

Redesigning Food Safety: Using Risk Analysis to Build a Better Food Safety System

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1. Introduction

In 1998, a National Academy of Sciences (NAS) committee called for a statutory and organizational redesign of the federal food safety system.¹ The NAS committee documented how a fragmented, century-old accumulation of food safety laws and agencies is impeding the efforts of regulators to reduce the risk of foodborne illness. The committee recommended a science-based, integrated food safety regulatory system under unified and accountable leadership – a system that would be better able to deploy resources in the manner most likely to reduce risk.

The NAS recommendations make common sense. However, fundamental policy and structural change of this kind is difficult to achieve politically. Over the years, most major reforms in public health and environmental laws have occurred in response to some galvanizing event or crisis. Fortunately, the U.S. food safety system is not in crisis. It is, in many respects, the strongest in the world, and it has in recent years made important strides toward regulatory policies that properly emphasize preventive process control to reduce significant hazards.²

Despite its successes, the U.S. food safety system is under serious stress, due largely to rapid change in the food system. The Centers for Disease Control and Prevention (CDC) recently reported new, more reliable estimates of the persistently high incidence of foodborne illness in the United States—an estimated 5,000 deaths, 325,000 hospitalizations, and 76,000,000

¹National Institute of Medicine/National Research Council , Ensuring Safe Food From Production to Consumption (National Academy Press, Washington, D.C, 1998).

² In 1995, the Food and Drug Administration (FDA) issued regulations requiring all seafood processors to adopt the system of preventive process control for food safety called Hazard Analysis and Critical Control Points (HACCP). 60 *Federal Register* 65096 (December 18, 1995). In 1996, the Food Safety and Inspection Service in the U.S. Department of Agriculture (USDA) adopted rules requiring HACCP for all meat and poultry slaughter and processing plants and imposing, for the first time, pathogen reduction performance standards for raw products. 61 *Federal Register* 38806 (July 25, 1996).

illnesses annually.³ Many of these cases are linked to new and emerging microbial pathogens, changing American eating habits, and an aging population.

Our food safety system is challenged also by new agricultural and food technologies, such as genetically engineered food crops; by an increasingly globalized food supply, which makes European and Latin American food safety problems potential problems for the United States; and by intense public and media scrutiny on issues like mad cow disease and biotech foods. Finally, chronically strained food safety budgets have seriously eroded the government's scientific staffing and inspection resources even as the food safety job has become more difficult.

In response to these stresses, and with an eye on lessons from the European Union concerning the fragility of public confidence in food safety, U.S. lawmakers and many non-governmental organizations are showing growing interest in modernizing our food safety laws and structures, along the lines contemplated by the NAS committee. Consumer groups that have been pushing for such reform have been joined recently by some food industry associations and scientific organizations.⁴ On Capitol Hill, Senators Richard J. Durbin (D. Ill.) and George Voinovich (R. Ohio) recently wrote to President Bush calling for a bipartisan effort to combine the food safety functions of the Food and Drug Administration (FDA), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) into a single food safety agency. The Senate Agriculture Committee is also showing interest in the subject, with the Ranking Member, Senator Tom Harkin (D. Iowa) supporting the single agency concept.

Of course, no one knows when the political climate will make such structural change possible, and change will, in any event, be a long-term process. It is not too soon, however, for the scientific and research community to take the possibility of change seriously and to consider what data and methods will be needed to design and implement a science-based, integrated system – one capable of prioritizing risk reduction opportunities and deploying resources in ways best calculated to reduce risk. *Importantly, better priority setting and use of available resources*

³ See CDC, FoodNet Surveillance Report for 1999 (November 2000) and Mead et al., Food-Related Illnesses and Deaths in the United States, 5 *Emerging Infectious Diseases* 607-25(1999).

⁴ The Center for Science in the Public Interest, based in Washington, DC, has long advocated a single food safety agency, as does the Consumer Federation of America and Consumers Union. The Food Marketing Institute, which represents retailers, has endorsed the concept, and the American Meat Institute and the National Cattlemen's Beef Association have expressed interest. The single food agency concept is also supported by the American Public Health Association and the American Society for Microbiology.

is a goal that should be pursued regardless of whether Congress modernizes the organizational structure for food safety.

Natural and social scientists working in the field of risk analysis have a crucial role to play in this process. Risk analysis must become more than a tool for making and justifying specific food safety decisions, such as the quantity of a food additive that can be considered safe or the magnitude of the risk posed by a specific food contaminant. Risk analysis should, for the first time, play a much broader role in designing and managing a more science-based, integrated food safety system. Such a system would rely more heavily on biological risk assessments to set food safety standards, with greater emphasis on risks posed by microbial pathogens.

Even more importantly, the science-based, integrated system contemplated by the NAS committee would require much more extensive work in comparative risk assessment, risk ranking (in terms of public health significance), and the prioritization of risk-reduction opportunities (taking into account feasibility, cost, and social considerations). We use the term risk analysis in this paper broadly, to encompass all of these activities. In that sense, risk analysis is an essential tool for ensuring that regulatory effort and available resources are properly targeted and efficiently applied.

The balance of this essay will elaborate on the role risk analysis can play in the food safety system and suggest some data and methodological improvements that are needed for risk analysis to fulfill its potential to improve food safety. The necessary starting point for this discussion, however, is a brief review of the government's role in food safety.

2. The Government's Role in Food Safety

The overarching purpose of food safety regulation and other government food safety interventions is to minimize the risk of foodborne illness. An effective food safety system provides an array of other important social and economic benefits, including maintaining public confidence in the safety of the food supply and supporting the export of U.S. food and agricultural products, but these benefits flow from success in minimizing food safety risk. The core public expectation, put simply, is that those involved in producing and overseeing the safety of food—the proverbial “they”—are doing everything reasonably possible to make the food safe.

Food safety is first and foremost the responsibility of food producers, processors and others throughout the food chain, including consumers. The government obviously does not produce food and cannot, by itself, make food safe or unsafe. The government does, however, play two important roles in the effort to minimize food safety risk.

The first and broadest role is to set and enforce food safety standards through laws, regulations, inspections, and compliance actions. Such standards range from general statutory prohibitions on adulterated food to specific limits on permissible levels of various chemical residues in food. Most of the government's food safety resources are devoted to setting and enforcing these standards, with the majority of those resources going to food inspection. This role fulfills the uniquely governmental function of ensuring that commercial firms involved in the food system have accountability to the public for meeting basic food safety standards. USDA's recently adopted Hazard Analysis and Critical Control Points (HACCP) system for meat and poultry plants is an example of a food safety standard that has had measurable benefits in reducing harmful contamination and the risk of foodborne illness.⁵

The government's second role in minimizing food safety risk is to mount initiatives to tackle food safety problems that are beyond the control of any individual participant in the food chain and that require more than a regulatory solution. The dangerous pathogen *E. coli* O157:H7, for example, originates in the gut of cattle, is spread through the environment to contaminate water and fresh produce, and contaminates beef during the slaughter process, posing a significant hazard when present in any raw or undercooked food. Tackling this and many other food safety problems requires a strong research base; development of effective control measures; and collaboration among growers, animal producers, food processors, retailers, and consumers. The government has an essential leadership role to play in fostering research and collaboration on such issues to reduce the risk of foodborne illness.

3. The Role of Risk Analysis in Food Safety

What, then, is the role of risk analysis in ensuring the safety of the food supply? How can it contribute to the design and management of a more science-based, integrated system that works better to reduce the risk of foodborne illness? In answering these questions for the future, it is important first to recognize and respect the traditional role of risk analysis in food safety. In the 1970s, the FDA developed rudimentary tools of quantitative risk assessment to implement the Delaney Clause, the famous anti-cancer provision of the Federal Food, Drug, and Cosmetic

⁵ Statement of Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA, prepared for delivery before the National Advisory Committee on Microbiological Criteria for Foods, Washington, D.C., May 7, 2001 (available on the web at http://www.fsis.usda.gov/oa/speeches/2001/tb_nacmcf050701.htm).

Act. Under the version of the Delaney Clause applicable to animal drug residues,⁶ FDA was authorized to approve drugs that had the potential to leave a carcinogenic residue in edible tissue, provided the residue was not detectable using an adequately sensitive analytical method approved by FDA. The agency decided that methods sensitive enough to detect any residue posing more than an upper bound one-in-one million risk over a lifetime of exposure would be deemed acceptable for this purpose.⁷

Since then, risk assessment methods have become more sophisticated, and quantitative risk assessment for animal carcinogens (and, to a lesser extent, other chemical toxins) has become a common feature of everyday food safety decisionmaking at FDA, EPA, and USDA. It is used routinely to determine safe levels in food of pesticide residues and other food production, processing, and packaging chemicals. More recently, microbial risk assessment has been used to evaluate the hazard posed by microbial pathogens—such as *Listeria*—in a range of food products, and to support regulatory interventions to control pathogens.⁸

There are, however, much broader roles for risk analysis at the level of system design and management, as discussed in the next two sections. They include: (1) guiding the allocation of inspection and enforcement resources, and (2) setting priorities for risk reduction initiatives. These are roles for risk analysis that can significantly enhance the effectiveness of the food safety system in reducing risk.

4. Allocation of Inspection and Enforcement Resources

Under current law, FDA is authorized to inspect food establishments but is not required to do so. With approximately 50,000 processing and storage facilities under FDA's jurisdiction and with resources to conduct about 15,000 inspections per year, many plants under FDA's jurisdiction go years without inspection. Even plants FDA rates as "high risk" may be inspected only once a year or less frequently. In contrast, USDA has a statutory mandate to inspect every carcass passing through slaughter establishments and to inspect every meat and poultry processing plant every day, without regard to the relative riskiness of the operations in these plants.

⁶ 21 USC 360b(d)(1)(H).

⁷ See 50 Fed. Reg. 45530 (October 31, 1985).

⁸ See 66 Fed. Reg. 12589 (Feb. 27, 2001).

These approaches to inspection, which reflect fundamental differences in statutory mandates and modes of regulation between FDA and USDA, skew the allocation of resources in ways that may not be optimal for public health and the government's ability to contribute to risk reduction. For example, USDA's budget for regulating meat and poultry is about \$800 million. FDA's budget for all the rest of the food supply is less than \$300 million. USDA employs about 7,600 meat and poultry inspectors, while FDA has a total field staff of 1,700 for all of its food programs, including inspectors, laboratory technicians, and administrative staff.⁹ This is despite the fact that there are more reported cases and outbreaks of foodborne illness associated with FDA-regulated products than USDA-regulated products.¹⁰ About 3,000 USDA inspectors are allocated to the statutorily mandated carcass-by-carcass inspection program in poultry plants alone, an organoleptic process that serves primarily to address product quality rather than food safety concerns and thus makes a fairly minor contribution to food safety.¹¹ Yet, this poultry slaughter inspection program costs about \$200 million, more than FDA has to inspect the entire food supply beyond meat and poultry.

The potential role of risk analysis in improving this situation is apparent. According to the 1998 NAS report, the agencies should be free to allocate their inspection and other resources across the entire food supply to "maximize effectiveness," which requires "identification of the greatest public health needs through surveillance and risk analysis."¹²

Within the existing statutory framework, USDA has very limited flexibility to adjust its inspection models so it can redeploy resources to more directly reduce risk, such as through enforcement of HACCP and pathogen-reduction performance standards and oversight of distribution, storage, and retail facilities. FDA has complete discretion legally to allocate its

⁹ General Accounting Office (GAO), *Food Safety – Overview of Federal and State Expenditures*, GAO-01-177, February 2001.

¹⁰ CDC says that, of the cases of illness reported to it in 1997 for which a food source was known, about 85% were associated with FDA-regulated food products, such as fish, shellfish, fruits, vegetables, and salads. The rest were associated with USDA-regulated meat and poultry products. *Ibid.* at 5. The Center for Science in the Public Interest (CSPI) has compiled a well-documented, multi-year database of foodborne illness outbreaks, which suggests that 80% of outbreaks (instances of multiple cases associated with a common cause) may be linked to FDA-regulated foods. CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food –Safety Net* (Washington, D.C. August 2000) (this document is available on the CSPI website at http://www.cspinet.org/reports/outbreak_alert/index.htm).

¹¹ See National Research Council, *Meat and Poultry Inspection – The Scientific Basis of the Nation's Program* (National Academy Press, Washington, D.C., 1985).

¹² See NAS report, n. 1, above, at 10.

resources as it sees fit. Both agencies are making an effort to consider risk in making resource allocations. For example, USDA is developing new inspection models that would permit redeployment of some of its resources to oversee higher risk activities, and FDA has traditionally attempted to target its limited inspection resource on plants that it judges to be high risk or likely to be committing safety violations.

Both agencies are severely constrained, however, by the current system. In USDA's case, the statutory inspection mandate commits most of the available resources to activities that are not planned primarily around risk. In FDA's case, inadequate resources are available for both the analysis of risk priorities and reallocation of effort. As a result, neither agency is able to systematically conduct comparative risk assessments, establish risk-based priorities for its inspection program, or allocate resources accordingly. For these and other reasons, the NAS committee recommended that Congress change the law so that resources could be reallocated and inspection and enforcement could be based on "scientifically supportable risks to public health."¹³

5. Setting Priorities for Risk Reduction Initiatives

As discussed above, the government has an important leadership role in mounting initiatives to reduce risks that are not fully addressable through its core function of establishing and enforcing basic food safety standards. Such initiatives could include research, collaborative efforts with the food industry, targeted regulatory interventions, and consumer education. These efforts require significant dollars, staff time, and management attention, but they are necessary to bring about the change in practices and behavior that are required to reduce the risk of foodborne illness. In recent years, for example, FDA and USDA have carried out initiatives to reduce the risk of illness posed by *Salmonella enteriditidis* in eggs. The result has been a decline in *Salmonella enteriditidis* outbreaks and cases, but only with a significant investment of time and energy.

Risk analysis has a critical role to play in deciding which initiatives to pursue and in managing the initiatives. For example, the CDC now reports through its FoodNet active surveillance program on cases of illness associated with nine specific bacterial and parasitic

¹³ Ibid.

pathogens.¹⁴ These pathogens, which comprise the most significant known sources of foodborne illness, enter the food supply through a range of foods and at different stages of the food production process. If the government is to make the best use of its food safety resources, it should assess and compare the risks posed by various pathogen/food combinations and prioritize opportunities for reducing these risks through targeted food safety initiatives.

Likewise, the presence in food of environmental contaminants, such as mercury, lead, and dioxin, continues to be a matter of public health concern. The government has had success in the past with initiatives to reduce the levels of such contaminants, lead being a notable example. Through risk analysis, the government can identify opportunities for further risk reduction and mount initiatives accordingly.

6. Improving the Role of Risk Analysis

As documented by the 1998 NAS report, there are numerous statutory, organizational, and resource constraints on the use of risk analysis in food safety decisionmaking, priority setting, and program design. Central among these are the statutory compartmentalization of the food supply and the antiquated USDA inspection mandate. Together, these features of the system allocate most of the federal food safety resources on the basis of factors other than risk, and impede risk-driven food safety initiatives that consider the food supply as a whole and address risk problems that cut across agency jurisdictional lines. These problems would have to be addressed through legislative action.

Beyond these structural issues, there also is much room for improvement in the data and methods available to carry out risk analysis of the kind contemplated here. The analyses include risk assessment, risk comparison and ranking (in terms of public health significance), and prioritization of risk reduction opportunities (taking into account feasibility, cost, and social considerations).

Regarding risk assessment, CDC reports foodborne illness cases and outbreaks by pathogen, but it does not have complete information about the specific food/pathogen combinations that account for the illness. Because regulatory initiatives are necessarily oriented toward food type and efforts to reduce the risk associated with a specific food, such information

¹⁴ See n. 3, above.

is necessary for risk assessments intended to support regulatory priority setting or resource allocation.

Chemical risk assessment also needs attention if it is to contribute as a priority-setting tool. For chronic effects such as carcinogenicity, risk assessment yields quantitative expressions of the estimated upper bound on the risk an individual might be exposed to, based primarily on animal toxicity data. For most other effects, the results of risk assessment for food substances are expressed as an “acceptable daily intake.” In neither case are the results readily comparable to the results of epidemiologically-derived estimates of risks posed by microbial pathogens, which typically are expressed in terms of the number of cases of illness associated with a specific pathogen. How can chemical risk assessment and the manner of expressing its results be adapted to foster risk comparison and ranking?

Comparison and ranking of food safety risks by public health significance are inherently complicated due to the diversity of risks and health outcomes of concern. Chemical risks range from the acute to the chronic, vary significantly with exposure, sometimes affect age groups differently, and often are predictable only with great uncertainty. Microbiological risks also are diverse, ranging from minor intestinal infections to permanently disabling disease and death, and vary among age groups, but risk assessments are typically grounded in epidemiological data on actual illnesses. How can these factors be taken into account when comparing and ranking food safety risks? There is a need for public health experts and social scientists to collaborate in developing methods to value risks so they can be compared and ranked.

The ultimate objective of risk analysis is not risk comparison and ranking for its own sake or to provide the basis for concluding that some food safety risks are unimportant. In the daily activities of people who produce, market, and consume food, any significant risk of harm is important and should be prevented to the extent reasonably possible. For the government, however, the question is how best to allocate finite resources to reduce the risk of foodborne illness. This requires building on risk comparison and ranking to prioritize opportunities for risk reduction. It means not stopping with an understanding of the relative magnitude of food safety risks but examining how the government can make the best use of its resources to reduce risk.

With respect to standard setting and inspection, for example, which segments of the food supply (e.g., meat, poultry, seafood, dairy products, fresh produce, processed foods) or which food types pose specific, significant risks that are most amenable to reduction through government intervention? This analysis should start with the magnitude of the risk but also should consider the tools available to government and industry (standards, inspection, testing,

new preventive controls) to reduce the risk, the feasibility and cost of reducing the risk in relation to other risk-reduction opportunities, and the value the public places on reducing the risk, as reflected, for example, in willingness to pay to reduce it. With respect to research, education, and other non-regulatory initiatives, where would government interventions have the greatest impact on risk reduction?

There is currently no accepted model for considering these and other relevant factors in resource allocation and priority setting for the government's food safety program. Such a model should be developed.

7. Conclusion

The 1998 NAS committee report said that, “[T]he cornerstone of a science-based system of food safety is the incorporation of the results of risk analysis into all decisions regarding resource allocation, programmatic priorities, and public education activities.” We agree. Achieving this goal requires statutory and organizational reform, so that the results of risk analysis can be fully implemented in program design and management. It also requires significantly greater investment to improve the data and methods available for risk analysis. With these changes, the regulatory system can most effectively reduce the risk of foodborne illness and, in turn, maintain public confidence in the food supply and preserve America’s international leadership role on food safety.