels to better alert consumers to the need to prepare products in a certain manner to avoid risk. The food safety agency is also pursuing control of this risk through regulations at the processing plant level, but user level information is likely to play a bigger role in assuring food safety in the U.S. market. Success clearly depends on users reading and acting upon the label information.

While labeling and self-protection may gain ground in the pur-

suit of a safe food supply, the dominant approach to food safety will continue to be regulatory programs that attempt to assure safety with minimal requirements for consumer awareness and action. This appears to align well with the expectations of the U.S. consumer.

Free Trade and Safe Food

Trade in food products raises two related problems. The first is assuring that importing countries are able to determine that imported foods, which are produced in different countries and perhaps under different regulatory programs, meet domestic safety standards. The second is assuring that importing countries do not use food safety standards and inspection procedures in a protectionist way to prevent safe products from competing countries from entering the domestic market.

Recent trade agreements and the World Trade Organization seek to balance these two assurances. They do this primarily by specifying that policies that affect imports be science based and not more restrictive than necessary to ensure a safe food supply. The U.S. food supply is becoming more diversified in terms of the variety of products imported, the number of sources of those products, and the volume of trade. At the same time, the United States remains a major exporter of agricultural and food products to the world market.

On the home front, several GAO studies have criticized the U.S. government's ability to assure the safety of imported foods. Trade disputes have arisen, particularly with the European Union, over access of U.S. products to foreign markets. While critics worry that freer trade threatens food standards at home, there is little evidence to suggest this is occurring. In fact, safety stan-

dards in the United States and in most countries abroad are getting stricter as consumer incomes rise and societies are able to pay higher prices for food. But translating those higher standards into a safer food supply depends on enforcement of the standards for both domestic and imported products.

Getting from Here to There

Food safety is an issue dear to the hearts—and stomachs—of all consumers. While food safety levels are high and improving, consumers may nonetheless be overly complacent about food safety and fail to take precautions necessary for their own self-protection. Simple issues such as the dangers of cross contamination among foods being prepared may be unfamiliar to home cooks with less knowledge of food safety. Lack of awareness and care can take a terrible toll when it occurs in restaurants as occurred last summer in Milwaukee, where cross-contamination of *E. coli* from raw beef to fresh salad bar items in a Sizzler restaurant caused over 500 illnesses, 23 hospitalizations, and one death. Since quality-control for safety is a complex process, we may need to build more redundancy into the system, with consumers working more effectively on the front lines, if we hope to attain desired improvements in safety levels. Labeling may be the vehicle for achieving this redundancy, although it may not apply well to food service situations.

At the same time, regulatory systems will need to place additional reliance on food-producing and distributing companies. This approach would alter the federal government's role in assuring food quality by increasing reliance on private quality assurance systems. For example, USDA and FDA have taken steps

in this direction with the adoption of the Hazard Analysis Critical Control Points (HACCP) approach to food safety in plants that process meat, seafood, and juice. HACCP requires companies to design and implement extensive quality control plans to assure food safety. It also shifts the regulatory emphasis from directly inspecting production processes to monitoring company quality-control plans.

Technologies for the assurance of food safety are rapidly changing. Genetic fingerprints can now link the source of outbreaks of food-borne illness to specific plants and even to specific farms. But at the same time, safety-assurance systems have to function over longer supply chains, as trade in food products continues to grow. Adaptation to these changing conditions and new technologies will determine the success of the system that assures food safety. The relatively slow response of this system to the introduction of biotechnology into the food chain suggests that more effort will be needed to keep regulatory programs ahead of, rather than behind, the curve.

Further modernization of the regulatory system is needed to get the most food safety for the dollar and to assure that additional dollars are effectively spent. Outdated statutes hamstring the agencies charged with regulating food safety. One of the major obstacles to consistent regulation of food safety is the varying statutes, written over a number of years, that govern how agencies approach regulatory questions. In some cases, these statutory differences may reflect legitimate factors that should be considered when regulating diverse risk sources such as pesticide residues or food-borne pathogens. But they also frequently reflect the persistence of

outdated approaches.

Consolidating the federal government's food safety activities into a single agency may be the most effective means of updating regulatory approaches and addressing problems in the current system. Consolidation might result in more-consistent regulation of risks like pesticide residues, which are under the jurisdiction of EPA and FDA, and pathogens, which are regulated by USDA and FDA. It might also result in more-consistent regulation of risks across food products like meat and poultry regulated by USDA, and other food products regulated by FDA. A further advantage could relate to introduction of new technologies and approaches. For example, we have separate new HACCP programs for meat and poultry (USDA), seafood (FDA), and juice (FDA). Consolidation may also allow a more coordinated response to changes in safety and quality standards for foods traded internationally.

On the other hand, the existing agencies have a solid record in assuring food safety. There is a risk that the variety and complexity of tasks to be accomplished would overwhelm the single agency assigned to perform them.

While different risk levels may dictate that meat plants be inspected more frequently than factories that produce tortilla chips, there is little reason to believe that the large existing disparities in inspection rates for different types of food processing plants are science based. Instead, these and other anomalies in the U.S. regulatory system stem from the fragmentation of responsibility for food safety. Further improvements in food safety may rest on consolidating responsibility.

Regardless of the regulatory approach, the goal must be to create a

food supply system that earns the trust of consumers. Failing that, American consumers may have their cake but fear to eat it.■

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NOTES

1. Paul S. Mead et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases* 5 (September-October 1999) <<http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>>.

2. The five bacterial pathogens are *Campylobacter* spp; *Salmonella*; *E. coli* 0157:H7; *E. coli*, non-0157:H7 STEC; and *Listeria monocytogenes*. See ERS Estimates Foodborne Disease Costs at \$6.9 Billion Per Year <<http://www.ers.usda.gov/Emphases/SafeFood/features.htm#start>>.

3. Centers for Disease Control and Prevention, *FoodNet Surveillance Report for 1999* (Final Report), U.S. Department of Health and Human Services, 2000 <http://www.cdc.gov/foodnet/annual/1999/pdf/99_annual_pdf.htm>.

4. National Academy of Sciences, *Ensuring Safe Food from Production to Consumption*, Institute of Medicine and National Research Council (Washington, DC: National Academy Press, 1998).

5. National Academy of Sciences, *Incorporating Science, Economics, and Sociology in Developing Sanitary and Phytosanitary Standards in International Trade: Proceedings of a Conference* (Washington, DC: National Academy Press, Research Council, Board on Agriculture and Natural Resources, 2000).

6. See "Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* among Selected Categories of Ready-to-Eat Foods," FDA/Center for Food Safety and Applied Nutrition, USDA/Food and Safety and Inspection Service, and Centers

for Disease Control and Prevention (January 2001) <<http://www.foodsafety.gov/~dms/lmrisk5.html>>.

7. See "Reducing the Risk of *Listeria monocytogenes*-Joint Response to the Presi-

dent (Action Plan)," FDA/Center for Food Safety and Applied Nutrition, USDA/Food Safety and Inspection Service, and Centers for Disease Control and Prevention (January 2001) <<http://www.foodsafety.gov/~dms/lmriplan.html>>.

8. Elise Golan et al., *The Economics of Food Labeling*, Agricultural Economic Report No. 793 (Washington, DC: USDA 2000.).