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Reduction of food-borne hazards, including microbiological and others, with emphasis on emerging hazards

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Introduction

The ultimate risk management goal of food safety regulators is the control or reduction of food-borne hazards and in turn, reduction in the incidence of food-borne illness. Risk management involves weighing policy alternatives in light of available data and selecting and implementing appropriate control options for protecting the public health. To be effective, risk management strategies must be developed with a continual exchange of information by all interested parties, thus ensuring that the process and the strategies are considered transparent and are trusted. In addition, risk management strategies must continually change as new hazards emerge and as scientific and technological advances occur.

The kinds of measures taken to reduce food-borne hazards may vary from country to country and depend on factors such as the hazards of concern, the country's regulatory system, and food storage, preparation, and consumption practices. However, countries will most likely follow a similar set of basic steps to develop their risk management strategies, including identifying the problem, determining contributing factors, evaluating the risks, and selecting risk management measures that are feasible and should yield the best results. These similarities make it worthwhile for regulators to share experiences in developing risk management strategies and discuss ways in which this process may be improved.

Risk Management Strategies

In the United States, a variety of risk management strategies are used by the Food Safety and Inspection Service (FSIS), which has jurisdiction over meat, poultry, and processed eggs, and the Food and Drug Administration (FDA), which has jurisdiction over all other foods at the federal level. Among these are regulatory measures, industry guidance, surveillance systems, and outreach activities such as industry training and consumer education.

Both FSIS and FDA have mandated Hazard Analysis and Critical Control Point Systems—FSIS for meat and poultry products, and FDA for seafood and fruit and vegetable juices. HACCP systems are mandated under regulations that are drafted, published for public review and comment, then finalized, taking into account the comments that have been received. Under HACCP, plants identify critical

control points at which hazards can occur during their processes, establish controls to prevent or reduce those hazards, and maintain records documenting that the controls are working as intended. HACCP serves to clarify the respective roles of industry and government. Companies are responsible for implementing an effective HACCP program that ensures their products are safe. Government is responsible for verifying that the regulatory requirements have been met, that the HACCP program is working as intended, and that appropriate actions are taken when the HACCP critical controls have not been met.

The United States also has established performance standards for various food safety hazards and tests products to ensure these standards are met. For example, along with mandatory HACCP in meat and poultry plants, FSIS has in place pathogen reduction performance standards for *Salmonella* that slaughter plants must meet. Such standards provide a basis for plants to calibrate their process control measures. FSIS also has established a 6.5-log pathogen reduction performance standard for *Salmonella* in cooked roast beef and cooked poultry. As another example, FDA has established a 5-log pathogen reduction performance standard in its juice HACCP regulation. Various pathogens have been involved in foodborne illness outbreaks associated with juices, and the processor determines which pathogen is the target of HACCP critical controls. Among the pathogens involved in foodborne illness outbreaks associated with juices are *E. coli* O157:H7, *Salmonella*, and *Cryptosporidium parvum.*

Regulatory requirements are an important, but not the only, risk management strategy available to food safety officials. Less formal than regulations, guidance to the industry can be effective in reducing foodborne illness risks. An example is the FDA's *Guidance for the Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds* and *Sampling and Microbial Testing of Spent Irrigation Water during Sprout Production*. This type of guidance, although not regulatory, is published for public review and comment. As another example, FSIS published guidance to industry on appropriate intervention measures to use to reduce the risk of *Listeria monocytogenes* (LM) from hot dogs and sliced luncheon meats.

Research is another risk management strategy. Research conducted by government, industry and academia on food safety hazards; data gathering; and technology development also are important in filling existing data gaps and in providing practical tools for detecting, controlling, and reducing foodborne hazards. Risk managers benefit from knowing how human pathogens grow, develop, and colonize in animals and how management practices on the farm may reduce the opportunity for these pathogens to contaminate fresh produce, meat, and other foods. They benefit from comprehensive data on the incidence of foodborne illness and what foods are responsible for these illnesses. And they benefit from having available new technologies such as improved diagnostic tests and vaccines that can be used as potential risk management strategies.

Education is another non-regulatory risk management strategy, and the United States has taken a farm-to-table approach to food safety education. Everyone has a responsibility for food safety, so education is aimed at those involved in producing, transporting, preparing, and consuming foods. For example, at the production level, food safety agencies are working with producers to develop and encourage measures to reduce hazards associated with animals presented for slaughter and fresh produce. The FDA has developed a *Guide to Minimize Microbial Risk in Fresh Fruits and Vegetables* that highlights production practices that will enhance the safety of fresh produce. An extensive outreach and education program for both domestic and international producers in these good agricultural practices is underway. Consumer education is an integral component of this risk management strategy and is provided through a variety of techniques. Methods include school-based educational campaigns, web sites, telephone hotlines, and safe handling labels. A consumer campaign, "Fight BAC!™," has emphasized four simple factors to keep food safe from bacteria: Clean, Separate, Cook and Chill, and has promoted these messages through the media and community-based education activities. Physician awareness programs have highlighted the importance of advising patients, particularly vulnerable patients such as pregnant women, the elderly, and individuals with compromised immune systems, about the impact of microbial hazards on their health.

Risk management strategies must continually change as new hazards emerge and new information becomes available. Regulators must be vigilant to trends in their own countries and abroad and must be open to new paradigms regarding pathogens. New pathogens such as Salmonella *typhimurium* DT104 have emerged in the United States. As another example, scientists learned relatively recently—that is, within the past several years—that *E. coli* O157:H7 is acid-tolerant, and the United States has had to adapt its risk management approach to these new findings.

Fortunately, new, effective tools are available to help keep pace with emerging hazards. For example, in the area of foodborne disease surveillance, the Foodborne Diseases Active Surveillance Network (FoodNet), a collaborative project among Federal, state and local governments, has been in existence since 1995. It currently involves 9 sentinel sites around the U.S., representing more than 25.4 million people. FoodNet provides national estimates of the burden and sources of specific foodborne diseases and includes studies designed to help public health officials better understand the epidemiology of foodborne diseases in the United States. In addition, public health officials are now better able to detect and rapidly respond to foodborne outbreaks through PulseNet—a national computer database that analyzes molecular fingerprints of foodborne pathogens. It has been used many times to link specific food products to specific human illnesses and to link what appear to be sporadic, unassociated cases of foodborne illness to a specific, single source. This enables public health officials at the Federal, State, and local levels to minimize the spread of outbreaks.

We are also seeing improved practices in areas such as steam pasteurization and carcass rinses used to remove pathogens from slaughtered carcasses and technologies to improve the safety of plant, seafood, egg, and dairy products. Irradiation has been approved by the FDA for a variety of food products. Government food safety policies encourage innovation by setting new food safety requirements, by guiding and conducting research that addresses the most critical data and technology gaps, and by implementing expedited reviews of new technologies and food-safety related food additives.

Two examples will be used to illustrate how the United States has used risk management strategies to successfully address food-borne hazards on fresh and processed products. The first example is *Listeria monocytogenes* (LM) in ready-to-eat products. The second example is *Salmonella* in raw meat and poultry products.

***Listeria monocytogenes* in Ready-to-Eat Products**

The U.S. experience with LM is a very dramatic indication of how risk management strategies can have a significant impact on rates of human disease. It has been only in the past two decades that researchers have recognized the association of LM with foodborne illness, and the impact of the pathogen in terms of human health became clear during the 1980's following a series of outbreaks. Of particular concern is that certain subsets of the population— newborns, the elderly, patients with compromised immune systems—are particularly susceptible to *Listeria* infections. Infections also are a major concern in pregnant women. Even though symptoms may be relatively mild in the mother, the illness can be transmitted to the fetus, causing serious illness or fetal death. One outbreak in 1985 in the State of California resulted in 142 cases of listeriosis, including 46 deaths; 85 percent of the cases involved pregnant women. This particular outbreak was traced to LM in soft, fresh Mexican-style cheese, manufactured with contaminated milk. Data collected by the U.S. Centers for Disease Control and Prevention (CDC) in the late 1980's determined that cases of listeriosis were most often associated with soft, fresh cheese; undercooked poultry; hot dogs not thoroughly reheated; and food purchased from delicatessen counters.

How the issue was addressed

Increasing concerns about LM led U.S. food safety regulatory agencies to take several steps. FSIS and FDA stepped up monitoring and surveillance programs for LM. The agencies worked with processing plants to improve their sanitation procedures, and many companies implemented hazard analysis and critical control point (HACCP) systems to minimize contamination. Government agencies also developed and distributed educational materials on food safety for consumers and special populations at increased risk for listeriosis. As a result of these efforts, between 1989 and 1993, the rate of illness from LM declined 44 percent.

LM is a good example of how risk management strategies must be continually reevaluated as scientific and technological developments occur. In the fall of 1998, CDC reported an increased number of cases of illness due to a specific subtype of LM. The illnesses were associated with ready-to-eat meat products, and FSIS announced a number of initiatives to address the immediate problem. For example, FSIS advised meat and poultry establishments to reassess their HACCP plans to ensure they were adequately addressing LM. The agency provided guidance to industry on practices that have been used successfully by other meat and poultry establishments to prevent LM in ready-to-eat products. FSIS also developed an in-depth verification protocol that is carried out by an interdisciplinary team of experts to evaluate whether plants producing ready-to-eat products have reassessed their HACCP plans to adequately address LM.

In addition, FDA, in cooperation with FSIS, conducted a risk assessment of the potential relative risk of listeriosis from eating certain ready-to-eat foods. The risk assessment supported the findings of epidemiological investigations of both sporadic illness and outbreaks of listeriosis in that it identified pâtés, fresh soft cheeses, smoked seafood, frankfurters, and some foods from deli counters, as potential vehicles of listeriosis for susceptible populations.

In response to findings of the risk assessment, HHS and USDA published a joint action plan, which focused on those ready-to-eat foods identified in the risk assessment as warranting additional control measures. Eight action areas were identified: 1) enhance health care provider and consumer information and education efforts; 2) develop guidance for processors identifying post-process contamination controls; 3) conduct regulator and industry training; 4) redirect inspections and surveillance sampling to firms producing at risk products; 5) propose new regulations and revisions to existing regulations concerning LM controls; 6) enhance disease surveillance and outbreak response to detect illness outbreaks more quickly and accurately; 7) initiate projects with retail operations such as delicatessens and salad bars to study behaviors and practices that control the spread and growth of LM; and 8) coordinate research activities to refine the risk assessment, enhance preventive controls, and support regulatory, enforcement and educational activities.

Summary of Findings

Risk management strategies must be evaluated to determine if they are effective. In the case of LM, as mentioned earlier, actions taken in the 1980's did indeed have a positive effect—a 44 percent decline in illnesses between 1989 and 1993. The success of these efforts can also be evaluated in terms of meeting the food safety objectives stated in *Healthy People 2000*. *Healthy People* is an initiative coordinated by the U.S. Department of Health and Human Services that sets goals every 10 years for a variety of health concerns, including targets for the reduction of foodborne illness. The United States met the food safety objectives for infections caused by key food-borne pathogens stated in *Healthy People* 2000. The incidence of LM decreased from 0.7 cases of infection per 100,000 in 1987 to 0.5 cases in 1996. The target for 2010 is 0.25 cases per 100,000—a 50 percent improvement. However, this target date was changed to 2005 by a presidential directive issued in May 2000.

In addition to illness data, prevalence data collected between 1990 and 1999 indicate a downward trend in LM in ready-to-eat meat products, suggesting that industry has made significant improvements in plant sanitation and control of post-process contamination.

Salmonella **in Raw Meat and Poultry Products**

Controlling pathogens in raw products required a change in the Nation's mindset about food-borne pathogens. The example provided for raw products focuses on meat and poultry products. Before the early 1990's, the pervasive attitude among industry, and even regulators, was that pathogens are a natural part of the environment and should be reduced primarily by food preparers through cooking. As scientific support emerged for changes that would better address pathogenic microorganisms in both raw and processed products, there was a growing realization that traditional attitudes towards pathogens in raw meat and poultry products had to change. An outbreak of *E. coli* O157:H7 in late 1993, attributed to undercooked hamburgers, provided the impetus for that change.

How the issue was addressed

In 1996, FSIS published its rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) systems, which required all plants that slaughter and process meat and poultry to implement HACCP systems as a means of preventing contamination from pathogens and other hazards. The rule, like other HACCP regulations, was based on the principle that prevention must be the first line of defense. HACCP did not address any one particular hazard but provided a flexible framework that could be used to address various hazards.

To make sure HACCP systems are working as intended, the rule also set in-plant, pathogen reduction performance standards for *Salmonella*. This was unique because pathogen reduction performance standards had not in the past been applied to raw products. *Salmonella* was selected as the target organism because it was the most common cause of food-borne illness associated with meat and poultry products, it is present to varying degrees in all major species, and interventions targeted at reducing *Salmonella* are expected to be beneficial in reducing contamination by other enteric pathogens.

FSIS based the current performance standards on what it believed was achievable at that time with current science and technology. Specifically, FSIS proposed that the prevalence of *Salmonella* contamination in carcasses of each of the major species and in raw ground products be reduced by each establishment to a level below the current national baseline prevalence. FSIS collects such data for various pathogens through its Nationwide Microbiological Baseline Data Collection Programs. This was done with the expectation that the performance standards would be revised periodically as new baseline prevalence data became available that reflected progress in pathogen reduction. Ideally, FSIS would have preferred to set such performance standards based on quantifiable risk related to human illness. Unfortunately, because such data are limited, The agency decided to rely on prevalence data and industry averages as its starting point. As more microbial and epidemiological data are collected, more precise, risk-based standards can be established.

Summary of Findings

Progress in addressing *Salmonella* can be evaluated by looking at both product data and epidemiological data.

In terms of product data, the results of three years of testing—representing aggregate data from all sizes of plants—show that all categories of products showed improvement over baseline studies conducted prior to HACCP implementation. For example, 10.2 percent of young chickens tested were positive for *Salmonella* under HACCP compared to a 20 percent baseline prevalence. Ground chicken averaged 14.4 percent under HACCP, compared to 44.6 percent before HACCP. These were the most dramatic reductions.

In addition, since the implementation of HACCP, the CDC has reported a reduction in the number of food-borne illnesses associated with meat and poultry products, including *Salmonella*. Thus, experience shows that performance standards for *Salmonella*—in concert with other regulatory requirements—have worked extremely well.

As with LM, a variety of risk management approaches have been used to reduce levels of pathogens, such as *Salmonella*, in raw products. The Pathogen Reduction and HACCP rule also mandated standard operating procedures for sanitation and performance criteria for generic *E. coli*—an indicator of fecal contamination. Consumer education programs emphasize the importance of proper food handling in the home, including how to avoid cross contamination between raw and cooked products. And research is ongoing to determine ways to prevent the colonization of pathogens such as *Salmonella* in food animals.

Conclusion

These examples illustrate the challenges and opportunities presented by risk management. To conclude, some lessons learned over the last decade are provided here.

First, no single technological or procedural solution exists that can solve the problem of food-borne illness. Rather, food safety goals are achieved through continuous efforts to improve hazard identification and prevention throughout the farm-to-table chain. Risk management strategies must be continually re-evaluated to keep pace with technological and scientific advances. We must be flexible enough to accept new paradigms when it comes to reducing hazards.

Second, risk management steps can be taken in the absence of formal, quantitative risk assessments. In the real world, risk management steps must be taken on the basis of incomplete information and qualitative data and adjusted as new and more precise information become available.

Third, risk managers need to evaluate the effectiveness of their risk management strategies. This can range from data on pathogens in foods, such as the data on *Salmonella* in raw meat and poultry products collected over the past several years, to consumer surveys of the adoption of safe food handling practices, to public health outcomes such as reductions in food-borne illnesses. The value of such data is that they represent a baseline against which future efforts to improve food safety can be measured.

Fourth, risk management activities should be carried out through a transparent public process. The public consultation process used in the United States for the development of regulations, and the various educational campaigns for producers, processors and consumers, have been described. Public policy that is made without the input of all interested parties is doomed to fail. This does not mean that everyone gets what he or she wants, but the public process, which includes consideration of a sound scientific basis, ensures that all parties are heard. Making risk management decisions through a transparent process also ensures that public trust in the food safety system continues.

Fifth, and finally, government alone cannot solve food safety problems. Government agencies at the Federal, State and local level must work with each other and through partnerships with industry, academic institutions, and the public to implement strategies to meet intended food safety goals.